The Patient-Reported Impact of Dermatological Diseases (PRIDD) measure: a mixed methods measurement development and validation study

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by

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Summary

Background

Dermatological conditions are associated with pain, disfigurement, disability, and stigma, causing a physical, psychological and social burden. Current dermatology-specific (used across dermatological conditions) patient-reported outcome measures (PROMs) do not comprehensively capture the wider impact of the condition on the patient's life. This thesis aims to complete the content validity phase of the development of PRIDD (Patient-Reported Impact of Dermatological Diseases), a new PROM designed to comprehensively measure the impact of living with a dermatological condition.

Methods

A mixed methods study, consisting of four sequential phases. 1) A COSMIN (consensus-based standards for the selection of health measurement instruments) systematic review evaluated the quality and suitability of existing dermatology-specific PROMs to comprehensively measure impact. 2) The qualitative interview study formed the basis of a conceptual framework of impact, which guided measure item generation. 3) A Delphi study elicited consensus on which items to prioritise for inclusion in PRIDD. 4) A cognitive interview study evaluated the content validity, acceptability and feasibility of PRIDD. Adults (≥18-years) worldwide either living with a dermatological condition or representing a dermatology patient organisation were recruited. The study was theoretically informed by measurement theory, the conceptual model of health-related quality of life, and the Common-Sense Self-Regulatory Model.

Results

1235 people across 62 countries and 96 dermatological conditions participated. None of the 36 PROMs evaluated in the systematic review was recommended for use as the 'gold

standard', primarily due to insufficient patient input. The conceptual framework depicted impact as a multifaceted construct involving physical, psychological, social, financial and daily functioning. Item generation, reduction and refinement produced a pilot-tested version of PRIDD consisting of 26 items.

Conclusions

This series of studies represents best practice in measurement development. PRIDD's development was patient-centred and met the gold-standard COSMIN criteria, providing strong evidence of content validity. The final phase, psychometric testing, is on-going.

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Publications and presentations arising from this work

Published journal articles

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Journal articles in preparation

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Published conference abstracts

Augustin M, Suthakharan N, Janus C, Austin J, Bundy C. & **Pattinson R**. 2018. The Global Research on the Impact of Dermatological Disease (GRIDD). *Advances in Dermatology and Venereology*, 98, 229.

Suthakharan N, **Pattinson R,** Bundy C, Janus C, Austin J. & Augustin M. 2019. Global Research on the Impact of Dermatological Disease (GRIDD): A Patient-driven Worldwide Program. *World Congress of Dermatology*.

Pattinson R, Hewitt RM, Trialonis-Suthakharan N, Chachos E, Courtier N, Austin J, Augustin M, & Bundy C. 2021. Defining, understanding and measuring the impact of dermatological conditions on patients' lives: a qualitative concept elicitation study for a new Patient-

Reported Impact of Dermatological Disease (PRIDD) measure. 19th Congress - European Society for Dermatology and Psychiatry (ESDaP) & 2nd Brain Skin Colloquium Conference. 11th - 12th June 2021. Br J Dermatol, 185: e70-e108.

Press

International League of Dermatological Societies. 2021. *Changing the Way the World Sees Dermatology Through the GRIDD Project.* 31 August 2021. Available at: https://ilds.org/news/iadpo-gridd-project-2021/.

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Presentations and meetings attended

Date	Event attended	Location	Work presented
12-16 Sept 2018	European Academy of Dermatology & Venereology (EADV) 27th Congress	Paris	POSTER: Global research on the impact of dermatological diseases
3 March 2019	GRIDD Stakeholder advisory committee meeting	Washington, D.C.	N/A
4 March 2019	GRIDD Scientific advisory board meeting	Washington, D.C.	N/A
7-9 June 2019	GlobalSkin conference	Milan	N/A
20-22 June 2019	European Society Dermatology and Psychiatry (ESDaP) Annual meeting	Giessen	POSTER: Patient-reported measures in dermatology: a systematic review

3 Oct 2019	Health & Care Research Wales Annual meeting	Cardiff	POSTER: Patient-reported measures in dermatology: a systematic review
8 Oct 2019	GRIDD Scientific advisory board meeting	Madrid	N/A
9 Oct 2019	GRIDD Stakeholder advisory committee meeting	Madrid	N/A
9-13 Oct 2019	EADV 28th Congress	Madrid	ORAL E-POSTER: Patient-reported measures in dermatology: a systematic review
29-30 Oct 2020	EADV 29th Congress	Virtual	ORAL E-POSTER: Global Research on the Impact of Dermatological Diseases (GRIDD): Improving Patient Leadership and Engagement in Dermatology Research
17th May 2021	GRIDD Scientific advisory board meeting	Virtual	N/A
11-12 June 2021	ESDaP 2021	Virtual	ORAL PRESENTATION: Defining, understanding and measuring the impact of dermatological conditions on patients' lives: a qualitative concept elicitation study for a new Patient-Reported Impact of Dermatological Disease (PRIDD) measure
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Statement of Contribution

This thesis was written entirely by the PhD candidate, Rachael Pattinson (RP) with comments and revisions from PhD supervisors Chris Bundy (CB) and Nick Courtier (NC). Other individuals collaborated on projects within the thesis and in some cases jointly-authored publications arising from the studies presented in this thesis. Contributions for each study chapter have been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis to the work of others.

Chapter 4: Systematic review

Candidate's contributions: Contributed to the conception and took a lead role in designing and registering the study protocol; took a lead role in and co-ordinated the article screening, data extraction, analysis and interpretation of findings; and drafted and finalised the thesis chapter and associated journal article.

Collaborators' contributions: CB, Matthias Augustin (MA) and Nirohshah Trialonis-Suthakharan (NTS) contributed to the study conception and design. NTS and Sunnia Gupta (SG) were involved in screening. NTS, SG, Alasdair Henry (AH), Jacqueline Lavallée (JL), Marina Otten (MO) and Timothy Pickles (TP) were involved in data extraction. NTS contributed to data analysis and interpretation. CB, NC, NTS, SG, AH, JL, MO, TP and MA revised the manuscript critically for important intellectual content. All authors approved the final version to be published. CB and NC reviewed the thesis chapter.

Chapter 5: Concept elicitation

Candidate's contributions: Took a lead role in the conception and design of the study, ethical permissions process and data collection, analysis and interpretation of findings and drafted and finalised the chapter and associated journal article.

Collaborators' contributions: CB, MA and NTS contributed to the study conception and design. NTS, Rachael Hewitt (RH) and Evan Chachos (EC) were involved in data collection. RH was the secondary coder in the analysis process. CB, RH, NTS and EC were involved in the interpretation of the data. CB, NC, RH, NTS, EC and MA revised the manuscript critically for important intellectual content. CB, NC and RH reviewed the thesis chapter.

Chapter 6: Item generation and reduction

Candidate's contributions: Contributed to the conception and took a lead role in designing the study protocol including data collection tools and the ethical permissions process. Contributed to data collection and took a lead role in analysing and interpreting the quantitative consensus data and qualitative free-text responses. Contributed to the drafting and reviewing of the associated journal article. Drafted and finalised the thesis chapter.

Collaborators' contributions: CB, Matthias MA and NTS contributed to the study conception and design. NTS and RH contributed to developing the data collection tools. NTS led data collection, data cleaning and analysing descriptive statistics. CB, MA and NTS contributed to the interpretation of results. CB, NC and NTS reviewed this thesis chapter.

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ABBREVIATIONS

ACT	Acceptance and Commitment Therapy
AD	Atopic Dermatitis
BAD	British Association of Dermatologists
BCW	Behaviour Change Wheel
BJD	British Journal of Dermatology
CBT	Cognitive Behavioural Therapy
CFA	Confirmatory Factor Analysis
CLCI	Cumulative Life Course Impairment
COMET	Core Outcome Measures in Effectiveness Trials
COSMIN	Consensus-Based Standards for The Selection of Health Measurement Instruments
COS	Core Outcome Set
CSM	Common-Sense Model of Self-Regulation
CVD	Cardiovascular Disease
CTT	Classical Test Theory
DALY	Disability-Adjusted Life Year
DIF	Differential Item Functioning
DLQI	Dermatology Life Quality Index
EB	Epidermolysis Bullosa
EBM	Evidence-Based Medicine
EFA	Exploratory Factor Analysis
ESD	Exploratory Sequential Design

ED-5D	EuroQOL 5D
FDA	US Food and Drug Administration
GBD	Global Burden of Disease Project
GRADE	Grades of Recommendation, Assessment, Development and Evaluation
GRIDD	Global Research on The Impact of Dermatological Diseases
HADS	Hospital Anxiety and Depression Scale
HRQoL	Health-Related Quality of Life
IADPO	International Alliance of Dermatology Patient Organizations
IAPT	Improving Access to Psychological Therapies
IBD	Inflammatory Bowel Disease
ICC	Intraclass Correlation Coefficients
ICD	International Classification of Disease
IRT	Item Response Theory
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
MI	Motivational Interviewing
MCID	Minimal Clinical Important Difference
MLCDP	Major Life-Changing Decision Profile
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
PASI	Psoriasis Area and Severity Index
PCC	Patient-Centred Care
PIS	Participant Information Sheet
PPI	Public and Patient Involvement

PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRO	Patient-Reported Outcome
PROM	Patient-Reported Outcome Measure
PROSPERO	International Prospective Register of Systematic Reviews
PRIDD	Patient-Reported Impact of Dermatological Diseases
PsA	Psoriatic Arthritis
PSI	Person-Separation Index
PSP	Priority Setting Partnership
QoL	Quality of Life
RCT	Randomised Controlled Trial
SEM	Standard Error of Measurement
SF-36	Short Form (36) Health Survey
TENS	Transcutaneous Electrical Nerve Stimulation
TSTI	Three-Step Test-Interview
WCD	World Congress of Dermatology
WHO	World Health Organisation

Glossary

Term	Definition
Concept	A specific and well-defined subject involved in the construct underlying a measurement instrument (i.e. the *thing* that is to be measured by a specific item).
Construct	A well-defined and precisely demarcated subject of measurement (i.e. the *thing* that is to be measured by an instrument). The term is often used by psychologists for unobservable characteristics such as intelligence, depression or quality of life.
Conceptual framework	A model representing the relationships between the items in a measurement instrument and the construct measured (e.g. reflective or formative model).
Domain	A sub-construct (or subscale) is represented by a score of an instrument that measures a larger construct comprised of multiple domains. For example, the impact of dermatological conditions is the larger concept containing the domains subdivided into items describing physical, psychological, social, financial and daily functioning.
Health-related quality of life	HRQoL is a multi-domain construct that represents the patient's general perception of the effect of illness and its treatment on the physical, psychological, and social aspects of life.
Instrument	A means to capture data (i.e. a questionnaire) plus all the information and documentation that supports its use. Generally, this includes clearly defined methods and instructions for administration or responding, a standard format for data collection, and well-documented methods for scoring, analysis, and interpretation of results in the target patient population.
Item	An individual question, statement, or task (and its standardised response options) on an instrument that is evaluated by the patient to address a particular concept.

Measurement properties	All the attributes relevant to the application of a measurement instrument including validity, reliability and responsiveness. These attributes are specific to the measurement application and cannot be assumed to be relevant to all measurement situations, purposes, populations, or settings in which the instrument is used.
Measurement theory	A theory about how the scores generated by items represent the construct to be measured (e.g. classical test theory or item response theory).
Method of measurement	Method of data collection or type of measurement instrument used (e.g. questionnaire, imaging techniques, biochemical analyses, performance tests).
Patient-reported outcomes	A measurement based on a report that comes directly from the patient (i.e. study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PRO can be measured by self-report or by interview provided that the interviewer records only the patient's response.
Questionnaire	A set of questions or items shown to a respondent to get answers for research purposes.
Recall period	The period of time patients are asked to consider in responding to an item or question.
Response option	One of multiple possible choices available for selection in response to an item or question.
Score	A number derived from a patient's response to items in a questionnaire. A score is computed based on a pre-specified, validated scoring algorithm and is subsequently used in statistical analyses of results. Scores can be computed for individual items, domains, or concepts, or as a summary of items, domains, or concepts.
Theoretical model	A model depicting how different concepts within a construct are related.

Context – The Global Research on the Impact of Dermatological Diseases (GRIDD) project

Despite evidence of burden and unmet need, dermatological conditions are often perceived as superficial, referred to as “just a rash”, and consequently are overlooked in the global health debate. The influential Global Burden of Disease (GBD) studies (Murray et al. 2012; Murray et al. 2015) systematically underestimate the burden of dermatological conditions (Hay et al. 2014; Hollestein and Nijsten 2014; Karimkhani et al. 2017; Seth et al. 2017). The GBD is the most comprehensive worldwide epidemiological study to date and provides burden and mortality estimates for a broad range of health problems - including 15 dermatological conditions - such as major diseases, injuries, and risk factors, at global, national, and regional levels. These burden estimates are extremely influential as they provide an important evidence-base for identifying patient need, developing policies, and determining resource-allocation and research priorities globally.

The GBD estimates are based on the disability-adjusted life years (DALYs) metric whereby each DALY represents the number of years lived with disability. Griffiths and colleagues (2017) argue that the DALY metric does not adequately capture the burden of dermatological conditions. In the GBD studies, the DALY scores for dermatological conditions were weighted according to symptoms that affect only the skin (itch, disfigurement) and did not factor in the impact of other symptoms or comorbidities such as depression and anxiety. In GBD 2010, psoriasis received a DALY ranking of 144 out of 176 conditions, below conditions such as gout. Griffiths and colleagues (2017) contend that, as a systemic disease associated with psychological, cardiovascular, and metabolic comorbidities, the GBD has likely underestimated the burden of psoriasis. Dermatological conditions were also missing from the World Health Organization's (WHO; 2014a) global status report on the prevention and management of non-communicable diseases. The result being that dermatological conditions

are not recognised as serious non-communicable diseases and policymakers are not incentivised to address them.

In 2015, WHO passed resolution WHA 67.9, which was the first to recognise psoriasis, or any dermatological condition, as a serious non-communicable disease (World Health Assembly 67 2014). It aimed to raise awareness and fight the stigmatisation of psoriasis. The resolution highlighted that people with psoriasis are at higher risk of developing several comorbid conditions (including cardiovascular disease [CVD], diabetes and psoriatic arthritis [PsA]) and that many suffer needlessly due to incorrect or delayed diagnosis, inadequate treatment options and insufficient access to care. Consequently, WHO (2016) published a report on psoriasis which aimed to a) help raise awareness of the multiple ways psoriasis can affect peoples' lives and b) empower policy-makers with practical solutions to improve the healthcare and social inclusion of people living with psoriasis in their patient populations by integrating the management of psoriasis into existing services for non-communicable diseases. The resolution was successful at raising the profile of psoriasis in the global health debate, but this has not been extended to other common dermatological conditions.

The WHO's International Classification of Disease (ICD)-10 (2004) classifies over 1,000 dermatological conditions. The term 'dermatological conditions' is used here rather than the more commonly used 'skin disease' to be inclusive of dermatological conditions that primarily affect the hair (e.g. alopecia), nails (e.g. psoriasis), or mucous membrane (e.g. mucous membrane pemphigoid). Dermatological conditions can be categorised in multiple ways according to their prevalence (common or rare), duration (acute or long-term), or type (e.g. inflammatory or non-inflammatory/cancerous or non-cancerous). These categorisations affect how the conditions are resourced and managed. The WHO, for example, categorises rare dermatological conditions as 'rare diseases' and they, therefore, qualify for the resources allocated to these conditions. It does not consider common dermatological conditions (except for psoriasis) as serious non-communicable diseases and, subsequently, they are often under-resourced.

The International Alliance of Dermatology Patient Organizations (IADPO) is a non-profit coalition of dermatology patient associations from around the world who share the common aim to improve the lives of people with dermatological conditions through advocacy, research

and support. Based on WHA 67.9, IADPO recognised that research evidence of the high burden of dermatological conditions was needed to raise awareness of them as serious non-communicable diseases and for the WHO and other key influencers to make policy changes. At the same time, key decision-makers including the WHO, policymakers and pharmaceutical companies had expressed a need for quantitative, patient-derived data on the impact of dermatological conditions, but patient organisations only had the resources to provide qualitative data in the form of 'patient stories.' In response, IADPO launched the Global Research on the Impact of Dermatological Diseases (GRIDD) project. GRIDD aims to collect global quantitative data on the impact of dermatological conditions on patients' lives and challenge the global burden estimates. However, the existing burden measures only partially capture the full impact of living with a dermatological condition. This PhD, therefore, aims to develop the new Patient-Reported Impact of Dermatological Diseases (PRIDD) measure capable of comprehensively measuring the impact of dermatological conditions.

Chapter 1: The burden and management of dermatological conditions

1.1 Background

Dermatological conditions are the fourth most common health condition globally (Hay et al. 2014; Karimkhani et al. 2017). They can be infectious, congenital, degenerative, inflammatory and cancerous and pervade all countries, cultures, ages and genders with consequences ranging from reduced quality of life (QoL) to death (Bickers et al. 2006; Basra and Shahrukh 2009; Murray et al. 2012; Hay et al. 2014; Karimkhani et al. 2017). Dermatological conditions carry a substantial physical, psychological, and social burden for patients, families, health services and society (Koo and Lebwohl 2001; Batchelor et al. 2013). The stigma of living with a visible condition, the symptoms experienced such as pain and itch, and financial implications go some way to explaining this burden (WHO 2016). Most dermatological conditions have associated co-morbidities (Wakkee and Nijsten 2009), further increasing the disease burden (Basra and Shahrukh 2009). The nature and degree of this burden may vary around the world depending on culture and healthcare provision.

Dermatological conditions affect 1.9 billion people, almost one-third of the world's population (Bickers et al. 2006; Murray et al. 2012; Hay et al. 2014). Since it is estimated that more than 70% of people with dermatological conditions do not consult a physician (Basra and Shahrukh 2009; Wehausen et al. 2016), the actual global burden may be markedly higher than estimated. In the UK, around 24% of the population consults a GP because of a skin complaint per year (British Association of Dermatologists [BAD] 2014) at an annual cost of £723 million to the National Health Service (NHS; British Pharmaceutical Industry Dermatology Initiative 2018). GPs refer over 6% of these cases to secondary care; 2.9 million outpatient appointments were made for dermatological conditions in 2010/11.

Accurate diagnosis and direct access to care are fundamental to the successful management of dermatological conditions, yet GPs only receive an average of six days of training across the whole of dermatology during their under- and post-graduate medical training (Schofield et al. 2009). Compounding this issue is the under-provision of dermatology services in the UK, with a shortfall of 250 dermatologists (Levell et al. 2013). Most dermatologists recognise that people with dermatological conditions benefit from psychological support, but psychological services are often limited by availability due to NHS financial constraints or lack of expertise among providers. Furthermore, the National Institute for Health and Care Excellence (NICE) guidelines only require psychological services for people with skin cancer rather than other dermatological conditions (Levell et al. 2013). The result is that the UK manages dermatological conditions sub-optimally increasing the burden for patients.

In this chapter, the burden of dermatological conditions and the central role of psychology in causing and addressing this burden is outlined. Psoriasis is used as an exemplar condition in this thesis to provide a coherent overview and context for the literature review. Much of the psychological research has been established in psoriasis, driven by, and contributing to, significant advances in treatments. For this reason, a summary of the characteristics of psoriasis is provided below. Note that skin cancers are not considered in this thesis as experiences with these acute health threats are unlikely to correspond to those of patients managing long-term dermatological conditions and different care pathways are followed.

1.2 Summary of the characteristics of psoriasis

Psoriasis is typically defined as a long-term inflammatory skin condition (WHO 2016; Griffiths and Barker 2010), though a growing body of evidence suggests that it would be more accurately described as a long-term, immune-modulated inflammatory skin and joint condition (Davidovici et al. 2010). There is no clear cause or cure (WHO 2016; Griffiths and Barker 2010). The WHO describes psoriasis as a serious global problem and not simply a cosmetic nuisance (WHO 2016). Like other dermatological conditions, it can have a profound physical, psychological, social and financial impact on patients' lives (de Korte et al. 2004;

Kimball et al. 2010; Obradors et al. 2016). The impact experienced stems from the symptoms experienced (e.g. chronic itch and bleeding), problems and costs related to treatments, pain from PsA, and the effect of living with a highly visible and stigmatising condition (WHO 2016).

1.2.1 Epidemiology

Psoriasis is a common dermatological condition and its prevalence appears to be increasing (Danielsen et al. 2013). It is estimated to affect around 0.09% to 11.4% of the global population (Danielsen et al. 2013) and around 1.5% to 5% of people in developed countries (Parisi et al. 2013). Research on the incidence of psoriasis is limited and often conducted according to demographics (Parisi et al. 2013). Age, gender, geography, and ethnicity appear to be important factors in the variation of prevalence of psoriasis.

Prevalence rates show geographical variation and appear to depend on the distance from the equator with populations located closer to the equator (e.g. Egypt and Tanzania) being less affected by psoriasis compared with those more distant from it (e.g. Europe and Australia; Parisi et al. 2013). The 'equator effect' is not well understood but is thought to reflect the fact that psoriasis is a complex condition, influenced by both genetic and environmental factors. Proposed mechanisms include the degree of solar irradiance, the metabolism of vitamin D and exposure to pathogens (Parisi et al. 2013; Griffiths et al. 2017). Parisi and colleagues (2013) argue that aspects of psoriasis, such as its remitting-relapsing course, diversity of clinical manifestations (Griffiths and Barker 2007) and variation in severity, may contribute to the wide variation in prevalence estimates. Methodological aspects such as the definition of prevalence, case definition of psoriasis and sampling techniques may also be important (WHO 2016; Parisi et al. 2013).

In the UK, psoriasis prevalence is steadily increasing, and estimates suggest that the condition now affects over 2.8% of the general population (Springate et al. 2017). The increase in prevalence may be the result of better awareness of the condition among clinicians and the general population and decreasing risk of mortality, rather than a real increase in prevalence

(Springate et al. 2017). Conversely, incidence cases of psoriasis are slightly decreasing from 159 cases per 100,000 person-years (95% CI 155–164) in 1999 to 129 per 100,000 person-years (95% CI 126–133) in 2013 (Springate et al. 2017). Similar to global trends, latitude appears to have a significant effect on psoriasis, with around 6.5 new psoriasis cases per 100,000 for every degree increase in latitude in the UK (Springate et al. 2017).

Caucasian people are more frequently affected by psoriasis than any other ethnic or racial group (Koo 1996; Johnson and Armstrong 2013). A systematic review found no agreement on whether the prevalence of psoriasis differed between men and women (Parisi et al. 2013), although there is some evidence that it may be more severe in men (Hagg et al. 2013). Onset is distributed bi-modally showing two peaks: early (between 20-30 years of age) and late (between 50-60 years of age; Cohen et al. 2012; Johnson and Armstrong 2013). Where psoriasis develops in childhood, it is typically more severe and less stable (Henseler and Christophers 1985).

1.2.2 Clinical features

Psoriasis symptoms are often unpredictable and typically follow a relapse-and-remitting course (WHO 2016; Griffiths and Barker 2007; Griffiths et al. 2007). Several clinical phenotypes are recognised, of which chronic plaque is the most common, accounting for 90% of cases (Griffiths et al. 2007). Nail psoriasis is also common, affecting approximately 50% of psoriasis patients (Griffiths et al. 2007). Psoriasis symptoms are mostly visible on, but not exclusive to, the skin, with systemic manifestation in many organ systems (Griffiths and Barker 2010). Characteristic manifestations of psoriasis are thick, red and heavily scaled plaques on the skin which can be itchy and painful (Griffiths and Barker 2010). The plaques can occur anywhere on the body, with the most commonly affected areas being the knees, elbows, trunk and scalp (Griffiths and Barker 2007,2010). The extent and severity of psoriasis vary over time and between individuals (Griffiths and Barker 2010).

1.2.3 Cause

Although the precise aetiology and pathogenesis of psoriasis are complex and much remains unknown, there is strong evidence that an interplay of genetic, immune, epigenetic and environmental factors contribute (Griffiths and Barker 2010).

Genetic factors

Psoriasis has one of the highest concordance rates of any inflammatory disease, up to 90% in monozygotic twins and 35% to 75% in dizygotic twins (Gudjonsson and Johnston 2009). It is also one of the most heritable complex genetic conditions (Elder et al. 1994; Swanbeck et al. 1994). Several genes have been identified as involved in psoriasis, most notably particular genes in the PSOR1 locus and human lymphocyte antigen Cw6 (Hawkes et al. 2016).

Epigenetic and environmental factors

Concordance rates in monozygotic twins do not reach 100% suggesting that environmental and epigenetic factors are involved. Several such factors are associated with the onset or exacerbation of psoriasis, including streptococcal infection; drugs including antimalarial and nonsteroidal anti-inflammatory drugs; ultraviolet light exposure; trauma to the skin (i.e. scratching, piercing, tattoos); hormonal changes; HIV infection and AIDS; obesity; psychological stress; smoking; and alcohol (Cohen et al. 2012; Johnson and Armstrong 2013; Vaughan Jones et al. 2014; Boehncke and Schön 2015; Young et al. 2017).

Immune factors

While psoriasis is considered an immune-mediated inflammatory condition, whether it is a 'bona fide' autoimmune condition is contested (Ayala-Fontánez et al. 2016). Association of psoriasis with other autoimmune diseases is an ongoing area of research: evidence exists for associations with rheumatoid arthritis, coeliac disease, Crohn's disease and inflammatory bowel disease (IBD), atopic dermatitis (AD), systemic lupus erythematosus, Sjögren's syndrome and vitiligo to varying degrees (Ayala-Fontánez et al. 2016).

There is considerable evidence that the dysregulation of immune cells in the skin, particularly T-lymphocytes (T-cells), plays an important role in psoriasis development (Griffiths and Barker 2010; Cai et al. 2012). Other immune cells are also overrepresented. Infiltration of T-cells in the epidermis and dermis leads to keratinocyte hyper-proliferation, which produces pro-inflammatory cytokines, further driving inflammation and keratinocyte production. The known immune mechanisms of psoriasis provide the rationale for the use of biologic therapies (Griffiths and Barker 2010).

1.2.4 Co-morbidities

Though psoriasis is rarely life-threatening, it is associated with several serious physical conditions, including CVD, metabolic syndrome (including Type II diabetes and arterial hypertension), and IBD (Takahashi and Iizuka 2012; Ryan and Kirby 2015; Ayala-Fontánez et al. 2016). Of note, up to 35% of people with psoriasis develop PsA, a form of inflammatory arthritis that can lead to joint deformations, further contributing to impairment (Zachariae 2003; Prey et al. 2010).

1.3 The central role of psychology in the skin

Other than the brain, the skin is the most psychological and social organ of the human body. It is the largest organ and serves as the boundary between the individual and the environment. In the *Remarkable Life of the Skin* (2019), dermatologist Monty Lyman refers to the skin as the 'swiss army knife organ' to reflect the myriad of important physical functions it performs. It provides a protective physical barrier between the body and the environment (including defence against exogenous chemicals and micro-organisms, absorbing UV radiation from the sun and waterproofing), heat regulation, immunological surveillance, and sensory and autonomic stimulation (Archer 2010; Hay et al. 2015).

The visibility of the skin has obvious social implications. As the most visible organ, it is among the most important determinants of identity and appearance. Appraisal of the skin plays a role in forming one's personal (e.g. perceived attractiveness) and social identity (e.g. ethnicity) and how one is perceived and treated by others (Tajfel and Turner 2001). The skin is also culturally important. Throughout history and across cultures, attention has been paid to the skin, beauty and skincare in line with contemporary dominant aesthetic and health parameters (Santoro 2017). Along with symmetry, well-proportioned and placed features, and white teeth, skin complexion is a key marker of beauty (Igarashi et al. 2007). The pursuit of attractive skin is centuries old. In 2015, the global skincare product market was valued at $110.69 billion and is expected to grow (Transparency Market Research 2015). Furthermore, our sense of touch originates in the skin. Touch deprivation – a lack of physical contact with others – is known to cause an increase in plasma cortisol levels and is linked to a range of physical and psychological problems including abnormal development of brain tissue, violence and drug misuse (Hatfield 1994; Floyd 2016). In contrast, tender and loving touch is associated with low levels of plasma cortisol, resulting in positive changes in brain tissues (Hatfield 1994).

There is a historical and commonly held belief in a 'skin-mind' connection, where the skin is viewed as a reflection of the individual's emotional state and vice versa. This connection makes intuitive sense since emotional states trigger a physiological response that can be

observed through changes in the colour, texture and moisture of the skin; for example, embarrassment can cause blushing, fear can cause sweating, and anger can cause redness. The emerging field of psychodermatology treats dermatological conditions using psycho-therapeutic techniques by addressing the skin-mind interaction, of which there are three broad, non-mutually exclusive groups described in the following three sections.

1.3.1 Psychiatric conditions with dermatological manifestations

There are several psychiatric conditions such as delusional infestation, factitious and induced skin disease, body dysmorphic disease, trichotillomania and other primary psychiatric diseases that manifest in the skin. These are less common than the following two interactions and are treated in dermatology departments by dermatologists trained in psychocutaneous medicine as these patients will usually not engage with mental health specialists in isolation (Bewley et al. 2012). This thesis will focus on the remaining two interactions.

1.3.2 Psychological functioning effects on the skin

There is now a growing body of evidence to support the existence of a 'brain-skin axis' (Paus et al. 2006), described as a continually functioning, bidirectional interaction between the skin and the brain. This relationship has been established mainly by research on the link between psychological stress and the skin.

Psychological stress is the psychological, physiological and behavioural response that occurs when an individual perceives that the demands placed upon them, or threats to their wellbeing, exceed their ability to cope with them (Lazarus 1966). The body reacts to stress by activating an array of physiological and behavioural central nervous system and peripheral adaptive responses (Orion and Wolf 2013). Because it is densely innervated and vascularised, the skin is particularly vulnerable and responsive to stress and research has confirmed that it is both an immediate stress perceiver and a target of stress responses (Chen and Lyga 2014).

Chronic psychological stress, for example, is known to have adverse effects on health, trigger or exacerbate multiple conditions including inflammatory skin conditions, and alter the immune and barrier functions of the skin (Altemus et al. 2001; Garg et al. 2001; Dhabhar 2002; Kleyn et al. 2008; Orion and Wolf 2012; Dhabhar 2013; Chen and Lyga 2014). Furthermore, psychological factors are frequently reported as a precipitant or exacerbating factor of skin disease (Papadopoulos et al. 1998; Schmid-Ott et al. 2009) and are a major determinant in the outcome of treatment (Fortune 2003).

As noted above, there are multiple causes and risk factors involved in psoriasis, yet in the clinical situation patients consistently report that stress or stressful life events are the precipitating factors. Historically, there is some evidence that stress causes psoriasis. In 1954, Ingram recognised emotional stress as the most potent precipitating factor in psoriasis. Farber and Nall (1974) later reported that 40% of patients report that their psoriasis occurred at times of worry. Later, Seville (1977) observed a consistent link between major stressful life events and disease manifestation. One of the few contemporary studies investigating the link between stress and psoriasis asked patients to keep a diary. This prospective study found that a high occurrence of daily stressors was significantly associated with increases in disease severity (Verhoeven et al. 2009). Preliminary research indicates that stress reduction can improve psoriasis outcomes (Fordham et al. 2015).

1.3.3 Dermatological conditions affect psychological functioning

Most patients seen by healthcare professionals have a primary dermatological condition with psychological comorbidities (All-Party Parliamentary Group [APPG] on Skin 2020). A survey conducted to inform the APPG on Skin's *Mental Health and Skin Disease* (2020) report found that 98% of dermatology patients report that their condition affects their emotional and psychological wellbeing, with 5% having suicidal thoughts linked to their condition, yet only 18% have received some form of psychological support. This is consistent with a previous national survey undertaken by the BAD in 2011 which highlighted the link between the skin and psychological factors and found that 85% of patients have indicated that the psychosocial

aspects of their conditions are a major component of their illness. These surveys are congruent with a growing body of evidence indicating that dermatological conditions impact patient's QoL and are associated with psychological distress (Picardi et al. 2007; Kurd et al. 2010; Sampogna et al. 2012; Ahmed et al. 2013), defined here as the negative emotions – stress, anxiety, depression – experienced by individuals in response to their ill-health.

Robert Willan, one of the founders of British dermatology, was the first person to accurately distinguish psoriasis from leprosy. In his book *On Cutaneous Diseases* (1808) he not only describes the morphology of psoriasis but recognised depression in psoriasis patients:

> The psoriasis most frequently occurs in persons who may be said to be of a mixed temperament, having some of the characteristics of the sanguineous, combined with other appearances belonging to the melancholic temperament.

In the 200 years since, progress has been made in the understanding of the immune mechanisms of psoriasis resulting in the development of highly effective cytokine targeted therapies which have been transformational for the management of patients with severe disease. At the same time, the understanding of the patient and how psoriasis and the brain interact, is lagging behind.

Dermatological conditions are commonly associated with psychological comorbidities (Gupta and Gupta 1998; Kurd et al. 2010; Dalgard et al. 2015). The levels of disability and distress experienced by people with psoriasis are comparable to other long-term conditions such as cancer, CVD, diabetes, arthritis, hypertension and heart failure (Finlay et al. 1990; Rapp et al. 1999; Baker et al. 2013a; Baker et al. 2013b). A systematic review and meta-analysis have found that the prevalence of anxiety (7 – 48%) and depression (10 – 25%) is considerably higher in people with psoriasis than for healthy controls (Dowlatshahi et al. 2014; Fleming et al. 2017).

Associations with other psychological comorbidities are less clear. The higher prevalence of mental illness is thought to account for the 15% increase in self-harm risk in people with

psoriasis compared to the general population (Parisi et al. 2019). Suicidal ideation is considered to be increased by 10% in people with psoriasis (Kurd et al. 2010), though the evidence is mixed (Chi et al. 2017). Methodological differences across studies such as varying outcome definitions (e.g. suicidal ideation, suicide attempt and death by suicide analysed separately vs. combined as a single outcome variable) may account for disparities. A recent large population-based cohort study (n = 50,000) found evidence of effect modification with age; specifically, the risk of suicide was higher among those individuals diagnosed when they were < 40 years old compared to those diagnosed aged ≥ 40 years (Parisi et al. 2019). These differences in suicide risk across the lifespan may go some way to explaining the conflicting findings in the predominantly cross-sectional studies. Increased suicidal ideation is also observed in other dermatological conditions. For example, a survey of 9,567 people with acne found that 22.5% had experienced suicidal ideation and 5.2% had attempted suicide (Purvis et al. 2006). A systematic review investigating the association between psoriasis, schizophrenia and disorders with psychotic features concluded that there "is some evidence of a relationship" (Ferreira et al. 2015, p. 3). This literature is based predominantly on cross-sectional research and there is a paucity of longitudinal research, so it is not clear whether psychological comorbidities are causally or indirectly associated, and in what direction; though qualitative research would suggest that psoriasis is likely to precede distress (Nelson et al. 2013b). This growing body of evidence suggests that it is important for clinicians to evaluate people with dermatological conditions for psychological comorbidities to improve outcomes and refer for psychological support.

Mechanisms of action between dermatological disease and psychological morbidity

The mechanisms of action between psoriasis and distress are not fully established but biological, psychological and social factors are involved. Much of the research in this area has focused on the biological mechanisms, reflecting the predominant psychiatric model of mental health and illness in the literature, which tends towards a reductionist, biomedical

approach. Proponents of biological mechanisms argue that inflammatory actions common to psoriasis and distress may account for the association. An oft-cited inflammatory action is increased stimulation of pro-inflammatory cytokines - high levels of which are present in both psoriasis and some psychological conditions - caused by chronic stress and its consequent effect on the hypothalamic-pituitary-adrenal axis and sympathetic-adrenal-medullary responses (Ferreira et al. 2016). A growing body of evidence supports this proposed mechanism. Raison and colleagues' (2006) review highlighted that inflammatory responses play an important role in the pathophysiology of depression, suggesting that targeting pro-inflammatory cytokines and their signalling pathways might represent a novel strategy to treat depression. A recent large-scale re-analysis by standardised procedures (mega-analysis) of patient-level data pooled from 18 randomised clinical trials (RCTs; n = 10,743) supports this strategy, finding that immune-therapeutics can produce antidepressant effects in depressed patients with primary inflammatory disorders that are not entirely explained by treatment-related changes in physical health (Wittenberg et al. 2020). Conversely, psychological interventions can affect the immune system. Shields and colleagues (2020) showed that interventions such as cognitive behavioural therapy (CBT) were not only positively associated with immune parameters such as pro-inflammatory cytokines and immune cell counts in patients with physical health conditions but actually rival pharmacological treatment options in terms of effectiveness. Taken together, these studies suggest that the relationship between dermatological conditions and distress is mediated by inflammatory processes and highlights the need to address psychological factors in the management of dermatological conditions.

Distress is linked to psoriasis severity and frequency of flare-ups (periods of symptom exacerbation; Schmitt and Ford 2007; Raho et al. 2012; Bangemann et al. 2014; Schmitt-Egenolf 2016; Kubanov et al. 2018; Yavuz Daglioglu et al. 2020). However, research shows that there is no simple, linear relationship between disease severity and distress (Fortune et al. 2000; Fortune et al. 2002). For example, high levels of distress may persist even after psoriasis has cleared (Fortune et al. 2004) as patients fear relapse (Husted et al. 2001). These findings suggest that, while biological mechanisms may contribute to the relationship between dermatological conditions and distress, other factors may be more important.

More recent thinking sees the relationship between distress and psoriasis as the result of the psychological and social challenges of living with a visible and challenging health condition, rather than as a result of purely biological processes (Kimball et al. 2010; Warren et al. 2011; Daudén et al. 2012). Impaired QoL is a proposed mechanism of action between distress and psoriasis, arising from a combination of psychological (chronic itch, pain, poor sleep, disfigurement and poor body image), social (stigmatisation and reduced social support), physical and functional factors (Rumsey and Harcourt 2004; Bundy et al. 2012; Bangemann et al. 2014; Kowalewska et al. 2020). Psoriasis can have a detrimental effect on most aspects of an individual's life including relationships, work, social functioning and sporting activities, with reduced levels of educational attainment, employment and income (Finlay and Coles 1995; Schmitt and Ford 2006; Griffiths and Barker 2010; Edson-Heredia et al. 2015; WHO 2016;) resulting in cumulative impairment across the life course (Kimball et al. 2010).

Kimball and colleagues (2010) proposed the concept of cumulative life course impairment (CLCI) to capture the long-term effect of psoriasis, its related comorbidities and stigma over a patient's life course. It is thought that CLCI results from 'an interaction between (a) the burden of stigmatization and physical and psychological co-morbidities and (b) coping strategies and external factors' (Kimball et al. 2010, p. 989). Similarly, Bhatti and colleagues (2011) developed the Major Life-Changing Decision Profile (MLCDP) to assist patients, clinicians and support services with insight into the affected goals and ambitions and life-long burden of people with long-term dermatological conditions to better manage and minimise their impact. MLCDP compliments CLCI by specifically addressing the impact of psoriasis on major life decisions such as career choice, having children, marriage, divorce, early retirement and moving abroad. Bhatti and colleagues (2011) hypothesise that major life decisions likely contribute to CLCI to an equal or greater extent than stigmatisation and coping strategies. In 2011, the British Journal of Dermatology (BJD) published a case series representative of typical patients with moderate-to-severe psoriasis to qualitatively explore the mechanisms of CLCI (Warren et al. 2011). The paper demonstrated that the condition influenced major life-changing decisions and altered the course of patients' lives, prevented patients from attaining their life goals, pursuing their chosen career, gaining a desired educational level, developing social relationships, gaining full pleasure from family life or having children. Crucially, all of

the patients believed that their lives would have taken a different course had they not had psoriasis. The concept of CLCI suggests that early psychological intervention is key to positive health outcomes and long-term wellbeing across the lifespan. In light of this, the APPG survey finding that children with psychological distress connected to their dermatological condition suffer without support is even more concerning (APPG on Skin 2020).

The 'brain-skin axis' is an emerging concept that may be useful in understanding how dermatological conditions cause psychological morbidity and how stressful life events may exacerbate inflammatory skin conditions (Bremner et al. 2005; Paus et al. 2006; Sternberg 2006). One in five people with psoriasis report being rejected or stigmatised because of their condition (Ginsburg and Link 1993) and commonly believe that they will be evaluated solely on their skin (Fortune et al. 1997a; Fortune et al. 2003). Previous studies have suggested the importance of cognitive forms of stress such as anticipatory anxiety and avoidance coping (Fortune et al. 1997a; Fortune et al. 1997b), fear of negative evaluation (Leary et al. 1998), pathological worry (Fortune et al. 2000; Fortune et al. 2002) and perceived stigmatisation (Richards et al. 2001). The existence of an automatic vigilance for threat may significantly contribute to the everyday stress experienced by people with psoriasis. Research using the Stroop test for attention, found that people with psoriasis were delayed in responding to self-referent and disease-specific words but not neutral words, compared to healthy controls. This suggests that people with psoriasis practice automatic vigilance for threats as they are hypersensitive to cues in the external environment (Fortune et al. 2003). Subsequently, researchers investigated whether the social impact of psoriasis was associated with altered cognitive processing in response to facial expressions of disgust by measuring brain activity in the insular cortex – a part of the brain triggered by both feelings and observations of disgust - using fMRI (Kleyn et al. 2009). Surprisingly, they found a significantly reduced response in the insular cortex when observing disgusted faces and were half as likely to recognise that a face was expressing disgust compared with healthy controls. There was no significant difference for other facial expressions, such as fear. The authors propose that people with psoriasis develop a coping mechanism to protect themselves from adverse emotional responses to their condition by others. This finding was replicated in a facial expression

recognition task, a decision-making task designed to assess the ability to recognise facial expressions of disgust at different intensities (Kleyn et al. 2009).

Specific psychopathological features, such as maladaptive schemas (Mizara et al. 2012) and alexithymia (Fortune et al. 2002; Sampogna et al. 2017) are known to be overrepresented in people with psoriasis and may be important mechanisms. Schemas are cognitive frameworks that organise and interpret information and represent an individual's knowledge and assumptions about the world (Beck 1994). Individuals with maladaptive schemas are vulnerable to negative psychological outcomes including anxiety and depression (Young 2003). Mizara (2012) identified six predominant forms of maladaptive schemas - emotional deprivation, social isolation, defectiveness/shame, failure, vulnerability to harm and subjugation - in people with psoriasis and AD which predicted anxiety and depression. Of particular note, a maladaptive 'emotional inhibition' schema, associated with difficulties discussing and expressing emotions, vulnerability or freely communicating needs, was present in patients but not in healthy controls – individuals with no skin-related problems or long-term conditions. This is in keeping with findings of high levels of alexithymia - a limited ability to both identify and verbally express feelings, paucity of fantasy life and externally oriented thinking - among people with psoriasis which, in turn, is associated with anxiety (Allegranti et al. 1994; Fortune et al. 2002).

The role of lifestyle behaviours

Modifiable behavioural factors (overweight, smoking, inactive, poor sleep and alcohol use) adversely affect health outcomes (Penley et al. 2002). People living with one or more existing health conditions are generally more susceptible to poor health and behavioural outcomes (Anderson and Ozakinci 2018). This is true in psoriasis where comorbidities are common (Takeshita et al. 2017) and patients are more likely than the general population to engage in a range of unhealthy life behaviours including poor diet, sedentary behaviour, obesity, poor sleep, excessive alcohol consumption and smoking (Naldi et al. 2005; Samarasekera et al. 2013; Ni and Chiu 2014; Henry et al. 2019; Manolis et al. 2019). The increased risk of CVD for

people with psoriasis is associated with these unhealthy behaviours (Manolis et al. 2019) and there appears to be a dose-response relationship between psoriasis severity and excess CVD risk (Armstrong et al. 2013).

Such lifestyle behaviours puts patients at greater risk of developing comorbidities (Stampfer et al. 2000; Yusuf et al. 2004; Vineis and Wild 2014) and interact with psoriasis itself (Poikolainen et al. 1990; Fortes et al. 2005; Hayes and Koo 2010; Naldi et al. 2014; Barrea et al. 2015; Upala and Sanguankeo 2015; Henry et al. 2017; Melikoglu 2017), complicating the understanding of comorbidities (Parisi et al. 2015). For example, being overweight and smoking contribute to psoriasis onset and exacerbation (Fortes et al. 2005; Setty et al. 2007; Wolk et al. 2009). Correspondingly, weight loss, healthy diet, and activity patterns are associated with improvements in psoriasis severity (Rucević et al. 2003; Frankel et al. 2012; Jensen et al. 2013). Weight loss can improve response to systemic psoriasis treatments (Gisondi et al. 2008). The challenges of patient self-management and lifestyle behaviour change are compounded by the high levels of distress present in many patients with psoriasis. Distress can increase risk behaviour (e.g. smoking, alcohol consumption) and reduce the motivation and capacity to engage in healthy behaviours (Tice et al. 2001; Kwan et al. 2016). To illustrate, non-adherence to treatment is a significant problem in psoriasis management (Thorneloe et al. 2013) and adherence to psoriasis medication can be an additional source of distress therefore some non-adherence could be interpreted as attempts to minimise distress and regain control.

Although these risk factors are modifiable and may reduce psoriasis severity and CVD risk, patients and clinicians may not be aware of their associations with psoriasis (Nelson et al. 2013a). Clinicians increasingly recognise the role of health behaviours in managing psoriasis, yet the same behaviours are still managed sub-optimally and patients do not receive evidence-based behaviour change support in line with clinical guidelines (Nelson et al. 2013a; Nelson et al. 2016). Instead, management of psoriasis has largely focused on the physical symptoms (Smith and Barker 2006). A significant contributing factor is that clinicians feel that they lack the skills, knowledge, training and confidence to support behaviour change. Behaviour change training for clinicians can enhance their communication skills and increase

the motivation and confidence to address the wider impact of psoriasis (Nelson et al. 2016). This will be increasingly important in light of the COVID-19 pandemic, where anxiety has increased this has adversely affected general health and coping (Zvolensky et al. 2020; Yıldırım and Arslan 2021). Pertinently, people with existing health conditions are more likely to engage in avoidance than active coping behaviours in response to the threat of SARS-CoV-2 compared to those without existing health conditions (Hewitt et al. 2021c) and may require additional psychological support (O'Connor et al. 2020; Pedrosa et al. 2020). Furthermore, the unhealthy lifestyle factors listed above are associated with an increased risk of hospitalisation, severe disease progression and death due to SARS-CoV-2 (Chang et al. 2020; Popkin et al. 2020).

1.4 The need for a biopsychosocial approach to dermatology

Mental and physical health are intrinsically and inextricably linked. It is not surprising, therefore, that disruptions to the skin's health and functioning through birth defects, trauma or disease can have a profound and potentially devastating impact on the affected individual. Evidence suggests that dermatological conditions are best understood and, by extension managed, as biopsychological conditions.

1.4.1 Models of health and illness

Models of health and illness implicitly underpin dermatology provision and healthcare more generally. To understand and evaluate current approaches to the management of dermatological conditions it is necessary to explicitly define ‘health’.

In 1948, the WHO defined health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” In the textbook *Health Psychology: Theory, Research and Practice* Marks, Murray and Vida Estacio (2021) persuasively criticise this definition of health. They point out the idealism and doubtfulness of anyone achieving “the state of *complete* physical, social and spiritual well-being” [emphasis added] and

highlight that this definition overlooks the psychological, cultural and economic aspects of health. Their alternative definition will be used to define health in this thesis:

> Health is a state of well-being with satisfaction of physical, cultural, psychosocial, economic and spiritual need, not simply the absence of illness (Marks 2021, p. 5)

Both the WHO and Marks and colleagues' definitions of health are at odds with the biomedical model of health and illness, the dominant healthcare model of today. Originating in the mid-1800s, the biomedical model defines health purely as the absence of illness and focuses exclusively on the physical or biological aspects of illness. The legacy of Cartesian dualism is evident as the model treats 'mental' and 'physical' health separately. Despite its reductionist and exclusionary approach, the biomedical model has been hugely successful. In the 20th century, the model's Germ Theory of Disease was credited with essentially eliminating the primary cause of death - infectious diseases such as tuberculosis, pneumonia, influenza and diarrhoea. Critics, however, argue that the observed health improvements were mainly a result of better hygiene, education and reduced poverty (McKeown 2014).

Long-term conditions now account for most morbidity and mortality in Western countries (Wade and Halligan 2017). Tinetti and Fried (2004) argue that the changing spectrum of health, the complex interplay of biological and non-biological factors, an ageing population and individual differences in health priorities render the biomedical model out of date and potentially harmful, claiming that the primary focus on disease may lead to under-treatment, overtreatment, or mistreatment. Healthcare systems designed around the model are struggling to improve patient-reported outcomes and reduce healthcare costs (Wade and Halligan 2017). With this in mind, Tinetti and Fried (2004) declared the "time has come to abandon disease as the focus of medical care" (p. 179).

The Alameda County (Wingard et al. 1982) and Framingham Heart (Doyle et al. 1962) studies demonstrated the central role of behaviour in disease aetiology. The Framingham Heart study coined the term 'risk factor' which specify targets for interventions. Together these studies found that engaging in healthy lifestyle behaviours - never smoking, getting regular physical

activity, drinking fewer than five drinks at one sitting, maintaining normal body weight, and sleeping 7 to 8 hours per night – reduced morbidity and mortality. The Whitehall I and II studies investigated the social determinants of health. Whitehall I found a social gradient in health with a strong association between lower grades of employment and all-cause mortality (Marmot et al. 1978). Whitehall II determined that the way work is organised (in particular, job control), the work climate, social influences outside work, influences from early life, and health behaviours all contribute to the social gradient in health (Marmot et al. 1991). Such research shows that the biomedical model is incongruent with the scientific understanding of health and illness.

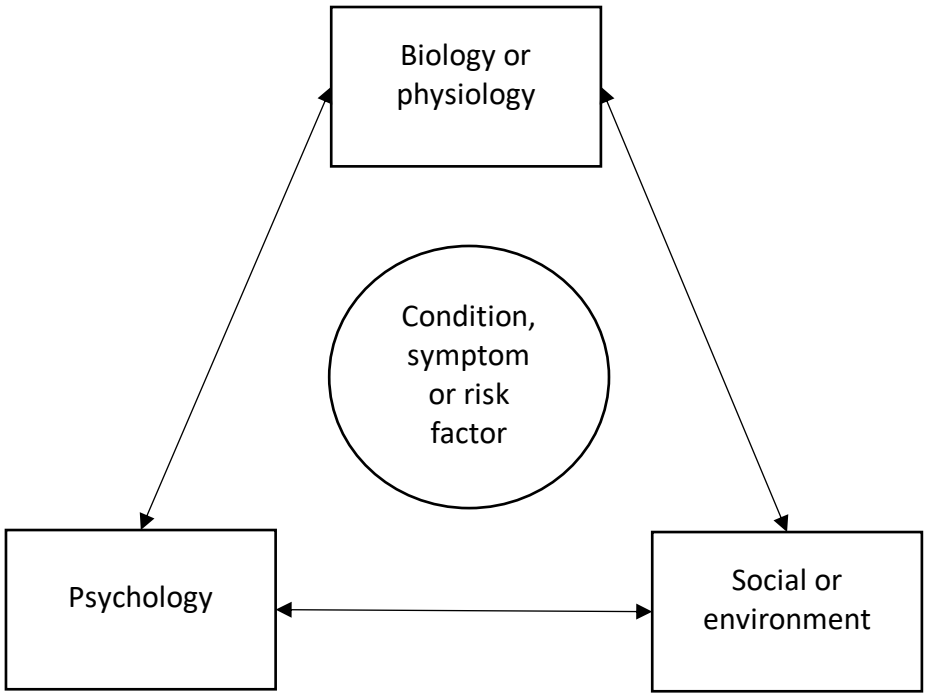
Emerging from dissatisfaction with the biomedical model, in his classic paper, George Engel (1977) proposed a paradigm shift in healthcare with the biopsychosocial model (Figure 1.) which posits that interactions between biological, psychological, and social factors determine the cause, manifestation, and outcome of wellness and disease (Engel 1977; Borell-Carrió et al. 2004). Thus, Engel integrated psychological ('psycho') and environmental ('social') factors into the traditional biomedical ('bio') model of health. The biopsychosocial model has been taken up in many healthcare fields, is used to structure clinical guidelines, is widely used in research into complex health interventions and is the basis of the WHO's ICD (Wade and Halligan 2017). However, despite evidence supporting its validity and utility, the model has had little influence on the larger scale organisation and funding of healthcare provision.

Clinicians and researchers require a sound theoretical model of health and illness but there has been little adoption of the biopsychosocial model into medical education. A study found that US physicians reported not receiving effective training regarding the role of the biopsychosocial model and consequently have low self-efficacy in managing biopsychological issues (Moser and Stagnaro-Green 2009). Linder (2015) argues that dermatological conditions are most often long-term and deeply and inextricably rooted in the psychological and social dimension of health and, therefore, provide the clearest example of how the biopsychosocial approach to research and clinical practice may substantially improve the quality of healthcare. Better understanding and employment of the biopsychosocial model by those

funding, structuring and delivering dermatology services and healthcare more generally is needed as is the development of applications that are acceptable to patients.

PRIDD is developed consistent with the biopsychosocial model of health, to identify key biological, psychological and social aspects of dermatological conditions. This thesis will be weighted towards the psychological aspects. This is because, a) as a patient-reported outcome measure, PRIDD will operate at the individual level, which inherently emphasises the psychological and biological over the social and b) the psychological aspects tend to be minimal in existing measures while being common for many with dermatological conditions. The focus on the psychological aspects at the individual level is an important contribution because the existing dermatology literature and guidance predominantly focuses on the physical aspects and many of the social aspects of health such as health service delivery operate at the meso and macro levels.

Figure 1: Biopsychosocial model of health and illness (Engel 1977)



1.4.2 The management of dermatological conditions

The Department of Health recognises the importance of "enhancing quality of life for people with long-term conditions" in the NHS Service Outcomes framework (2021). The UK Government has an agenda to improve psychological support for patients, particularly those suffering from long-term conditions through the 'long-term care' and 'no health without mental health' strategies. These are in line with the WHO and UK policy, which advocate for a person-centred approach to health service delivery, which implies a biopsychosocial model focusing on all factors that influence the individual's health and functioning. Many long-term conditions are managed according to a biopsychosocial model. For example, understanding IBD through the framework of the biopsychosocial model has been important in establishing interdisciplinary treatment approaches for the condition (Drossman 2016). Yet, despite evidence that people with dermatological conditions experience levels of disability and distress comparable to other serious, long-term conditions (Finlay et al. 1990; Rapp et al. 1999; Baker et al. 2013a; Baker et al. 2013b) their management remains predominantly biomedical with little psychological support in place.

The 2014 WHO resolution highlighted that many people in the world "suffer needlessly from psoriasis due to incorrect or delayed diagnosis, inadequate treatment options and insufficient access to care, and because of social stigmatization" (WHO 2016, p. 1). Globally, barriers to accessing appropriate care include a low level of knowledge about dermatology conditions among non-dermatology trained health professionals, high costs of treatment and limited access to health care (WHO 2016). In addition, many low- and middle-income countries have no dermatology specialists and referral is difficult due to geographic distance and availability of travel funds. Current estimates suggest approximately 77% of people with psoriasis have not sought medical help (Wehausen et al. 2016).

In the UK, the majority of psoriasis patients are managed in primary care (NICE 2012). Specialist referral is necessary at some point for up to 60% of patients and supra-specialist tertiary care is required in a very small minority with especially complex, treatment-resistant and/or rare manifestations of psoriasis. A UK-wide audit conducted by the BAD found wide

variations in practice and capacity to meet BAD guidelines and standards (Eedy et al. 2009). Among the most significant deficiencies in care were a shortage of specialist nurse support and psychological services, access to specialist treatment (including biological therapy) and appropriate drug monitoring (NICE 2012; Eedy et al. 2009). Subsequently, patients report dissatisfaction with health care and may disengage with services due to frustration (Richards et al. 2004; Nelson et al. 2013b). The APPG report on *Skin Disease and Mental Health* (2020) states that commissioners and providers should ensure that multidisciplinary teams consisting of a dermatologist, liaison psychiatrists, psychologists, and specialist dermatology nurses are developed regionally. Dermatology staff should also be trained in the basic assessment and support of psychological comorbidities and be able to signpost to mental health services.

Patient self-management

Because many dermatological conditions are currently incurable, management focusses on improving symptom control and QoL. These outcomes are of course related – an international survey found that patients and carers believed that the ability to control their eczema effectively would be the single most important improvement to their QoL (Howells et al. 2019). The majority of patients in this survey did not feel confident managing their eczema without direction from a clinician, yet patients with long-term conditions typically spend less than 1% of their time in contact with clinicians, meaning that they are expected to manage their condition themselves (Department of Health and Social Care 2010). There is a clear educational need for extended clinical skills training among dermatology specialists to enable patients to self-manage better.

The Chronic Care Model has been advocated to improve the quality of care for people with long-term conditions (Wagner et al. 2001). In this model, the healthcare system is viewed as one part of a larger 'health organisation':

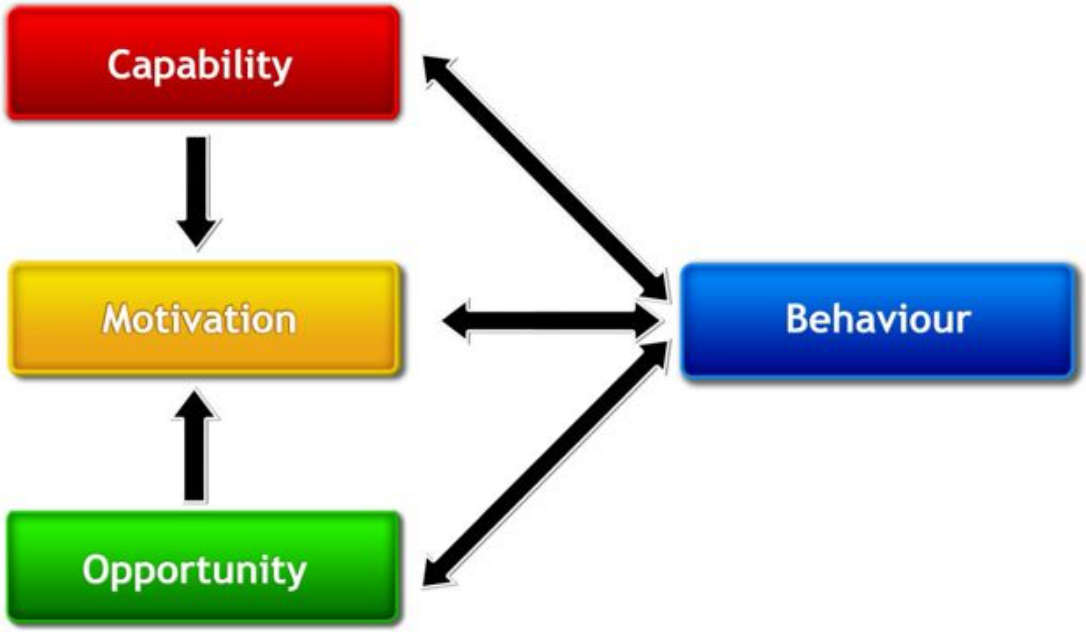
> Effective self-management support and links to patient-oriented community resources help to activate and inform patients and families to better cope with the challenges of living with and treating chronic illness. Traditional patient education emphasized knowledge acquisition and didactic counselling. Mounting evidence indicates that while such interventions increased knowledge, they were unsuccessful in changing behaviour or improving disease control and other outcomes. More recent theoretical and empirical research has shifted the focus from patients' knowledge of the disease and its treatment to their confidence and skills in managing their condition. The interventions that have emanated from this research reinforce the patient's (and family's) crucial role in managing the condition, help patients to set limited goals for improving their management of their illness, identify barriers to reaching their goals, and develop a plan to overcome the barriers. (Wagner et al. 2001, p. 69)

In the UK, the NHS has led a policy shift towards patient self-management of long-term conditions (NHS 2014). This includes monitoring and managing symptoms, treatment adherence, adopting healthy lifestyle behaviours, and managing the physical, psychological and social impacts of the condition. Evidence shows that improvements in self-management are associated with improvements in disease outcomes, QoL and health cost reductions (Bodenheimer et al. 2002). Patients need support from clinicians to develop these skills, including regular assessment of progress, goal setting, action planning and problem-solving skills, but clinicians report not having the time, training or skills to perform this role consistently with evidence-based approaches.

Successful management of long-term conditions depends on the active behavioural involvement of the patients (Department of Health 2001; Michie et al. 2003). Achieving behaviour change depends on a range of factors including beliefs about health and illness as well as effective communication with clinicians (Michie et al. 2003). The COM-B model (Figure 2.) conceptualises behaviour as arising from the interaction of capability (physical and psychology), opportunity (physical and social) and motivation (reflective and automatic;

Michie et al. 2011). As a dynamic model, engagement in a behaviour influences the individual's capability, opportunity and motivation to perform the behaviour again through a feedback loop. COM-B can be used to design behaviour change interventions.

Figure 2: The COM-B Model of Behaviour Change reproduced from Michie et al. (2011, p. 4)



A recent systematic review found that most interventions designed to promote self-management of eczema were educational interventions focused on giving information about symptoms and medication management (Ridd et al. 2017). However, the attainment of knowledge and understanding (which are not synonymous), and also skills and confidence, is required to self-manage effectively. Furthermore, it was uncommon for the interventions to be underpinned by an explicit theory regarding the mechanism of action (Ridd et al. 2017).

The lack of confidence in managing dermatological conditions as complex conditions point to a gap in dermatology education. PsoWell™ (psoriasis and wellbeing) is a Motivational Interviewing (MI)-based training programme and clinical initiative that advocates a holistic, multidisciplinary approach to managing psoriasis (Chisholm et al. 2017). Research has shown that PsoWell™ training improves primary and secondary care clinicians' psoriasis-related knowledge, consultation skills and confidence to address the psychological aspects of psoriasis and health behaviour change with patients during standard dermatology consultations (Chisholm et al. 2017). In a recent study of the acceptability and feasibility of

PsoWell™ training and clinics, dermatology-specialist staff recognised MI skills as transferable to other dermatological and long-term conditions (Hewitt et al. 2021b). Appropriate training may not only improve patient outcomes but may also improve retention as clinicians who have sophisticated models of psoriasis and report actively addressing psychology and social issues with patients tend to have higher levels of job satisfaction and self-efficacy (Chisholm et al. 2016).

1.4.3 Assessment and treatment of psoriasis

NICE guidelines recommend a biopsychosocial approach to the management of dermatological conditions such as psoriasis (2012), eczema (2007) and acne (2021). This includes screening for physical and psychological comorbidities in addition to managing the physical aspects of the condition (e.g. skin lesions and joint paint). Growing evidence indicates that managing patients holistically from the start of their illness reduces the physical, psychological and social impact in the long term (APPG on Skin 2020).

Still, research shows that clinicians tend to manage only the physical symptoms (Smith and Barker 2006) and work with a restricted concept of dermatological conditions as 'simple skin conditions', suggesting a lack of understanding of these conditions (Nelson et al. 2013a). Even when clinicians recognise psoriasis as a complex condition many manage it as a simple skin condition (Chisholm et al. 2016), reporting that they lack the knowledge, skills, training and confidence to provide psychological and social support, including lifestyle behaviour change support (Nelson et al. 2013a; Nelson et al. 2014). In keeping with clinicians' simple model of skin conditions, healthcare providers report believing that improvements in the skin inevitably result in the resolution of associated psychological and social difficulties (Chisholm et al. 2016). Subsequently, psoriasis is managed 'episodically' as if it was a resolving and returning condition (Chisholm et al. 2016), rather than actively pursuing a review and follow-up strategy with patients in line with other long-term conditions (Nelson et al. 2013a) which would require a high degree of patient self-management.

Treatment for psoriasis is lifelong (Laws and Young 2010; NICE 2012). A wide variety of treatment options are available; all require monitoring (NICE 2012). The NICE (2012) guidelines classify psoriasis treatments into three broad categories: topical, phototherapy and systemic treatments, and systemic/biological treatments; generally representing a treatment ladder of first-, second-, and third-line treatments, respectively. NICE recommends escalating treatment if it fails to result in skin improvement, if there is frequent recurrence or high levels of psychological distress (Laws and Young 2010). In addition to managing skin lesions and joint involvement, clinicians should screen for known physical and psychological comorbidities (NICE 2012; WHO 2016). Psychological and social interventions, such as psychological therapies, patient education, and behaviour change support may be required (WHO 2016; Nelson et al. 2017; Xiao et al. 2019).

High levels of psychological distress, however, may not always be obvious (Richards et al. 2004), but can be assessed through standard consultation and measurement instruments (Bewley et al. 2012), such as the Dermatology Life Quality Index (DLQI; Finlay and Khan 1994a). These can identify particularly vulnerable patients and provide diagnostic and assessment evidence. Psychodermatology UK recommends the assessment of patients' psychological comorbidity across a stepped model of care (Bewley et al. 2012) with levels of psychological distress - assessed using measurement tools such as the DLQI, Skindex-29 (Chren et al. 1997a) and Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith 1983) – determining the psychological support given (Table 1.). Through the stepped model of care, these assessments make a significant contribution to treatment decision-making; affecting not only medication prescribed - as a patient progresses up the therapeutic ladder, treatment options increase in both their efficacy and potential for toxicity (Ashcroft et al. 2000; Fairhurst et al. 2005) - but also the psychological support afforded.

Table 1: Psychodermatology UK recommendations for assessment of patients across a stepped model of care

Low-level distress	The majority of Dermatology patients with low-level psychological distress (DLQI 5-9, HADS anxiety or depression 5-7) can be managed by Dermatologists and allied health professional staff who have level 1 training
Moderate level distress	Most Dermatology patients with moderate levels of distress (DLQI 10-18, HADS anxiety or depression 8-10) or patients with skin cancer can be managed locally (either within the community or hospital setting) but may need higher-level support from local Psychologists or health practitioners, psychological well-being practitioners or Cognitive Behavioural Therapy (CBT) trained therapists.
High-level distress and more serious mental health issues	Patients with disfiguring and long-term skin conditions and high levels of distress (DLQI > 17, HADS anxiety or depression ≥11), complex mental health needs which cannot be addressed in a local service should be referred to a **regional service**, for specialised care.

Psychological assessments are rare in primary and secondary care (Psoriasis Association and Mental Health foundation 2012). In keeping with the biomedical approach to dermatology management, the most commonly used tool in clinical practice is the Psoriasis Area and Severity Index (PASI; Fredriksson and Pettersson 1978), which measures disease severity, followed by the DLQI. Many of the measurement instruments currently in use are of poor quality. A systematic review of patient-reported outcome measures used in psoriasis research and practice found that no measure, including the DLQI, had adequate evidence of validity, reliability, and sensitivity to change to measure QoL in psoriasis (Kitchen et al. 2015). Similar findings have been found for AD (Gabes et al. 2020). Despite this, NICE still recommends the use of the DLQI alongside the PASI when making treatment and referral decisions (NICE 2012). The development and validation of the DLQI is the third most cited journal article in the whole field of dermatology since the 1970s (Maymone et al. 2020). Given its prevalence in dermatology research and clinical practice, the DLQI is given particular attention among dermatology assessments in this thesis.

1.4.4 Psychological support in dermatology

Psychological interventions alone (Papadopoulos et al. 1999) or as an adjunct treatment (Fortune et al. 2002)can be helpful in treating and coping with many dermatological conditions (APPG on Skin 2020). There is increasing evidence for the effectiveness of evidence-based psychological interventions including CBT, patient education, lifestyle behaviour change support, internet-based therapies, and bibliotherapy in dermatological conditions (Naylor et al. 2010; Hilvert-Bruce et al. 2012; Lavda et al. 2012; WHO 2016; ; Nelson et al. 2017; Xiao et al. 2019). Shields and colleagues (2020) demonstrated that psychological interventions rival pharmacological treatment options in terms of effectiveness to positively affect the immune system. Taken together, the evidence suggests that patients with dermatological conditions, particularly those with psychological and social comorbidities, are best treated by a multidisciplinary team (Chisholm et al. 2017; Hewitt et al. 2021b) using a biopsychosocial approach, which recognises the complex relationships in health and wellbeing involving psychological and behavioural factors.

Psychological services

Yet, people with dermatological conditions remain “desperate and frustrated” (p. 5) at being unable to receive the psychological support they need (APPG on Skin 2020). Despite growing demand, clear recommendations from the APPG (2003 and 2013) and Psychodermatology UK (Bewley et al. 2012) to expand psychodermatology services across the UK, and evidence of both its clinical and cost-effectiveness, this has not been implemented (APPG on Skin 2020). The APPG survey and previously the BAD survey (2011) both showed reductions in psychodermatology provision since 2003. Psychodermatology provision remains “very scant” across the UK, resulting in an unacceptable level of service provision for an established clinical need (Bewley et al. 2012). Furthermore, the BAD’s consensus statement outlines the minimum standards required to support psychodermatology service provision in the UK, yet Getting It Right First Time for Dermatology (Levell 2020) has highlighted wide geographical variation in access to Psychodermatology in England. This is particularly worrying in light of

the COVID-19 pandemic. As shown above, dermatology patients were already known to experience significant distress and the pandemic has exacerbated psychological distress in those with existing health conditions (Hewitt et al. 2021c).

People with dermatological conditions and psychological distress can receive care from a range of healthcare professionals, depending upon the severity of their condition and service availability. The recognition and management of patients with serious mental health issues presenting to dermatology require specific skills from clinicians with experience and expertise in this area (Bewley et al. 2012). In reality, little psychological support is provided beyond compassion. The level of psychological support is dependent upon both referral pathways and the confidence of clinicians to adequately address psychological issues. Unfortunately, where patients have low-to-moderate physical or psychological symptoms, primary care clinicians are often unable to make direct referrals to specialist care due to long waiting lists. Even when referred to dermatology services in secondary care, many clinicians (dermatologists, psychiatrists, and psychological practitioners) lack psychodermatology training and, therefore, may lack the confidence to diagnose and treat patients with dermatological conditions and psychological comorbidity (Muralidharan et al. 2020). There are only 13 psychodermatology clinics across the UK and many are dedicated to a specific disease such as psoriasis, so are not general psychodermatology services. Furthermore, these services are not uniformly distributed; only around one-quarter of dermatology consultants have access and Wales has no services at all. Therefore, UK psychodermatology provision is insufficient to meet national demand.

Because psychological support is typically not integrated within dermatology services, referral to outside services is required. In England, people with anxiety and depression associated with their dermatological condition can be referred to Improving Access to Psychological Therapies (IAPT) services for people with long-term physical health conditions, where these exist. In IAPT services practitioner psychologists provide evidence-based psychological therapies with routine outcome monitoring. However, IAPT training is usually generalist and there is only one dermatology-specific pathway within IAPT. Supposedly, individuals with moderate-to-severe psychological disorders can be referred to Community Mental Health

Teams where there is access to psychiatry assessment and secondary care psychology input, as well as occupational therapy and social work input. However, these services are currently under-resourced and are forced to focus only on those patients with 'severe mental illness' or at high risk to themselves or others. There are some support and self-help resources provided by professional associations (e.g. BAD) and charities that patients can access (e.g. Psoriasis Association and Changing Faces).

Psychological versus psychiatric approaches to managing psychological comorbidities

In the same way that the current approach to dermatology was inherited from the biomedical model, the current provision of psychological support for dermatology patients can be viewed as the legacy of the psychiatric model of mental health and illness.

The psychiatric approach explicitly or implicitly relates psychological phenomena to biological causes and, therefore, promotes biological intervention. It follows diagnostic criteria that artificially classify individuals dichotomously as either having a mental illness or not, before offering treatment. Within a psychiatric model, patients who may be experiencing distress but do not meet diagnostic criteria for a primary mood disorder often struggle to access psychological support. This means that there is an unmet need for patients who require psychological support.

A psychological approach to identifying and managing psychological comorbidities of psoriasis and potential mechanisms offers an alternative to the predominant psychiatric approach (Kinderman 2005). The psychological model of mental health and illness, an extension of the biopsychosocial model, is based on the notion of multiple simultaneous causes of health and illness and proposes that three main variables (biological, social, and circumstantial) contribute to mental disorder through the disruption of psychological processes (Kinderman 2005). The psychological approach, therefore, addresses different mechanisms than exclusively biomedical theories and seeks to incorporate more than the

mechanics of any individual variable and to address interactions and interrelationships (Kinderman 2005).

1.5 Summary of chapter

Dermatological conditions have a substantial impact on patients. The current biomedical approach to their management - from individual clinicians to high-level decision-makers - causes unnecessary additional burden for patients. Dermatology assessment, by extension, is not truly biopsychosocial and therefore presents a potential avenue for improvements. Psychological distress in people with dermatological conditions should be viewed as a continuum rather than a dichotomy and assessment, management and service provision should follow. PRIDD will be designed to address this gap in assessment.

Chapter 2: Assessing the impact of dermatological conditions

2.1 Patient-centred care

Patient-centredness has been strongly emphasised in offering care to patients with long-term conditions. The Institute of Medicine (2001) defines patient-centred care (PCC) as compassionate, empathetic and responsive care that reflects the needs, values and preferences of patients. Over the last half a century, there has been increasingly widespread recognition and acceptance of PCC as a core dimension of high-quality healthcare (Compton et al. 2005; Wilson 2008; Epstein and Street 2011). The WHO promotes the concept of people-centred health care, emphasising the need for fair access to health care for the right patient at the right time (WHO 2007). Globally, governments (NHS 2005; US Department of Health and Human Services 2008; Australian Commission on Safety and Quality in Health Care 2010), international organisations (WHO 2000), patient and health policy organisations (Picker Institutue 2004; Health Foundation 2011; King's Fund 2011), and lobby groups (International Alliance of Patients' Organisations 2007), have all emphasised the need for healthcare to be explicitly centred on the needs of the individual patient. Similarly, international quality and safety agencies (Australian Commission on Safety and Quality in Health Care 2009) and healthcare reform initiatives (Department of Health 2008) prioritise the philosophy and practice of PCC as core to effective models of care delivery and it is taught during medical education (Barr et al. 2014).

The term 'patient-centredness' was coined by Enid Balint in 1969 to describe a way of understanding the patient as a unique human being. Many other definitions have been proposed (e.g. Brown et al. 1986; Levenstein et al. 1986; McWhinney 1986). Epstein and Street (2011) believe in the "essential and revolutionary meaning of what it means to be patient-centred" (p. 100). They further propose that the originators of PPC were well aware of the moral implications of their work, which was based on "deep respect for patients as

unique living beings, and the obligation to care for them on their terms" (p. 100). Consistent with the biopsychosocial model, PCC aims to reach a shared understanding of the patient's health condition that takes the psychological and social contexts that underpin their experiences into account. This is consistent with the Department of Health's (2012) vision of an NHS that puts patients and the public first, where 'no decision about me, without me' is the norm. Lohr and Zebrack (2009) have commented on the intersection between patient-reported outcomes and bioethics, noting their contribution to beneficence, patient autonomy and distributive justice. PCC is more than a moral stance, however. There is a growing body of evidence demonstrating its value to patient (health, QoL and satisfaction; Hall et al. 2010; Rathert et al. 2013), clinician (job satisfaction and work-related health outcomes; van Diepen et al. 2020) and organisational outcomes (increased quality and safety of care; Rathert et al. 2013). Despite its focus on individual needs, PCC is consistent with evidence-based medicine, which tends to focus on populations, with proponents of evidence-based medicine accepting that a good outcome must be defined by what is meaningful and valuable to the individual patient (Guyatt et al. 2004).

Despite the emphasis on the value of PCC, the concept has not been well-defined and is often used without reference to a specific definition (Illingworth 2010; Ishikawa et al. 2013). The lack of a universally agreed-upon definition hinders the transition of PCC from a theoretical approach to clinical practice. Many definitions have been proposed. Following a review of the conceptual and empirical literature, Mead and Bowers (2000) proposed what became an influential conceptual framework of PCC with five dimensions: biopsychosocial perspective; `patient-as-person'; sharing power and responsibility; therapeutic alliance; and `doctor-as-person'. A more recent systematic review supported the first four of Mead and Bowers' dimensions, though found few articles regarding the *doctor-as-person* dimension (Kitson et al. 2013). The authors added a new dimension, 'co-ordinated care' and proposed a succinct definition of PCC as encompassed by three elements: the patient, the doctor-patient relationship and the framework of care (i.e. the health care system).

2.1.1 Outcome measures

Outcome measures can facilitate PCC (Abernethy et al. 2008). Long and Dixon (1996) propose patient-centredness is one point on a spectrum of outcome measures. On one end of the spectrum is a 'patient-defined outcome' where the patient perspective has been incorporated. On the other end is a clinician-defined outcome where assessments are made based on the clinician's observations without taking account of information from the patient.

Traditionally, research (including clinical trials) and clinical practice have focused on biomedically defined outcome measures based on the prevailing view that such data are 'hard' and scientific (Feinstein 1987). Over the past decades, a paradigm shift has occurred in the evaluation of medical care (Bullinger and Quitmann 2014). The shift reflects the move from a biomedical to a biopsychosocial understanding of health and consequently a greater focus on PCC (Laine and Davidoff 1996; Barry 2011; Barry and Edgman-Levitan 2012). With this, the focus of assessment moved from clinical indicators of disease activity or health status alone to include patients' perception of the impact of their health condition and related treatment. The recent APPG *Skin Disease and Mental Health* report (2020) acknowledged the central role of assessment in the holistic management of dermatological conditions writing:

> [There is an] urgent clinical need for healthcare professionals to be equipped with the necessary skills and resources to provide the holistic care that patients need. This must include patient assessments and care that treats the mind and skin together, otherwise you will not break the vicious circle, in which skin problems create psychological problems that in turn exacerbate the skin condition. (p. 4)

Three broad categories of outcome measures can be distinguished: patient- and observer-reported. This thesis uses the term 'patient-reported outcome measures' (PROMs) to refer to standardised questionnaires that ask people with dermatological conditions about their perspective on their health or the impact of their condition using the same questions, in the same format with a restricted range of response options to produce quantitative data (Collins 2003). The standardisation of PROMs ensures that differences observed are the result of real

changes, rather than artefacts of the data collection methods, and create data that can be quantified and analysed statistically (Streiner 2015).

The US Food and Drug Administration (FDA; 2009) defines PROMs as "a measurement based on a report that comes directly from the patient (i.e. study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else" (p. 32). Observer-reported outcomes are based on a clinician or caregiver's observation where they may also interpret or give an opinion based on their observation (FDA 2009).

The issue of 'objectivity'

The most commonly used outcome measures are clinician- and patient-reported and these are often erroneously distinguished as objective and subjective measurements, respectively. Research indicated that some clinicians are less trusting of 'subjective PROMs' than they are of 'objective' measures (Konan et al. 2014; Luna et al. 2017), such as the size of skin lesions, which they perceive to be 'hard' evidence, though this is not in line with the evidence (Hamilton et al. 2017). Hahn and colleagues (2007) analysed the degree of error inherent in clinician measurement and various validated PROMs. They found that PROMs compared favourably to the 'objective' measures, for example, demonstrating greater test-retest reliability. Hamilton and colleagues (2017) argue that there is varying quality of well-established measures aligned with either 'objective' or 'subjective' measurement. They further argue that PROMs are not a subjective opinion but an objective evaluation that quantifies issues perceived by the patient.

2.2 Patient-reported outcome measures

A systematic review of all RCTs in eczema conducted in patients between 2000 and 2014 found that 93% of the 303 trials reviewed included at least one PROM (Heinl et al. 2016) and this now an FDA requirement for drug trials, demonstrating the importance of PROMs within

dermatology. Furthermore, clinicians understanding of the impact of disease and treatments on patient's lives is poor (Nelson et al. 1983). Research has consistently found discrepancies between dermatologist- and patient-reported measurements of disease burden (Hermansen et al. 2002; Sampogna et al. 2004; David et al. 2005; Augustin and Radtke 2008). The low concordance means that both are required to holistically evaluate dermatological conditions. In support of this, research in the area of doctor-patient communication styles has found that the use of both patient- and clinician-reported outcomes is the best predictor of patient satisfaction and health expectations (Huynh et al. 2018). Yet, as shown in the previous chapter, dermatology still often relies on clinician assessment of symptoms.

Evidence shows that the systematic use of PROM data is associated with better patient-clinician communication and shared decision-making and improves patient satisfaction with care (Wasson et al. 1999; Marshall et al. 2006; Valderas et al. 2008; Chen et al. 2013; Santana and Feeny 2014; Nelson et al. 2015). There is also some evidence that PROM use improves patient outcomes, for example, improvements in depression (Ahles et al. 2006). Many quantitative systematic reviews have investigated the effectiveness of PROMs in individual patient care (Valderas et al. 2008; Knaup et al. 2009; Boyce and Browne 2013; Chen et al. 2013; Gondek et al. 2016), but less is known about the mechanisms of action. It has been proposed that PROMs affect dermatology outcomes by helping to identify unmet needs or unspoken concerns (Lohr and Zebrack 2009; Finlay et al. 2017). More recently, reviews have included qualitative work on the barriers and facilitators of clinician and patient interactions using PROMs (e.g. Antunes et al. 2014; Boyce et al. 2014; Etkind et al. 2015). Greenhalgh and colleagues' (2018) realist synthesis showed that PROM completion is neither a simple nor neutral act of information retrieval but can prompt a process of self-reflection that can change how patients understand, frame or think about their condition (Mallinson 2002; Neale and Strang 2015). This supported patients to raise issues with clinicians by providing a framework for discussion and signalling the clinician's interest in their views. Similarly, PROMs can raise clinicians' awareness of patients' problems, acting like a test result that prompts clinicians to open up discussions and support symptom management.

However, there are methodological and conceptual issues with PROMs. PROMs recommended in dermatology typically measure disease severity or health-related quality of

life (HRQoL). Since this study aims to develop a measure of the impact of dermatological conditions on patients' lives, such issues will be explored through HRQoL PROMs.

2.2.1 Health-related quality of life

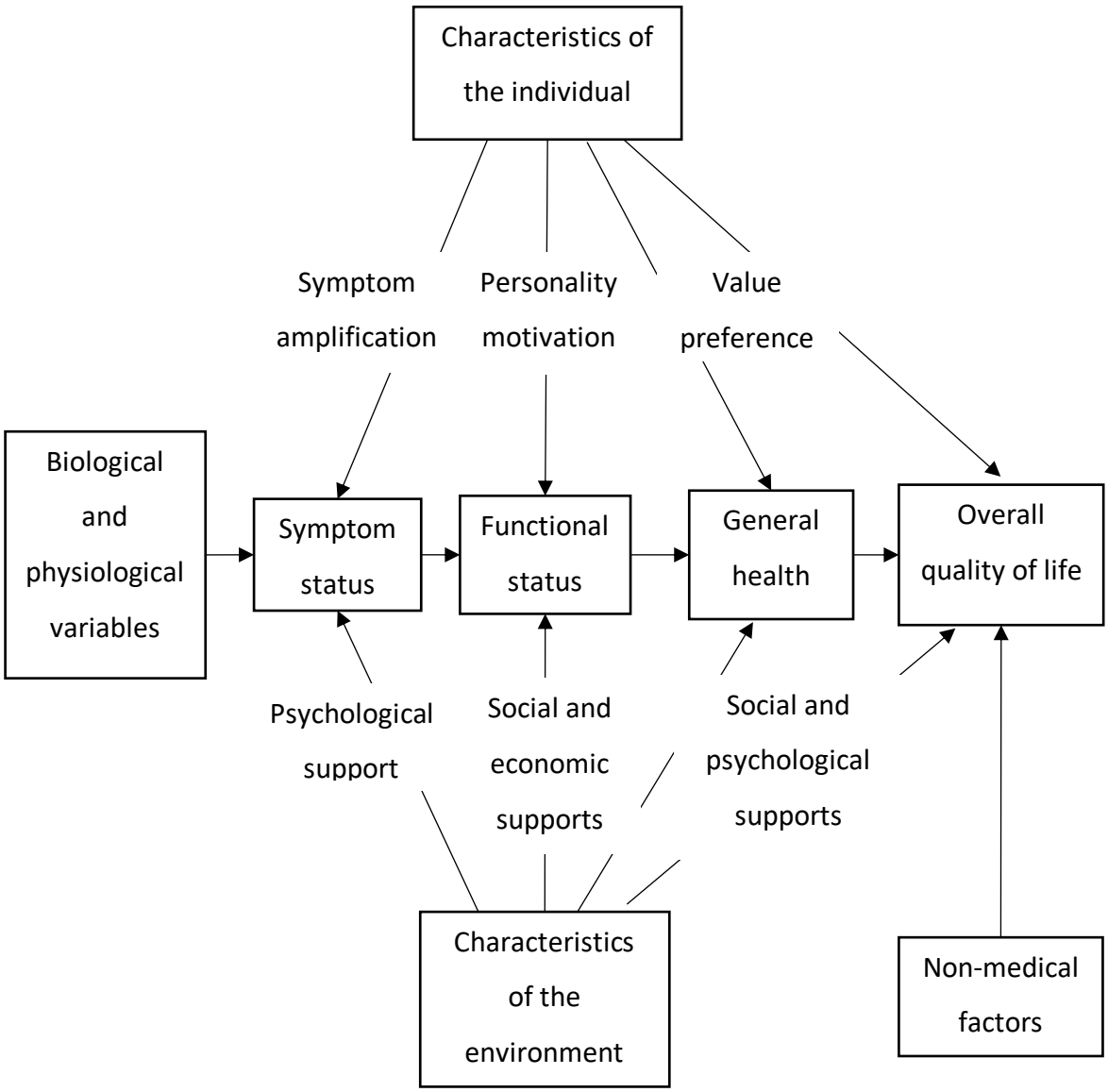
Since the publication of the DLQI over 30 years ago, dermatology research studies now frequently include dermatology-specific QoL PROMs (Ali et al. 2017a). Dermatology guidelines across many countries recommend the measurement of QoL using validated measures (Alper et al. 2010; Baker et al. 2013a; Zweegers et al. 2014). Though dermatologists make treatment decisions based on the degree of impact the condition has on the patient (Salek et al. 2007), often little information about QoL is elicited during routine dermatology consultations (David et al. 2005). Routine use of QoL PROMs has been shown to identify patients experiencing high QoL impairment and those patients who were more severely affected than the clinician recognised (Salek et al. 2007). Aawar (2016) suggests that QoL data can optimise treatment decision-making, prioritise problems, facilitate communication, screen for potential risks, identify preferences and monitor responses to treatment.

HRQoL is a broader concept than health status and can indicate the wider burden of disease. Measuring HRQoL is particularly important when managing dermatological conditions, where the goal of treatment is to improve QoL, rather than prolong it. While there is no consensus on its definition (Ogden 2012), it is generally agreed that HRQoL represents individual responses to the physical, psychological and social effects of illness on daily living, which influences the extent to which personal satisfaction with life circumstances can be achieved (Bowling 1997).

Because of the multidimensional aspects of HRQoL, a variety of models have been used to guide research. Wilson and Cleary (1995) presented a conceptual model for measuring the concept of HRQoL (Figure 3.), which became the most commonly used (Bakas et al. 2012). This model combines biomedical and social science paradigms and includes five major domains - biological, symptoms, function, general health perception and overall HRQoL – and illustrates how these are interrelated. The model hypothesises a causal pathway through

which the domains influence HRQoL, with the arrows in the model indicating the most important pathways of influence, but the authors acknowledge that there may be reciprocal relationships. The model is also used to distinguish different levels of health measurement ranging from the molecular and cellular level on the left and moving to the overall impact of health or disease on individuals on the right. PRIDD captures the overall impact of dermatological conditions on patients and would therefore sit on the far righthand side of this model. Because the model proposes a causal pathway to this overall impact, all domains depicted should be considered when developing PRIDD, though some may be more relevant than others. In this way, the conceptual model of health related quality of life demonstrates that PRIDD should be developed with a broad focus on aspects of health, rather than narrowly on a singular domain (e.g. symptoms), across the micro, meso and macro levels.

Figure 3: Wilson and Cleary (1995) conceptual model of health-related quality of life. Reproduced from de Vet et al. (2011, p. 9)



2.2.2 Conceptual and methodological issues with dermatology-specific PROMs

While useful, current dermatology-specific PROMs have a number of limitations. First, PROMs are often used to assess the impact of *interventions* on patients' lives (outcomes), rather than the impact of the *condition* on patients' lives (impact). This is reflected in the recall period feature of PROMs, whereby patients are asked to evaluate the impact that their dermatological conditions have within a specified timeframe only. However, the impact of

dermatological conditions is understood to be cumulative across the life course (Linder and Kimball 2013). To understand the burden of dermatological conditions on patients, there is a need to move away from patient-reported *outcome* measures and adopt patient-reported *impact* measures.

Patient-centred measures are those whose content is derived from patients' views. Because PROMs aim to assess health status from the patient perspective, patients must be involved in PROM development (FDA 2009). However, this does not guarantee that the final instrument is patient-centred. The systematic review presented in Chapter 4 demonstrates that dermatology PROMs are often developed without appropriate input from patients. A top-down approach to their development is evident with developers usually not engaging enough patients, not engaging them appropriately (i.e. used text-based rather than face-to-face elicitation techniques) or limiting patients to assessing effects based on clinician knowledge, theory or research. Even when patients are sufficiently involved in the item generation stage, they are very rarely consulted during the item reduction process. Consequently, these PROMs are more likely to measure concepts important to clinicians and researchers, rather than patients, rendering their reliability and validity questionable.

Because these PROMs are based on the broad and amorphous construct of HRQoL, they may not be specific or sensitive enough to concepts important to dermatology patients. Furthermore, PROMs allow patients to rate their own health but do not allow them to choose the dimensions along which to rate it. A measure that asks about an individual's work-life, for example, assumes that work is important to that individual - but it might not be. These deficiencies limit the assessment of dermatological conditions and their treatments, making it more challenging for clinicians to address patient concerns. Individualised PROMs address this issue by allowing respondents to define the dimensions to be measured (Ogden 2012) but are unfeasible for use in research and inappropriate for use across populations (i.e. people with dermatological conditions). At the population level, measure developers can engage patients to prioritise and seek consensus on dimensions important to them to be included in a measure.

Finally, PROMs do not address all of the HRQoL dimensions adequately. As early as 1981, Wilson-Barnett criticised the lack of measures purporting to measure QoL in a psychological

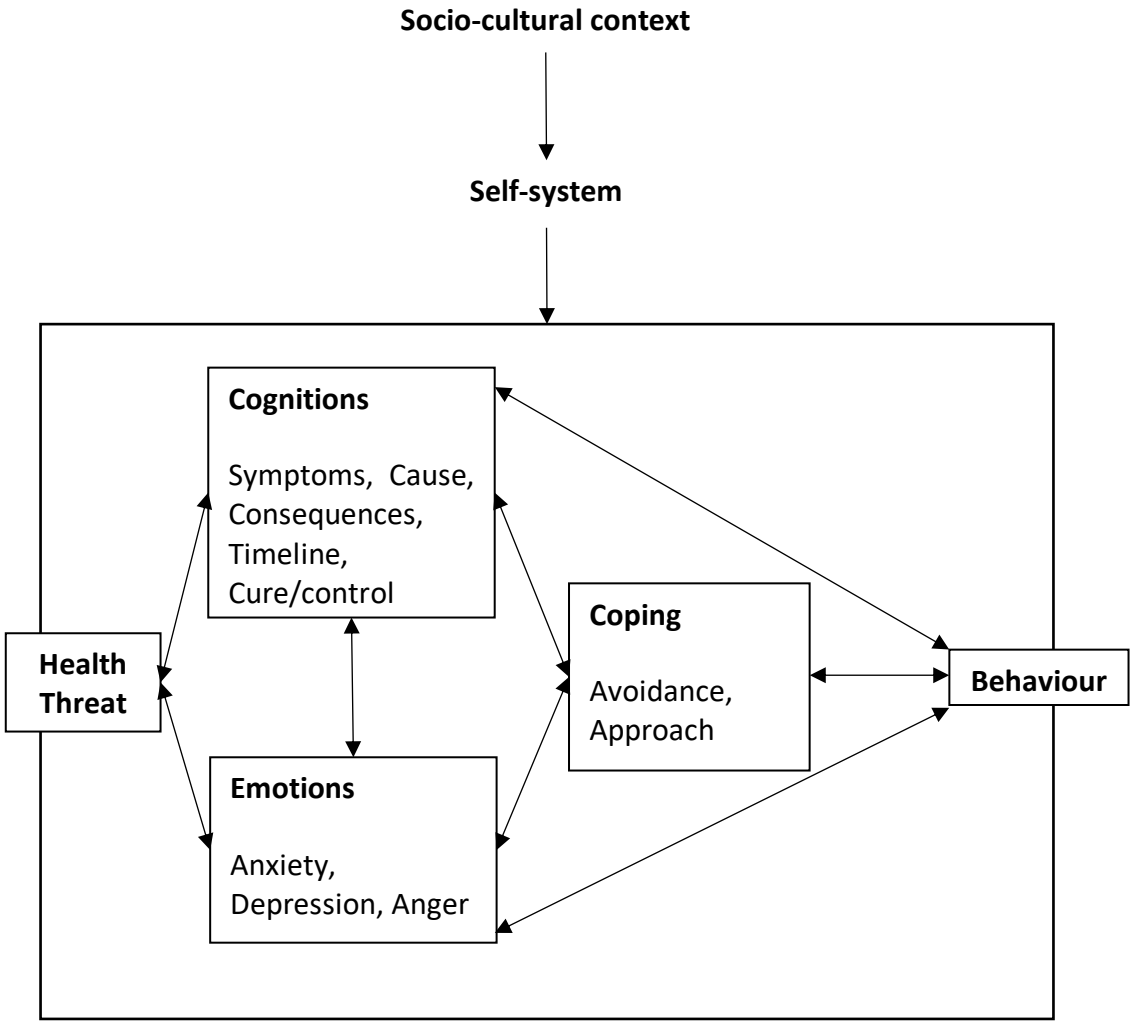
and social sense and noted that measures that did examine these dimensions were rarely used. Instead, measures focussed on activity levels, 'compliance' with medical advice, social activities, sexual activity and patient satisfaction. Since then, there has been greater recognition of the need to assess the patient's views on the psychological and social impact of disease on their everyday lives, although this has focussed on the impact of treatments rather than the impact of the condition itself. Dermatology-specific PROMs that assess the psychological aspects of QoL, such as the DLQI and Skindex (Chren et al. 1996), have largely focused on emotions and coping with little attention given to cognitions. A recent review of PROMs used in psoriasis found that the DLQI focuses mainly on the related physical aspects and negative emotions (Sommer 2021). Identifying the patient's cognitive representations of their condition is important because beliefs predict the individuals' emotional and behavioural responses to their condition (i.e. whether they seek care, accept treatment and consider themselves to be well and recovered). To capture HRQoL, PROMs should cover all relevant dimensions adequately: HRQoL measures need to capture the psychological dimension, including emotions, coping *and* cognitions.

2.2.3 The Common-Sense Model of Self-Regulation

The Common-Sense Model of Self-Regulation (CSM; Figure 4.; Leventhal et al. 1984) provides a framework to capture the perceive impact of dermatological conditions while adequately addressing the psychological aspects of HRQoL by capturing the cognitive, emotional and behaviours (coping) responses to health and illness.

Like other dominant models of response to illness, including stress and coping (Lazarus 1984) and social-cognitive models (Bandura 1977), the CSM describes how individuals process information and respond to an illness, symptom or health threat (i.e. dermatological condition) and helps us to understand individual differences in these responses. The response to illness models vary in the cognitions specified and the level of measurement achieved (Johnston and Johnston 1998). The CSM provides the most extensive work on cognitions, identifying five key cognitive representations: the cause, identity, timeline, curability/controllability, and consequences of health threats.

Figure 4: Schematic representation of the Common-Sense Self-regulatory Model adapted from Leventhal et al. (1984)



The CSM posits that, following the identification of a health threat, cognitive representations associated with an illness label (e.g. dermatological condition) are developed and/or activated to make sense of and respond to the threat. These cognitive representations interact with parallel emotional responses (emotional representations) and together they guide the individual's selection of an appropriate coping strategy - a 'common sense' solution to the health threat - thus affecting disease outcomes. The coping strategy is appraised according to whether it resulted in improvement, no change, or deterioration in symptoms and representations are adjusted accordingly. These feedback loops characterise the model as a dynamic framework of self-regulation. According to the model, patient behaviour - such

as coping and self-management of conditions, including adherence and lifestyle behaviours – is a function of the individual's cognitive and emotional responses.

While HRQoL would be an appropriate framework for developing a PROM of the impact of dermatological conditions, the dimensions included are rather broad and vague and indeed many measures of HRQoL minimise the psychological component rendering it a relatively blunt instrument to develop PRIDD with. The CSM, on the other hand, is suited to develop a PROM as it emphasises the psychological dimension. The CSM provides a more psychologically sophisticated means of exploring the impact of dermatological conditions and by specifying cognitive, emotional and behavioural responses to dermatological conditions addresses some of the limitations of existing dermatology HRQoL PROMs and may provide a clear point for psychological intervention. Though some specific illness representations, such as cause, may be less relevant to the development of PRIDD (i.e. item generation), they will be valuable for understanding the context and drivers of impact. While both models propose that illness responses occur within a social context, the CSM has been criticised for placing little emphasis on the effect of personal and contextual factors (Leventhal et al. 1997; Hale et al. 2007). PRIDD's development will primarily draw upon the CSM but the conceptual model of HRQoL will be useful in specifying contextual (e.g. 'social and economic supports') and personal factors (e.g. 'personality motivation') to consider as well as situating the level of measurement required. The use of the CSM along with particular aspects of the conceptual model of HRQoL will ensure that factors operating at the individual through to the environmental levels are adequately addressed. This will improve HRQoL PROMs and allow dermatologists and researchers to better understand where to target interventions.

2.3 Development of the Patient-reported Impact of Dermatological Diseases measure

Dermatological conditions have a substantial impact on patients' lives that is not captured by the current measures. This thesis, therefore, aims to develop a new PROM called PRIDD (Patient-Reported Impact of Dermatological Diseases) that can comprehensively measure the impact of living with a dermatological condition. This section will consider the background,

theoretical underpinnings and evaluation of measurement instruments and will inform the research design of this study.

2.3.1 Measurement in healthcare

Measurement is a fundamental activity of science. Wright (1997) argues that "science is impossible without an evolving network of stable measures" (p. 33) because to acquire knowledge of people, objects, events and processes, quantification of these elements is often required. Each area of science has its own set of measurement procedures. In the physical sciences, variables can typically be measured directly, with well-established and calibrated tools that conform to international standards and follow standardised units. By contrast, in psychology and many other specialities, variables or characteristics of interest (e.g. depression, anxiety, and intelligence) are often unobservable and therefore cannot be measured directly. These unobservable characteristics are often referred to as constructs.

Measurement is often defined as the assignment of numbers (or scores) to objects, events or phenomena according to rules in order to represent facts and conventions about them (Ferguson et al. 1940; Stevens 1946). Duncan (1984) challenged this definition as incomplete and proposed an extended version, arguing that measurement is the assignment of numbers in a way that represents different *degrees* of a quality or property of an object, event or phenomenon. Methods of measurement (e.g. a weighing scale, questionnaire etc.) and procedures can differ between and within physical and non-physical sciences but all measurements follow a systematic procedure for assigning scores to represent the characteristic of interest (Thurstone 1928; DeVellis 2017). Thus, the scientific legitimacy of a measure is established by its fundamental properties.

In the highly influential paper *On the Theory of Scales of Measurement,* Stevens (1946) proposed that scores can be assigned in a way that communicates more or less quantitative information. Stevens classified four 'levels of measurement' - nominal, ordinal, interval and ratio – that correspond to four different levels of quantitative information that can be communicated by a score. Following this order, progressively more sophisticated quantitative procedures can be performed on both the measurement instrument and the data it produces. The requisite level of measurement depends on the intended application of the instrument

and on the research problem it is used to answer (Bowling 2005). Because the most rigorous methods of data analysis require quantitative data, measures that yield interval or ratio data should be used; however, this is often difficult in the social sciences (Bowling 2005). The main challenge to measuring psychological variables is that measurement requires a ratio scale, but psychological phenomena often do not follow a linear line (Michell 2001).

2.3.2 Traditions of assessment – medical and psychological approaches

Measurement is central to clinical practice and medical research. This is reflected in the vast number of measures available and in development for both general and specific patient or population groups. The advances in diagnosis and care arising from the widespread use of the Apgar scale - a method to quickly summarise the health of new-born children - demonstrate the power of well-designed and appropriate measures (Li et al. 2013). In the past, research problems approached by clinical researchers frequently relied on 'objective' measures such as mortality rather than the assessment of unobservable variables (Streiner 2015). In recent decades, health researchers have become increasingly aware of the impact of health and healthcare on *quality* of life and acknowledge that the effects of health interventions on the *quantity* of life are often marginal in comparison (Streiner 2015). Dermatology primarily aims to improve the quality not quantity of life. For these therapeutic efforts to be based on scientifically sound evidence, there is a need to devise methods to measure unobservable but important constructs such as QoL, symptoms or social functioning in a valid and reliable (psychometrically sound) manner. Marshal and colleagues (2000) clearly demonstrated the need for valid and reliable measures in medical research. In a systematic review of 300 RCTs on treatment for schizophrenia, the authors found that studies that used an unpublished measurement instrument were 40% more likely to report that treatment was effective compared with studies that used peer-reviewed measurement instruments with evidence of validity. Furthermore, they found that, in non-pharmacological trials, one-third of claims of treatment superiority would not have been made if a published instrument was used. It follows that measurement instruments that are not validated can be a source of bias and their use could be considered unethical.

Since the 1930s, psychologists have been concerned with how to measure constructs that are not directly observable such as individual differences in intelligence (Streiner 2015). As a result, the field of psychometrics has emerged as a subspecialty of psychology and has established a sound methodology for the development and application of instruments to assess psychological and social phenomena. Psychometric methods are increasingly applied to other fields such as health and medicine and the use of psychometric definitions of validity and reliability are widespread.

Differences in the traditional medical and psychological approaches to assessment have led to variation in how and why measurement instruments are constructed and interpreted. In line with the biomedical model, the medical approach typically adheres to a categorical model of diagnosis. Here, individuals are categorised as a case (e.g. depressed) or non-case (e.g. not depressed) according to their score on a measure. 'Caseness' is determined using a cut-off score which implies that a clear distinction exists between the two categories. Conversely, the psychological approach adheres to a dimensional model of measurement where attributes are thought of as a continuum and, therefore, caseness is a matter of degree with no clearly divided line. Psychometricians argue that more information is obtained by measuring an attribute continuously than by dividing the attribute into categories.

While physicians have argued that psychometricians do not appreciate how the results of measures can be used to facilitate clinician decision-making, psychologists claim that the medical approach ignores many principles of measurement instrument construction, such as reliability and validity (DeVellis 2017). Multi-dimensional (or multi-item) measurement instruments permit a variety of attributes to be measured dimensionally so that results can be used both categorically and discretely. Thus, where appropriate, multi-item measures can merge the medical and psychometric approach to assessment to produce a measure that is both sound psychometrically and clinically useful.

2.3.3 Measurement properties

All measurement instruments should be evaluated for their measurement properties, such as validity, reliability and responsiveness (Nunnally 1978; de Vet et al. 2011). However, there is wide variation in the terminology and definitions of measurement properties, which confuses what properties are relevant and permits the use of different methods to evaluate the same measurement property, leading to different conclusions (Terwee et al. 2003). Mokkink and colleagues (2010c) conducted an international Delphi survey of 43 experts with backgrounds in epidemiology, statistics, psychology and clinical medicine to reach consensus on the taxonomy, terminology, and definitions of measurement properties of health-related instruments. The study also determined which measurement properties were considered important, and how they should be assessed in terms of study design and statistical methods. This thesis adheres to the resultant COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) taxonomy which defines the measurement properties (Table 2.) and their inter-relationships (Figure 5.).

Table 2: Definitions of measurement properties adapted from Mokkink et al. (2010)

Domain	Measurement property	Definition
Reliability *The degree to which the measurement is free from measurement error*	Internal consistency	The degree of the interrelatedness among the items.
	Reliability	The proportion of the total variance in the measurements which is because of 'true' differences among patients.
	Measurement error	The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured.
Validity *The degree to which an instrument measures the construct(s) it purports to measure*	Content validity	The degree to which the content of an instrument is an adequate reflection of the construct to be measured.
	Construct validity	The degree to which the scores of an instrument are consistent with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the instrument validly measures the construct to be measured.
	Structural validity	The degree to which the scores of an instrument are an adequate reflection of the dimensionality of the construct to be measured.
	Criterion validity	The degree to which the scores of an instrument are an adequate reflection of a ''gold standard.''
Responsiveness	Responsiveness	The ability of an instrument to detect change over time in the construct to be measured.

Figure 5: COSMIN taxonomy of the relationships of measurement properties reproduced from Mokkink et al. (2018, p. 9)

Validity

Validity is considered to be the most important measurement property (Prinsen et al. 2018). Because validity is concerned with how well an instrument measures the variable it purports to measure it is of particular importance when evaluating a measure of an unobservable construct, its uses and the inference that can be drawn from it (de Vet et al. 2011; DeVellis 2017). Evaluation of validity requires that the researchers have a) clearly defined the construct they intended to measure, b) detailed knowledge of the construct and, c) a conceptual framework to hypothesis relationships with other constructs (de Vet et al. 2011).

To be valid, a measure should have sensitivity (accurately defines the construct of interest) and specificity (does not confuse the construct of interest with other, similar constructs). Validation is an ongoing process: a measurement instrument must be re-validated if it is applied in a new situation (e.g. target population, language, or mode of administration) or for another purpose (FDA 2009).

The COSMIN taxonomy distinguishes three types of validity: content validity, construct validity and criterion validity.

Content validity

Content validation is concerned with establishing whether the items reflect the latent variable (DeVellis 2017). It can be more difficult to evaluate when measuring attributes such as beliefs or attitudes because it can be harder to determine the range of potential items. Content validation should be the starting point for measurement instrument validation and two steps are specified (de Vet et al. 2011). First, an initial subjective global assessment of the items, referred to as face validation, is performed. There are no assessment standards for face validity, and it cannot be quantified. For this reason, the value of face validity can be underestimated but the lack of face validity can be a strong argument for not using an instrument or to end further validation. If an instrument passes the test of face validation a more detailed assessment follows. The content validation focuses on whether the content of the instrument corresponds with the construct it is intended to measure, with regards to item comprehensiveness, comprehensibility and relevance (de Vet et al. 2011). This is assessed qualitatively with experts such as patients and clinicians.

Criterion validity

Criterion validation evaluates how well the scores of the measurement instrument agree with the gold standard instrument for the construct to be measured (de Vet et al. 2011). As there

is no gold standard instrument for the impact of dermatological conditions on an individual's life, criterion validity is not relevant to PRIDD.

Construct validity

Construct validity is required in situations in which there is no gold standard instrument (de Vet et al. 2011). It is concerned with evaluating whether the instrument provides the expected scores based on the existing knowledge of the construct and therefore the definition of the construct and the underlying conceptual model are very important. Structural validity, hypothesis testing, and cross-cultural validity are subtypes of construct validity:

- Structural validity is relevant to multi-item instruments and assesses whether the scores reflect the dimensionality of the underlying construct. Confirmatory factor analysis (CFA) is preferred over exploratory factor analysis (EFA) as a means of evaluating structural validity because existing theory or previous knowledge can be used to test whether scores fit the hypothesised structure or dimensions of the instrument.
- Hypotheses about the relationship of scores on the instrument with scores on other instruments measuring similar or dissimilar constructs, differences in scores between subgroups, and internal relationships (e.g. subscales) are tested (Mokkink et al. 2010c; de Vet et al. 2011). When a large number of specific or challenging hypotheses are met there is powerful evidence of construct validity.
- Cross-cultural validation is assessed after an instrument has been translated or adapted to another culture.

Reliability

The concept of reliability is a fundamental way to reflect the amount of error, both random and systematic, inherent in any measurement (Streiner 2015). Reliability, therefore, refers to the consistency of the score, not to its validity - an instrument may measure something

reliably and consistently but may not necessarily be measuring the intended construct (Fayers 2016). In addition to the general definition given in Table 2., Mokkink and colleagues (2010c) provide an extended definition of reliability as:

> The extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: e.g. using different sets of items from the same multi-item measurement instrument (internal consistency); over time (test-retest); by different persons on the same occasion (inter-rater); or by the same persons (i.e. raters or responders) on different occasions (intra-rater). (p. 743)

COSMIN distinguishes three types of reliability – internal consistency, reliability (or test-retest), and measurement error (Mokkink et al. 2010c; de Vet et al. 2011; Streiner 2015).

Measurement error

Measurement error refers to the discrepancy between the true score and the observed score of a construct. Sources of error include variations within a test, variations between tests and systematic errors between observers (Nunnally 1978). Multiple factors influence how individuals respond to self-report scales, including item comprehension, attention and concentration, and carry over and practise effects (Ingram and Ternes 2018).

Internal consistency

Internal consistency is concerned with the homogeneity of the items within a scale (DeVellis 2017). A scale is considered internally consistent if its items are highly correlated as this suggests that all the items are measuring the same construct. If an item measures a different construct, it will have a lower item-total correlation than the other items (de Vet et al. 2011). Thus, a unidimensional scale or a single dimension (subscale) of a multidimensional scale should consist of a set of items that correlate well with each other.

Reliability (test-retest)

Reliability estimates using a test-retest approach measure the degree to which the same instrument produces similar results when administered to the same individual in as similar a manner as possible over a period of time (Ingram and Ternes 2018). In contrast with internal consistency, test-retest reliability is a measure of temporal stability and refers to the repeatability and the stability of the instrument (Fayers 2016; Ingram and Ternes 2018). It is based upon analysis of correlations between repeated measurements where the closer the obtained scores are to one another over two administrations the higher the test-retest reliability. The rationale underlying this form of reliability is that if a measure truly reflects a meaningful construct, it should assess that construct comparably on separate occasions (DeVellis 2017). Higher reliability coefficients indicate a greater portion of true score measurement and a lesser amount of error. Thus, higher reliability coefficients indicate a more precise and stable measurement (Ingram and Ternes 2018). Test-retest reliability assumes that true scores of the measured characteristic for an individual do not change over time and that all variation in an observed score is due to either random or systematic error. For this reason, it is crucial that a test-retest assessment is conducted with individuals who are stable regarding the construct of interest and an appropriate period of time has passed between tests (Ingram and Ternes 2018; Prinsen et al. 2018).

Responsiveness

Responsiveness refers to the ability of an instrument to detect changes over time (Mokkink et al. 2010c) and is therefore only relevant for measurement instruments with evaluative applications (explained below; de Vet et al. 2011). When assessing responsiveness, it is hypothesised that if patients change on the construct of interest their scores will change accordingly. In this way, responsiveness is an aspect of validity. The distinction is that while validity refers to the validity of a single score, responsiveness refers to the validity of a change score. Responsiveness should be evaluated in a longitudinal study in which at least some of the participants are known to have changed on the construct to be measured. As with validity, a criterion and a construct approach to testing responsiveness are distinguished. When a gold

standard instrument is available, changes on the instrument can be compared with the gold standard. Where there is no gold standard available, the assessment of responsiveness relies on testing hypotheses about expected mean differences between changes in subgroups or expected correlations between changes in the scores on the instrument and changes in other variables. The more specific and the greater number of hypotheses, the more evidence gathered for responsiveness.

Acceptability and feasibility

The collection of PROM data within routine clinical practice places additional requirements on their development and selection. This means that the reliability, validity and responsiveness must be supplemented with acceptability and feasibility.

Acceptability and feasibility are not measurement properties because they do not refer to the quality of a measurement instrument but they are considered important features to assess (Prinsen et al. 2018). They are related aspects that are concerned with the ease of application of the instrument in the intended context of use, given constraints such as time or money, for example, completion time, cost of an instrument, length of the instrument, and the type and ease of administration. Acceptability refers to whether individuals are *willing* to complete the instrument and feasibility refers to whether or not they are *able* to complete the instrument (de Vet et al. 2011). These considerations apply to both the respondents and the administrator of the instrument, typically clinicians and researchers (Prinsen et al. 2018). The length of an instrument is a key determinant of both acceptability and feasibility. In terms of acceptability, a longer instrument takes more time to complete, leading to an increased respondent burden. The same measurement instrument may be feasible for research purposes but too long to be used in a clinic setting. A further consideration for research is that an individual measurement instrument may be relatively short, but a battery of such measures may become unfeasible. Response burden is well-documented in questionnaire research (Hoerger 2010; Rolstad et al. 2011) and clinicians report patients' frustration with completing too many PROMs in clinician practice (Taliercio et al. 2021). Other factors affecting feasibility include the difficulty of the instrument and the age and capacities of the

respondents. Acceptability and feasibility are often assessed according to response rates and length of time taken to complete the instrument.

2.3.4 Typology of measures

Single or multi-item instruments

Health is a broad field and the measurement of both observable (e.g. age, body mass and red blood cell count) and unobservable (e.g. QoL and depression) variables form the basis of diagnosis, prognosis and outcome evaluation. Constructs captured by self-report measures (e.g. PROMs) can have single or multiple items. Single-item measures have the advantage of simplicity but lack detail (Sloan et al. 2002). Multi-item measures have the advantage of providing a complete profile of the construct but increase the respondent burden (de Vet et al. 2011; DeVellis 2017). The latter are considered more stable and have better reliability when measuring complex constructs than single-item measures (Bowling 2005). As impact is a complex, unobservable construct, it is anticipated that PRIDD will be a multi-item instrument and would, therefore, require a measurement model.

Generic, speciality- or condition-specific instruments

PROMs can be generic (i.e. applicable across a broad range of therapeutic areas such as dermatology, diabetes, and cancer), speciality-specific (i.e. use is restricted to one therapeutic area such as dermatology and is applicable across all sub-conditions), or condition-specific (i.e. use is restricted to a specific condition such as psoriasis or acne). The measurement level required is based on the nature of the study (Bowling 2005). Generic instruments permit comparisons between conditions but lack specificity and sensitivity (Chren et al. 1997b). As instruments move from generic to condition-specific, they become more clinically sensible, often have good conceptual validity, and may be more responsive (Chren et al. 1997b; Hilde et al. 2007). Condition-specific instruments have the highest level of specificity and, as a

result, are best able to capture the clinical course of the condition in individual patients but preclude the possibility of comparison across conditions (Chren et al. 1997b; Bowling 2007).

To achieve the GRIDD project's aim of collecting global impact data on the impact of dermatological conditions, PRIDD will designed for use *across* conditions and will therefore be a dermatology-specific PROM. This measurement level can include items specific to dermatological conditions while also allowing for use across conditions.

Diagnostic, evaluative and prognostic applications

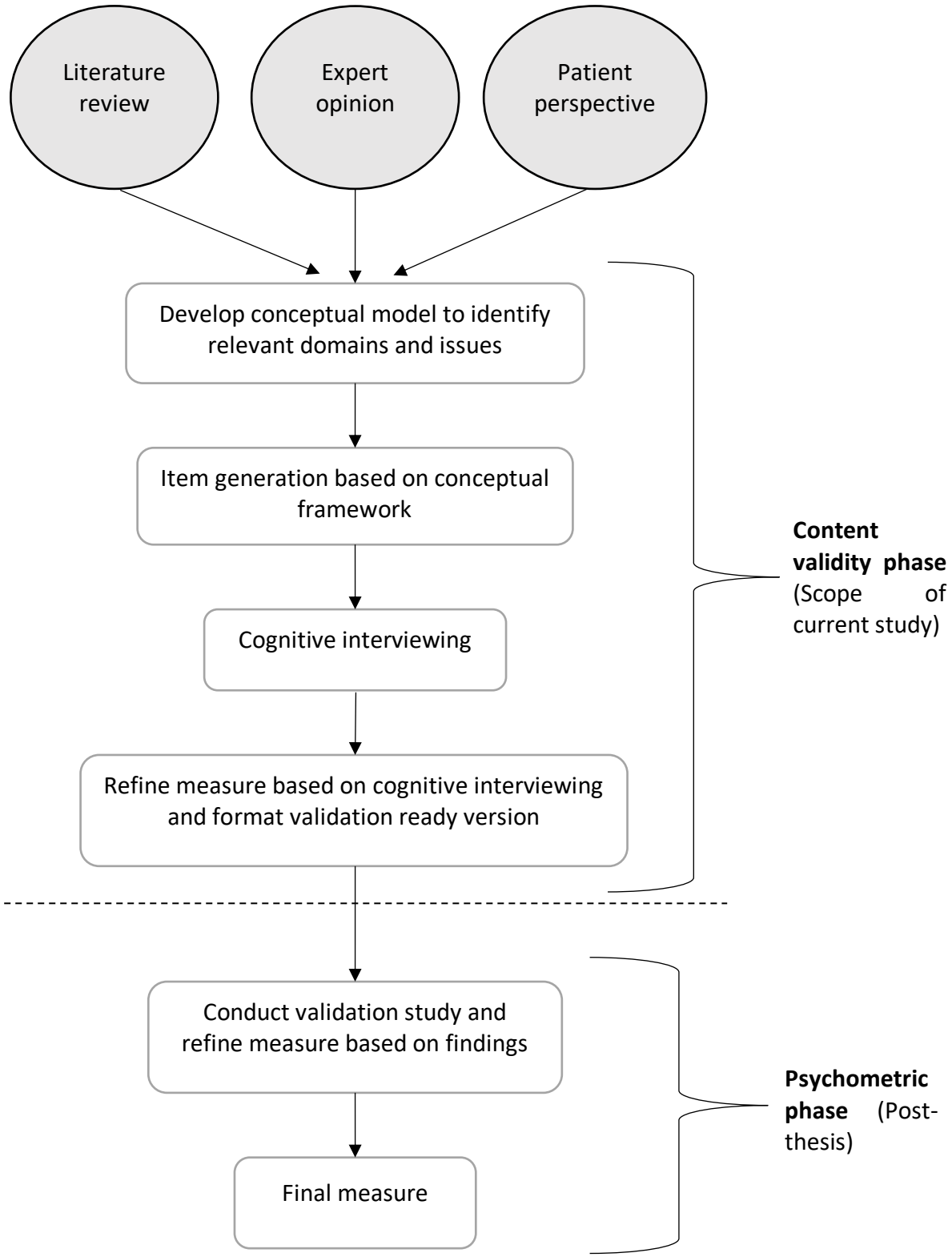
De Vet and colleagues (2011) identify three purposes of health measurement instruments: diagnosis, evaluation of intervention, and prediction of future course. The same instrument can be used for different purposes. Diagnostic (or discriminative) instruments can discriminate between persons at a single point in time (Guyatt et al. 1992). Evaluation instruments can measure the effects of treatment or other longitudinal changes in health status over time (de Vet et al. 2011). Predictive instruments aim to classify individuals according to their prognosis. PRIDD will be primarily developed to have a discriminative application to distinguish people according to the amount of impact their dermatological condition has had on their lives.

2.3.5 Development of a PROM

The development of PROMs can be broken down into two sequential phases – the content validity phase and the psychometric phase – as shown in

Figure 6. (Apfelbacher and Nelson 2017). While it was initially planned to complete development *and* validation of PRIDD during this PhD, delays to the timeline arising from the SARS-CoV-2 pandemic prevented the psychometric testing phase from being completed. This thesis, therefore, focuses only on the content validity phase of development. The psychometric testing phase is currently underway as part of my post-doctoral work.

Figure 6: The process of developing patient-reported measurement instruments, adapted from Apfelbacher and Nelson (2017, p. 286)



2.3.6 Conceptual framework

When measuring an unobservable construct with a multi-item instrument, an understanding of the nature and direction of the relationships between the items and the construct of interest is required (de Vet et al. 2011). This relationship forms a conceptual framework. The conceptual framework is of theoretical and practical importance as it determines the measurement theory to be used in the development and evaluation of the instrument (de Vet et al. 2011; DeVellis 2017). Conceptual frameworks can be categorised broadly as formative and reflective models, however, this distinction is not always clear cut (de Vet et al. 2011). Distinguishing whether an instrument is based on a formative or reflective model is important for three main reasons:

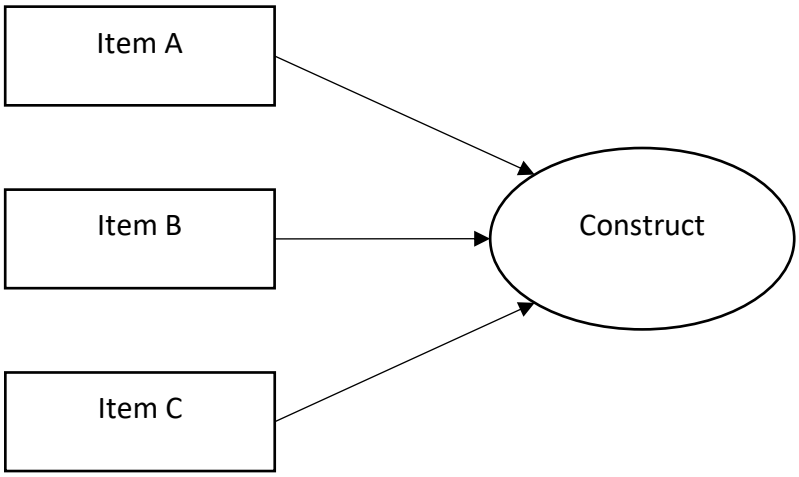
1. The best practice approaches for selecting items differs between the two models (de Vet et al. 2011).
2. Using an incorrect measurement model can undermine content validity of the construct and misrepresent the relationship between the domains (Coltman et al. 2008).
3. Evaluation of the internal structure of a measure is only relevant to reflective models (Streiner 2003; Prinsen et al. 2018).

Formative model

As depicted in Figure 7., in a formative model, the items (known as causal indicators) each capture a unique concept which when combined 'form' or 'cause' the construct or determine the level of the construct (de Vet et al. 2011; DeVellis 2017). Multi-item measurement instruments based on a formative model are called indexes (DeVellis 2017). A construct whose value is caused by the items is called an emergent variable (DeVellis 2017). Each item contributes a part of the construct, and together the items form the whole construct. Consequently, when developing an instrument with a formative model, the challenge is to identify all items that substantially contribute to the construct. Because items in this model usually do not share a common cause and do not necessarily correlate with each other, they

are not interchangeable; therefore, missing an item means that the construct is not measured comprehensively. Measurement theories underlying indexes are less well developed than those underlying multi-item instruments with a reflective model (Edwards and Bagozzi 2000).

Figure 7: Graphical representation of a conceptual framework representing a formative model

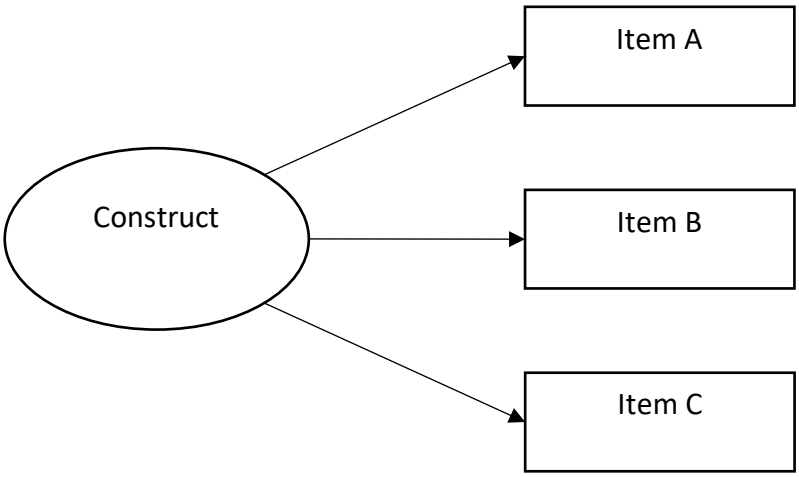


Reflective model

As opposed to a formative model, the items in a reflective model are manifestations or indicators of the construct (de Vet et al. 2011). Multi-item measurement instruments based on a reflective model are often referred to as scales (de Vet et al. 2011). As depicted in Figure 8., in a reflective model the value of each item (known as effect indicators) is determined by the construct (known as the latent variable) and provide a way of measuring the presence or degree of the latent variable. Thus, a change in the latent variable will influence all items. Consequently, the items correlate with each other and so can be interchangeable; therefore, it is acceptable to miss items that are good indicators of the latent variable (de Vet et al. 2011). A related assumption, known as local independence, is that if the latent variable was accounted for, there would be no correlation between any of the items (Streiner 2015). Two well-known measurement theories apply to reflective models: Classical Test Theory (CTT) and

Item Response Theory (IRT). These measurement theories offer some tools and advantages in the development and evaluation of measurement instruments (de Vet et al. 2011).

Figure 8: Graphical representation of a conceptual framework representing a reflective model



2.3.7 Measurement theory

Scales are essentially proxies for variables that cannot be directly observed (DeVellis 2017). This is why the underlying construct that a scale is intended to measure is often called the latent variable. The score of a scale (test score), therefore, is the observable magnitude of the latent variable and this will include some error (Ward 2010; DeVellis 2017). The true score is the unobservable actual magnitude of the latent variable if there was no error. The notion of a latent variable implies that there is a relationship between it and the items that tap it (DeVellis 2017). The causal relationship between a latent variable and a scale implies certain empirical relationships.

While a conceptual framework describes the relationship between the items and the construct (de Vet et al. 2011), measurement theory provides a conceptual schema for understanding the statistical relationship between the items and the latent variable (DeVellis 2017). For this reason, the development and validation of scales that measure unobservable

constructs needs both a conceptual framework *and* measurement theory (de Vet et al. 2011). A measurement theory is not required for single-item measures or multi-item measures of observable constructs because in those cases it is usually obvious how the items contribute to the construct.

Measurement theory is the formal and logical theory of the necessary and sufficient conditions for attributing measures to objects or events (Scheiblechner 2015). It provides the foundation for evaluating measurement instruments and their applications and interpretations and therefore is fundamental to the development, evaluation and selection of appropriate scales.

Choosing the measurement theory

There are two approaches to measurement theory: CTT and IRT. Both are concerned with creating and using multi-item scales to evaluate latent variables that cannot be measured directly (Fayers 2004) but have important distinctions in their underlying philosophies and the statistics employed for implementation (Wang and Osterlind 2013). CTT has dominated the field of psychometrics for nearly a century, in part because of its relative conceptual and computational accessibility (DeVellis 2017), and also because the assumptions CTT makes about the items and the scale are relatively 'weak' ones, meaning that the theory is appropriate in most situations (Streiner 2015). IRT has received increasing attention in recent years (DeVellis 2017) and is being applied increasingly in the field of QoL research (Fayers 2004). It does not obviate or contradict CTT, but rather extends CTT by overcoming many of its flaws. For this reason, it is often presented as a modern and superior alternative (DeVellis 2017). Despite IRT's recognition as a powerful tool for scale design, many researchers continue to use CTT almost exclusively (Fayers 2004). The reasons for IRT's limited use are predominantly practical rather than scientific – there is a lack of mainstream IRT statistical software packages and an absence of easily accessible resources on IRT.

A particular strength of IRT is that it makes it possible to estimate the position of patients on the construct continuum from their scores on a set of items. In IRT, items also have a position

on the construct continuum, called the item location. Measurement instruments based on IRT, therefore, provide information on both the location of the patient and the location of the items. Items can be ordered according to difficulty because IRT is based on Guttman scales. Gutmann scales are deterministic scales consisting of multiple items measuring a unidimensional construct that can be ordered hierarchically. The principle of a Guttman scale is that if an individual endorses an item, they will also endorse all less severe items. Contrariwise, if an individual does not endorse an item, they will not endorse any of the more severe items. If there are no misclassifications then the total score of the scale provides direct information about the individual's ability (de Vet et al. 2011). IRT allows for more misclassifications than a strict Guttman scale as it is based on probabilities.

Given the many advantages of IRT over CTT, we developed and evaluated PRIDD according to the principles of IRT. Specifically, the Rasch model, the simplest model within the IRT framework, was employed but, as the work is on-going, the results are not included in this thesis. The Rasch model is a unidimensional measurement model that satisfies the fundamental assumptions of IRT (Luce and Tukey 1964; Newby et al. 2009), meaning it provides a measurement template against which scales can be tested (Horton et al. 2019). Essentially, the Rasch model provides a way to assess scales to ensure that it is valid to sum the items to form an overall score. When the assumptions of the Rasch model are satisfied, the interval level scores can be transformed into linear scores thereby optimising the level of quantitative information that can be obtained by the scale and the analyses that can be conducted on it (Tennant and Conaghan 2007).

2.4 Aims and objectives

The overall aim of this thesis is to complete the content validity phase of PRIDD development. This will be achieved through five key linked objectives, to:

1. Systematically review existing dermatology-specific PROMs.
2. Develop a conceptual framework of the impact of living with a dermatological condition.

3. Generate an item pool for PRIDD from the concept data generated through objective 2.

4. Reduce and refine the item pool in collaboration with people with dermatological conditions.

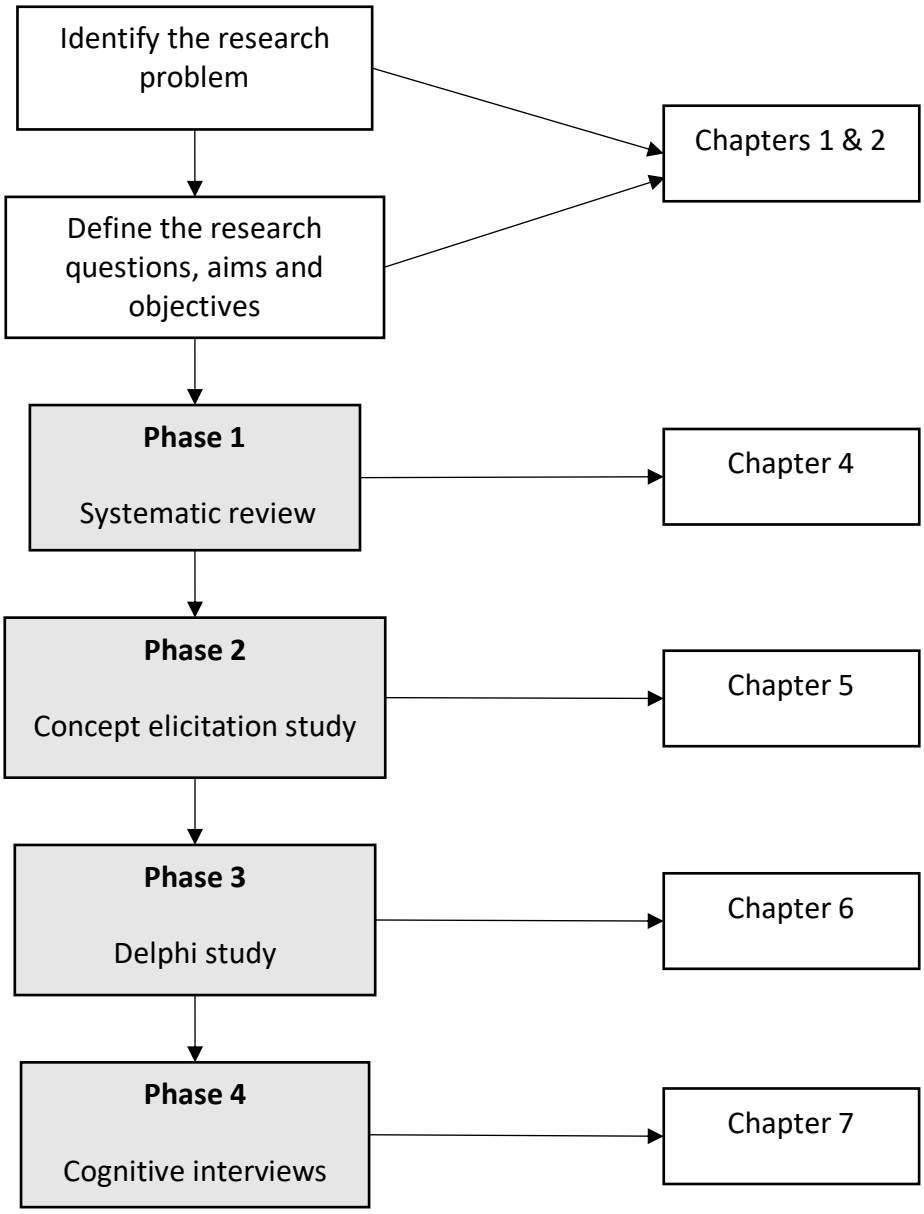
5. Pilot test the first draft of PRIDD with patients for content validity (comprehensiveness, comprehensibility and relevance), acceptability and feasibility.

Chapter 3: Methodology

The overarching aim of this study was to complete the content validity phase of new measurement instrument for PRIDD. The best practice development of a measurement instrument is a multi-step process requiring a blend of qualitative and quantitative research (Apfelbacher and Nelson 2017). Thus, a mixed methods study following an exploratory sequential design (ESD; Creswell and Plano Clark 2017) with three sequential phases was conducted.

The philosophical and theoretical underpinnings and methodological considerations of this study along with these assumptions and methodologies - together with the literature and systematic review - provide the rationale for the study design and methods used. The methods employed, including data collection techniques and tools, analysis strategy, sampling, and recruitment, are described in the associated study chapters. A schematic diagram of the study is presented in Figure 9. with each phase mapped to the respective chapter in this thesis.

Figure 9: Schematic diagram of the research methodology (left) and respective chapters for each study (right)



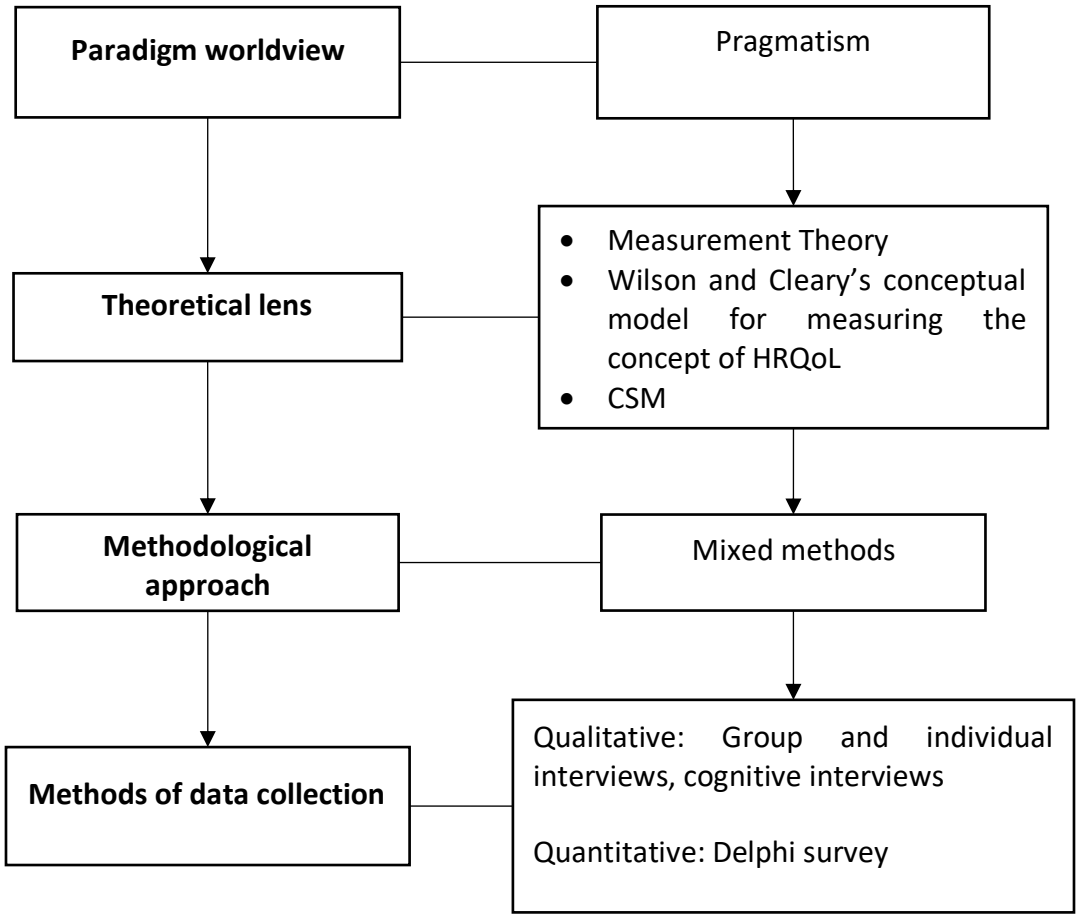
3.1 Structure of the chapter

Mixed methods researchers are expected to make their 'worldview' (philosophical beliefs and assumptions about knowledge) explicit as this provides the foundations of the study, is instrumental in shaping the research and affects the conclusions that can be drawn from the

findings (Braun and Clarke 2006). Creswell and Plano Clarke (2017), respectively co-founder and associate editor of the Journal of Mixed Methods Research, advocate the use of Crotty's (1998) conceptualisation of the four major elements in research design - paradigm worldview, theoretical lens, methodological approach, methods of data collection – as a generic framework to position the researcher's philosophy or worldview within a mixed methods study. Making these major elements in research design explicit is particularly useful when conducting mixed methods research as it has a shorter and less-well defined history meaning that underlying paradigms are less clear compared to purely quantitative or qualitative designs and apparently incompatible (Creswell and Plano Clark 2017). Figure 10. summarises the four major elements of research design in this study. Critically, these elements are related to each other, with each level informing the next. This chapter is structured according to the four elements in research design as follows:

1. Paradigm worldview
2. Theoretical lens
3. Methodological approach
4. Research design

Figure 10: Crotty's conceptualisation of the four levels of research design (left) and the four major elements in the design of the current study (right)



3.2 Paradigm worldview

Mixed methods research emerged in the mid-1980s as a framework for combining different methods of data analysis in empirical studies. It arose during a period where it was expected that research would have a paradigm based on the philosophy of knowledge, which understands research in terms of ontology, epistemology, and methodology (Morgan 2014). Quantitative approaches are traditionally aligned with positivist beliefs in an independent reality that exists apart from our understanding of it (Morgan 2014). Here, it is assumed that reality is knowable and objective measurement is an essential part of gaining knowledge of it

(Bishop 2015). Fundamental to positivism is the principle of 'methodological naturalism' – the belief that the methods and procedures of the natural sciences are appropriate to the social sciences. Consequently, positivists view the logic and procedures of the natural sciences as the 'epistemological yardstick' by which empirical research in the social sciences must be appraised before it can be treated as valid knowledge (Bryman 2006). Following this comes the 'doctrine of empiricism' which entails the belief that only phenomena which are observable can be validly warranted as knowledge. On the other hand, phenomena that cannot be directly observed or indirectly measured have no place in science. Positivism, therefore, rules out the possibility of incorporating 'subjective experience' that cannot be rendered observable into scientific knowledge. Post-positivism, however, has moved away from the purely objective stance of positivism and instead recognises the multiplicity and complexity of humanity and consequently values both subjectivity and objectivity (Ryan 2006). This has led to an emphasis on meaning, seeing the person, experience and knowledge as "multiple, relational and not bounded by reason" (Henriques et al. 1998, p. xviii).

Qualitative approaches originate in philosophical traditions such as phenomenology and constructivism. Common to these philosophies is the belief that the world is created by our construction of it, which may differ between individuals and cultures (Morgan 2014; Bishop 2015). From this perspective, knowledge is embedded in values and cultures so is inevitably mediated and constrained by our own perspective, purposes, language, and culture (Yardley 2017). Contextualised understandings, therefore, are sought through subjective means (Bishop 2015).

Whether and how qualitative and quantitative methods should be combined has been a source of controversy, centred around the appropriateness of applying a natural sciences model to the social sciences (Bryman 2006). Tashakkori and Teddlie (1998) distinguish two methodological standpoints within this debate: the purists and pragmatists. The purists tend to take an absolutist standpoint, arguing strongly in favour of their preferred methodology (McEvoy and Richards 2006). They tend towards the epistemological version of the debate - which assumes a correspondence between epistemological position and research method (Bryman 2006) - arguing that quantitative and qualitative methods are based on mutually exclusive assumptions and are therefore incommensurable (Guba and Lincoln 1989). In

contrast, pragmatists view the two approaches as distinctive but compatible arguing that each research method is appropriate to different kinds of research problems.

Pragmatism is a popular paradigm in mixed methods research (Shook and Margolis 2006; Tashakkori and Teddlie 2016). It presents a departure from philosophical arguments about the nature of reality and acts as a new paradigm for research, regardless of whether it uses quantitative, qualitative or mixed methods (Morgan 2014). This does not mean that pragmatism lacks a philosophy of knowledge, but rather focuses on a process-based approach to knowledge instead of traditional metaphysics. Inquiry - conceptualised as a continuous process involving an iterative process between beliefs and actions to form a resolution – defines this approach. Pragmatism acknowledges the philosophical differences between quantitative and qualitative approaches but does not see these as irreconcilable (Cornish and Gillespie 2009). Rather, pragmatism recognises that, on one hand, experiences are constrained by the nature of the world and, on the other hand, our understanding of the world is inherently limited to our interpretations of experience. Instead of focusing on whether knowledge reflects an underlying reality, pragmatism focuses on the application of knowledge and its consequences for real-world practice and thereby loses epistemology (Creswell and Plano Clark 2017). Accordingly, pragmatism rejects the concept of a 'hierarchy of evidence' arguing that different forms of knowledge serve specific purposes and the best knowledge is that which works to solve the research problem. Pragmatism, therefore, stresses the importance of the research question, rather than the research methods, and the use of multiple methods of data collection capable of addressing the question (Creswell and Plano Clark 2017). Pragmatism gives the researcher the freedom to choose the methods, techniques and approaches that will provide the best understanding of the research problem. This allows for the combination of quantitative and qualitative and inductive and deductive approaches to optimise the strengths and limit the weaknesses of each.

In the same way that the current understanding of the impact of dermatological conditions is built upon a body of evidence consisting of both qualitative and quantitative research, the development of PRIDD can benefit from combining both approaches. Besides, a purely quantitative approach to PRIDD's development would be incongruent with a biopsychosocial understanding of health and illness and the person-centred approach to healthcare outlined

in the previous chapters. The positivist notion that the scientific methods of the study of objects also applies to people is congruent with the biomedical view that all illness can be explained by tissue pathology. It is less adept in accounting for the psychological and social aspects of health and illness. For example, how dermatological conditions impact on individuals is likely to be influenced by the social context: the impact on a patient may be greater if they live in a society that stigmatises dermatological conditions or where appropriate healthcare is unaffordable or inaccessible. A mixed methods approach accounts for the fact that the way in which individuals make meaning of their experiences is influenced by the broader social context (Braun and Clarke 2006).

Pragmatism is implicit in the field of measure development and validation where it is assumed that a combination of quantitative and qualitative approaches is necessary to create a high-quality measurement instrument (FDA 2009; de Vet et al. 2011; Apfelbacher and Nelson 2017). The mixed methods approach adopted in this study focuses on employing the appropriate methods at each stage in the development of PRIDD.

3.3 Theoretical lens

Measurement theory is the primary theoretical lens of this study. The principles of measurement theory, explored in Chapter 2, guide the methodological approach and subsequently the research design of the study, discussed in more detail in Section 3.4.

Good measures are built on a theory or conceptual framework of the construct (de Vet et al. 2011). Two distinct approaches to the development of a measurement instrument are evident – a deductive (application of theory) and an inductive approach (building of theory; Tay and Jebb 2017). A deductive approach uses an already formed theory of a construct to generate items within its domain. This approach is useful when the definition of the construct is known and there is sufficient knowledge to generate a pool of items. Inductive approaches use data from the target population to provide descriptions of the construct of interest to develop a conceptual framework that forms the basis for generating items. This approach is useful when uncertainty exists in the definition or dimensionality of the construct.

Kelle (2015) encourages the role of previous theoretic knowledge in developing new knowledge. Wilson and Cleary's conceptual model for measuring the concept of HRQoL is used to inform the level of measurement of PRIDD which, in turn, suggests that the micro, meso and macro levels should be considered and outlines domains that sit on the causal pathway to impact and therefore should be considered during development. The CSM is the primary model used to understand how patients respond to their dermatological conditions, the impact it has had on their lives along with the drivers of impact. Use of the CSM within the level of measurement required by the conceptual model of HRQoL ensures that intra- and inter-personal and contextual factors are adequately addressed. The aim is not to test these existing theories, but to draw on relevant aspects of both to situate the study findings within the existing body of knowledge.

3.4 Methodological approach

3.4.1 Development guidelines and reporting standards for PROM development

Although there are no set international guidelines on how to develop a PROM, this study adheres to best practices for reporting on measure development and validation studies (Streiner 2015). Several such guidelines exist, including the Standards for Education and Psychological Testing (American Psychological Association et al. 1999), the Standards for Reporting Diagnostic Accuracy (Bossuyt et al. 2003), the Guidelines for Reporting Reliability and Agreement Studies (Kottner et al. 2011), and COSMIN (Prinsen et al. 2018).

Of the guidelines, only COSMIN covers the development, validation and reporting of health-related instruments. The COSMIN group conducted a Delphi study of an international panel of 57 experts (psychologists, epidemiologists, statisticians and clinicians; Mokkink et al. 2010a) to develop the COSMIN methodology for conducting systematic reviews of PROMs (Prinsen et al. 2018). Consensus was reached on the inclusion and means of assessing the following measurement properties: internal consistency, reliability, measurement error, content validity (including face validity), construct validity (including structural validity, hypotheses testing and cross-cultural validity), criterion validity, responsiveness, and interpretability. In addition, the methodology encompasses the two approaches to

measurement theory, CTT and IRT. The COSMIN methodology is considered the 'gold standard' critical appraisal tool for preparing, selecting, evaluating, interpreting and reporting on PROM development and validation studies. The COSMIN group subsequently published *Measurement in Medicine* (de Vet et al. 2011) based on the COSMIN methodology, which provides guidance on developing and evaluating measurement instruments in all fields of medicine.

3.4.2 Development and validation of a PROM

From a methodological viewpoint, all measurement instruments are developed following the same basic steps outlined in

Table 3. (de Vet et al. 2011). The content validity phase consists of steps 1 to 5. Step 6 refers to the psychometric testing phase, which is beyond the scope of this thesis.

For some steps, decisions regarding the development and formulation of the instrument can be made prior to data collection, whereas for others, data collection is required. Each step in the development process of PRIDD is explained in further detail below. Where decisions can be made before data collection these are explained in detail. Where decisions require data collection, the recommended approaches to data collection are stated.

Table 3: Six steps in the development of a measurement instrument (de Vet et al. 2011)

Step 1	Definition and elaboration of the construct intended to be measured
Step 2	Choice of measurement method
Step 3	Selecting and formulating items
Step 4	Scoring issues
Step 5	Pilot-testing

Step 6	Field-testing

3.4.3 Step 1: Definition and elaboration of the construct intended to be measured

Clearly defining the construct of interest, target population and purpose is considered essential when developing a new measure (de Vet et al. 2011).

Construct

Since a definition or conceptual framework of impact does not exist, these are developed through qualitative research with the target population.

Target population

Measurement instruments should be tailored to their target population (de Vet et al. 2011). Given that the purpose of a PROM is to capture patients' experiences, it is not credible without evidence of its usefulness from a range of people within the target population (FDA 2009). As PRIDD will be used to collect global data on the impact of dermatological conditions, the target population will include all adults (≥ 18-years) living with a dermatological condition. PRIDD will focus only on adults because the impact of dermatological conditions on children's lives differs from that of adults and instrument items and format should be tailored to age (Lewis-Jones and Finlay 1995).

Purpose

As discussed in Chapter 2, measurements can have a diagnostic, evaluative and/or prognostic purpose (de Vet et al. 2011). The purpose of a measure has consequences for how it is

developed. PRIDD is primarily developed to have a discriminative application to distinguish people according to the amount of impact their dermatological condition has had on their lives.

3.4.4 Step 2: Choice of measurement method

De Vet and colleagues (2011) argue that the method of measurement should correspond closely to the construct being measured (de Vet et al. 2011). The method of measurement includes the type of measure used (e.g. questionnaire, thermometer or performance test), number of items (i.e. single- or multi-items) and issues concerning the definition of the construct.

Assessing the impact of dermatological conditions on patients' lives requires either an interview or questionnaire method to access information directly from the patient (de Vet et al. 2011). Interviews are not a feasible method of collecting data on the impact of dermatological conditions in a large sample therefore PRIDD will have a questionnaire measurement method.

Questionnaires can be broadly categorised as single- or multi-item. Single-item measures have the advantage of simplicity but lack detail (Sloan et al. 2002). Multi-item measures have the advantage of providing a complete profile of the construct of interest but increase the respondent burden. A multi-item questionnaire is most suited to measuring complex constructs such as impact (de Vet et al. 2011) because multiple aspects can be distinguished and sub-scores generated for each domain. In addition, in multi-item instruments, all dimensions considered relevant to the construct are included and the content of the items is usually more specific. This aids the respondent's understanding of the items and increases confidence that the same construct is being measured for all patients. Thus, PRIDD is developed as a multi-item questionnaire.

3.4.5 Step 3: Selecting and formulating items

Selecting and formulating items for a multi-item questionnaire can be broken down into two sequential steps:

1. *Input for the items from the literature and experts*: Reviewing the literature for similar instruments may provide a set of potentially relevant items and experts should also be consulted. Expert clinicians are often consulted during the development of PROMs as they have treated a large number of patients with the target condition and have expertise on characteristics of the condition and its impact (de Vet et al. 2011). However, expert clinicians, in this case, dermatologists and dermatology-specialist nurses, are likely to have limited knowledge of the impact of dermatological conditions on patients' lives as this is often not covered in clinical consultations (NICE 2012). Patients are the key experts when developing a measure of a construct at the level of patients' sensations, experiences and perceptions such as impact and, therefore, should be involved in the development (de Vet et al. 2011). Group discussions and in-depth interviews are considered the best way to obtain information from experts about relevant items (Krueger and Casey 2014). A key step in the development of PRIDD will involve group discussions and interviews with people with dermatological conditions.
2. *Formulating items (first draft)*: The information obtained from experts is transformed into items. Based on the literature review and expert input received in the previous step, a conceptual framework of impact was developed to indicate whether PRIDD follows a reflective or formative model. Consistent with PROM development guidance (de Vet et al. 2011), the aim was to generate as many items as possible based on the conceptual framework to be reduced through participatory and statistical methods.

3.4.6 Step 4: Scoring issues

Typically, items in a PROM consist of two parts: a stem and a series of response options (DeVellis 2017). Response options refer to the options given to respondents from among

which they select their answers (Fink 2003). Whether the measurement instrument provides classification or quantification of responses is dependent on the response options (de Vet et al. 2011). Responses can be expressed at either the nominal (e.g. female or male), ordinal (e.g. Likert scale), interval or ratio level.

Researchers have a considerable amount of freedom to choose the level of measurement of response options but certain considerations such as the application of the measure will guide this (de Vet et al. 2011). Qualitative research is conducted to explore how many categories are necessary. In addition, statistical analysis conducted during the psychometric testing phase can determine the number of categories by examining how informative each category is.

3.4.7 Step 5: Pilot-testing

A pilot test should be conducted on the first draft of a PROM. It should be rigorous and time should be reserved for adaptations and retesting (de Vet et al. 2011). The target population must be involved in pilot-testing because only they can judge comprehensiveness, comprehensibility and relevance. However, it is unlikely that patients understand the principles of measurement instrument development so final judgements are usually made by the researcher (DeVellis 2017).

3.4.8 Step 6: Field-testing

Field-testing can begin once the pilot-testing has established that the PROM is satisfactory in terms of comprehensiveness, comprehensibility and relevance, marking the end of the content validity phase and commencement of psychometric testing. As opposed to pilot-testing, which entails an intensive qualitative analysis of the items in a relatively small number of individuals from the target population, field testing entails a quantitative analysis, necessitating data from a larger number of individuals. The quantitative analysis can be

performed with CTT techniques, however, CTT has some limitations (e.g. treating ordinal data as though it is interval level data) that can be overcome using Rasch analysis.

3.4.9 Summary of methodology

Existing guidance recommends that both qualitative and quantitative approaches are employed in the development of a new measure (FDA 2009; de Vet et al. 2011; DeVellis 2017). This section demonstrated that quantitative and qualitative approaches and methods are aligned to and recommended for each of de Vet's (2011) six steps in the measurement development and validation process (summarised in

Table 4.). Although mixed methods are increasingly accepted and employed in many social, behavioural, and health science fields, they remain somewhat controversial (Creswell and Plano Clark 2017) so an explanation of the method and a justification for its use in the current study is warranted.

Table 4: Summary of recommended approaches and methods for each of de Vet's (2011) six steps in the development and validation of a measurement instrument

Step	Purpose	Approach	Method
Step 1	Definition and elaboration of the construct intended to be measured	N/A	
Step 2	Choice of measurement method	N/A	
Step 3	Selecting and formulating items	Qualitative	• Group discussions • Individual Interviews
Step 4	Scoring issues	Mixed	• Interviews • Statistical testing
Step 5	Pilot-testing	Qualitative	Cognitive interviews
Step 6	Field-testing	Quantitative	Classical Test Theory or Item Response Theory

3.5 Research design

3.5.1 Mixed methods

Mixed methods research entails both philosophical assumptions and technical methods of inquiry (Creswell and Plano Clark 2017), and are viewed as both a methodology and/or a method (Teddlie 2009). Many definitions of mixed methods have emerged which have varied in their focus on the elements of methods, research processes, research purpose, and philosophy. In *The Oxford Handbook of Multimethod and Mixed Methods Research Enquiry,* Hesse-Biber and Johnson (2015) argue that while the definition of mixed methods continues to be contested, most definitions share the mixing of at least one qualitative and one quantitative method in the same or related research projects (e.g. longitudinal study; Hesse-Biber and Johnson 2015; Creswell and Plano Clark 2017). In this vein, Creswell and Plano Clark (2017) propose a definition of mixed methods according to the following core characteristics:

- includes the rigorous collection and analysis of both quantitative and qualitative data in response to research questions and hypotheses,
- integrates (or mixes or combines) the two forms of data and their results,
- organises these procedures into specific research designs that provide the logic and procedures for conducting the study, and
- frames these procedures within theory and philosophy.

A major advantage of mixed methods research is that the limitations of one method can be offset by the strengths of the other. It is argued that by combining quantitative and qualitative data a more complete understanding of the research problem can be obtained than by either approach alone (Creswell and Plano Clark 2017). Qualitative methods are particularly useful in facilitating a detailed understanding of social and psychological phenomena and allow the framework of cognitions, emotions and perceptions of participants to be explored (Bowling 2005; Gill et al. 2008). Quantitative methods allow researchers to set and confirm 'a priori' criteria and results can be generalised.

In general, research problems suited to mixed methods are those in which one form of data may be insufficient, such as the current study (Creswell and Plano Clark 2017). Mixed methods

are also useful when exploratory findings need to be generalised, participants need to be involved in the research, and projects have many components connected to an overall objective. A mixed methods approach has the advantage of allowing methodological choice to be driven by the nature of the problem or the aim of the research (Creswell and Plano Clark 2017) and so is compatible with both PROM development methodology and pragmatism.

Quantitative research is often perceived to be orientated towards the specific concerns of the researcher whereas qualitative research is concerned with the participants' perspectives (Bryman 2006). Developing PRIDD following a mixed methods approach ensures that the quantitative data it collects reflects issues important to patients, rather than the clinician or researcher, and is therefore consistent with the aims of patient-centred medicine.

Though a mixed methods approach appears to be most suitable for PROM development, some general disadvantages are worth noting (Creswell and Plano Clark 2017). Firstly, the researcher must be able to conduct and integrate rigorous quantitative and qualitative research. Secondly, mixed methods often require more time and resources than quantitative or qualitative approaches alone. Finally, others may not understand or view mixed methods as legitimate.

3.5.2 Exploratory sequential design

Research designs represent an organising logic for collecting, analysing, interpreting and reporting data. Creswell and Plano Clarke (2017) identify three core mixed methods designs: the convergent design, the explanatory sequential design, and the exploratory sequential design.

To align with the PROM guidance presented in the previous section, this study adopted an ESD mixed methods design. The primary aim of ESD is to develop and apply a quantitative tool (e.g. PROM), intervention or new variable that is grounded in qualitative data and, therefore, the views of the participants (Creswell and Plano Clark 2017). ESD is so often employed in measurement development that it has also been referred to as the instrument

development design (Creswell et al. 2004). ESD allows information to be obtained in an initial qualitative study that helps to develop an empirically grounded conceptual framework that can be used to construct the quantitative measurement instrument (Kelle 2015). The qualitative aspect increases the likelihood that the instrument will be relevant to the target population (Creswell and Plano Clark 2017). The quantitative aspect tests and generalises the qualitative results to develop the measure.

ESD typically consists of three distinct phases: a qualitative phase, a quantitative phase where the tool, intervention or new variable is developed, and a quantitative test phase. In this way, qualitative data are collected and analysed to explore the topic (stage 1); these data are then used to inform the development of the measurement instrument (stage 2); and, finally, quantitative data are collected and analysed to test the measurement instrument (stage 3).

In keeping with measurement development and validation guidance, this study extends the classic ESD to include an additional qualitative phase to pilot test PRIDD and complete the content validity phase of its development. Table 5. presents the design of this study in terms of the phases, data collection and analysis techniques adopted and their relation to the six steps in measurement development. Following a systematic review (Phase 1) of dermatology-specific PROMs, the ESD as applied to the current study briefly comprises:

- Phase 2: developing a conceptual framework of the impact of dermatological conditions on patients' lives based on group and individual interviews. (qualitative)
- Phase 3: a Delphi survey to a) seek consensus on which candidate items to prioritise for inclusion in PRIDD; b) test whether the findings obtained in the previous study generalised to a wider group; and c) identify important missing concepts. (mixed)
- Phase 4: cognitive interviews to test the content validity, acceptability and feasibility of PRIDD and make evidence-based refinements. (qualitative)

Table 5: Overview of the study design including the phases and data collection and analysis techniques in relation to de Vet's (2011) six steps in measurement instrument development

De Vet (2011) steps of measurement instrument development	ESD Phase	Aim of phase	QUANT/QUAL	Data collection technique	Data analysis
1 - 4: Definition of construct, choice of measurement model, selecting and formulating items & scoring issues	1, 2 & 3	Systematic review	QUANT	Systematic review	COSMIN analysis
		Concept elicitation and item reduction and refinement	QUAL	Interviews	Framework analysis
			MIXED	Delphi survey	Descriptive statistics of consensus and framework analysis
5: Pilot-testing	4	Item refinement	QUAL	Cognitive interviews	Thematic model of cognitive interview analysis

*ESD; exploratory sequential design

3.6 Research ethics and governance

This study was conducted in accordance with the UK Policy for Health and Social Care Research. The dignity, rights, safety and wellbeing of participants were the primary considerations. Ethics approval was obtained from Cardiff University School of Healthcare Sciences Ethics Committee (SREC: 637).

Participants were asked to read the participant information sheet (PIS) and sign an informed consent form before involvement in the study. The PIS included information on the purpose, methods and intended uses of the research, what participation entailed, and any risks or benefits anticipated from participation. Also detailed was the data storage plan, details of the lead researcher (RP) and how to make a complaint. Participants were made aware of their right to withdraw at any time without reason or fear of penalisation. Potential participants were given a minimum of 24 hours to consider the study before returning the consent form.

Participants were advised to seek appropriate services, such as telephone helplines or support groups, should they experience distress following their participant. As a global research project with participants from across the world, it was not possible to identify specific services that may be available. RP is a psychologist and was supervised by CB, an experienced and practising psychologist, so was able to provide support, if necessary.

Data (including consent forms and contact details) were kept confidential. Participants' data were anonymised, and any personally identifying characteristics were removed in any oral or written dissemination of the research. The audio files, transcripts and electronic survey data did not contain the names or contact information of the participants. A separate, password-protected 'key' was created to match the file with the participant.

Electronic data were stored and password protected on a hard disk at Cardiff University. Paper copies were stored in a locked filing cabinet within the School of Healthcare Sciences. The data will be kept for a minimum of 5 years, in line with University policy. Audio files were downloaded and deleted from the Dictaphones.

Chapter 4: Phase 1: A systematic review of PROMs in dermatology

A modified version of this chapter has been published by Acta Dermato-Venereological (Appendix 1.).

4.1 Introduction

PROMs must meet pre-defined criteria across a range of measurement properties for the data they produce to be meaningful (Terwee et al. 2007; DeVellis 2017; Souza et al. 2017). Without knowledge of their measurement properties, it is impossible to judge the quality of a measure nor have confidence in the data it produces. The measurement properties of most PROMs used in dermatology have not been evaluated according to the 'gold standard' COSMIN criteria (Mokkink et al. 2018). Furthermore, de Vet and colleagues (2011) urge researchers to conduct a systematic review of the measurement properties of all existing instruments intended to measure the construct of interest before developing a new measure.

Systematic reviews aim to identify, appraise and synthesise all the empirical evidence that meets pre-specified eligibility criteria to answer a specific research question. Unlike narrative reviews which tend to be descriptive and focus on a subset of studies based on availability or author selection, systematic reviews use explicit, systematic methods to minimise bias, produce more reliable findings and inform decision making. These methods typically include a detailed and comprehensive plan and search strategy derived *a priori*. A 'Summary of Findings' or, as in COSMIN, 'Best Evidence Synthesis' table presents the main findings of a systematic review in a transparent and simple tabular format. The table provides key information regarding the quality of evidence and the sum of available data. In terms of the development of a new measure, a systematic review serves three additional functions:

1. Prevents the development of new measurement instruments where others already exist. The use of different instruments to measure the same construct across studies yields incomparable results.
2. Allows researchers to become familiar with what a new measure should or should not look like and mistakes to avoid. Related to this, researchers can create an item pool based on items that work well.
3. Identifies whether time and effort can be saved by translating or adapting an existing measurement instrument. Only if no adequate instrument is available should a new one be developed.

To fully understand the impact of dermatological conditions on patients' lives there is a need to develop a measure specifically designed to capture this. As the first step in the development of PRIDD, a systematic review of all published dermatology-specific PROMs was conducted following the COSMIN methodology to identify measures of impact and to establish the quality of dermatology-specific PROMs currently in use. The review aimed to:

1. Identify all published dermatology-specific PROMs.
2. Assess identified PROMs in terms of suitability for use as a measure of impact.
3. Evaluate the identified PROMs' measurement properties according to the COSMIN criteria.
4. Make evidence-based recommendations for their use.

4.2 Methods

This systematic review was developed and conducted following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (Moher et al. 2009). The study protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO: CRD42018108829).

4.2.1 Literature search

A systematic literature search was performed in PubMed (1966-Present), PsycInfo (Ovid; 1806-Present) and CINAHL (EBSCO; 1937-Present) to identify articles. The last search was run on 25th June 2018. The search strategy was designed to identify published evidence of the development and validation of dermatology-specific PROMs (Appendix 2.). It consisted of three blocks of search terms, including MeSH terms and keywords: (i) dermatological conditions (target population); (ii) life impact (construct of interest); and (iii) a validated highly sensitive search filter for measurement properties that was adapted for PsycInfo and CINAHL and supplemented with terms for PROMs (Terwee et al. 2009). Searches were limited to journal articles and human subjects to reflect the exclusion criteria. No limits were applied for language and non-English papers were translated. The ProQolid database (http://www.proqolid.org), a comprehensive online database of outcome measures, was used to confirm that measures identified were patient-reported.

4.2.2 Eligibility criteria

According to COSMIN, all PROMs in a review should be assessed according to both the construct of interest and target population of the review (Prinsen et al. 2018). This review aimed to identify measures of impact and to establish the quality of dermatology-specific PROMs currently in use. As such, the target population was people with dermatological conditions (as opposed to disease-specific samples e.g. vitiligo) and the construct of interest was that of the PROM assessed. This way, measures of impact could be identified *and* the quality of PROMs currently used in dermatology could be established.

Studies were selected if published as full-text journal articles and if their purpose was to report on the measurement properties, development, cross-cultural validation, feasibility or acceptability of one or more PROMs used in dermatology. Measures were eligible only if they were both patient-reported and dermatology-specific. Both adult and children PROMs were included. Papers were excluded if:

- The PROM studied was observer- or proxy-reported.

- Evaluation of the PROM was not the main aim of the article (e.g. secondary or exploratory).
- The PROM studied was used only to validate another instrument.

4.2.3 Article selection

Three reviewers (RP, NTS, SG) independently screened titles and abstracts. To satisfy the inclusion criteria, the title and/or abstract had to include at least one term from each of the three search strategy blocks. The three reviewers independently assessed and ranked full-texts of the selected articles according to adapted criteria by Kitchen and colleagues (2015; Table 6.). Reviewers screened and ranked 10% of each other's samples to determine inter-rater reliability. Results were compared and any discrepancies were resolved through discussion.

Table 6: Ranking criteria for articles adapted from Kitchen et al. (2015)

Rank	Criteria
1a	• Published journal article (excludes conferences, dissertations, books or chapters). • Relevant terms are included in the title and/or abstract. • The main focus is on the development, validation, feasibility or acceptability of a dermatological condition PROM with complete reporting of the measurement property. • The measure must be patient-reported.
1b	• As above but with partial reporting of the measurement property(ies).
2	• Relevant terms included in the title and/or abstract. • PRO term is in the abstract but *not the main aim of the article (i.e. secondary or exploratory*). • Relevant results in the abstract.
3	• Relevant terms in the background or as an implication in the discussion of the article. • No relevant data.
X	• Exclude if no relevant terms. • Papers related to carer-rated measures and proxy-rated measures.

4.2.4 Data extraction

An electronic data extraction form was developed to comply with the COSMIN guidance (Prinsen et al. 2018). The key data extracted included: summary data of included studies (i.e. author, publication date, and study characteristics); the characteristics of included instruments (i.e. name of instrument, purpose, country of origin); the measurement properties of the studied instrument(s); and information on the interpretability and feasibility of included instruments. The form was pilot-tested on two randomly selected articles and refined accordingly. A team of six reviewers (RP, NTS, SG, AH, MO, JL) extracted the data independently with a random 10% of each reviewer's sample checked by another reviewer. Discrepancies were resolved through discussion.

4.2.5 Methodological quality of included studies

The COSMIN Risk of Bias Checklist (Mokkink et al. 2018) was used to evaluate the methodological quality of included studies. The assessment was performed independently by the team of six reviewers.

4.2.6 Quality of measurement properties

Measurement properties from the COSMIN checklist (Table 2.) were evaluated against predefined criteria (Table 7.; Prinsen et al. 2018). Criterion validity was not assessed as no gold standard exists for impact, HRQoL or related concepts (Feeny et al. 2013). Interpretability and feasibility data were collected where available.

Table 7: Predefined COSMIN criteria for good measurement properties adapted from Mokkink et al. (2018)

Measurement property	Rating	Criteria
Structural validity	+	• CTT: CFA: CFI or TLI or comparable measure >0.95 OR RMSEA <0.06 OR SRMR <0.08[2] • IRT/Rasch: No violation of unidimensionality[3]: CFI or TLI or comparable measure >0.95 OR RMSEA <0.06 OR SRMR <0.08 *AND* • no violation of local independence: residual correlations among the items after controlling for the dominant factor < 0.20 OR Q3's < 0.37 *AND* • no violation of monotonicity: adequate looking graphs OR item scalability >0.30 *AND* • adequate model fit: • IRT: χ^2 >0.01 • Rasch: infit and outfit mean squares ≥ 0.5 and ≤ 1.5 OR Z-standardized values > -2 and <2
	?	• CTT: Not all information for '+' reported • IRT/Rasch: Model fit not reported
	-	Criteria for '+' not met
Internal consistency	+	At least low evidence[4] for sufficient structural validity[5] AND Cronbach's alpha(s) ≥ 0.70 for each unidimensional scale or subscale[6]
	?	Criteria for "At least low evidence[4] for sufficient structural validity[5]" not met

Measurement property	Rating	Criteria
	-	At least low evidence[4] for sufficient structural validity[5] AND Cronbach's alpha(s) < 0.70 for each unidimensional scale or subscale[6]
Reliability	+	ICC or weighted Kappa ≥ 0.70
	?	ICC or weighted Kappa not reported
	-	ICC or weighted Kappa < 0.70
Measurement error	+	SDC or LoA < MIC[5]
	?	MIC not defined
	-	SDC or LoA > MIC[5]
Hypotheses testing for construct validity	+	The result is in accordance with the hypothesis[7]
	?	No hypothesis defined (by the review team)
	-	The result is not in accordance with the hypothesis[7]
Cross-cultural validity/measurement invariance	+	No important differences found between group factors (such as age, gender, language) in multiple group factor analysis OR no important DIF for group factors (McFadden's R^2 < 0.02)
	?	No multiple group factor analysis OR DIF analysis performed
	-	Important differences found between group factors OR DIF was found
Criterion validity	+	Correlation with gold standard ≥ 0.70 OR AUC ≥ 0.70
	?	Not all information for '+' reported
	-	Correlation with gold standard < 0.70 OR AUC < 0.70

Measurement property	Rating	Criteria
Responsiveness	+	The result is in accordance with the hypothesis7 OR AUC ≥ 0.70
	?	No hypothesis defined (by the review team)
	-	The result is not in accordance with the hypothesis7 OR AUC < 0.70

4.2.7 Best evidence synthesis

For each PROM, evidence for the methodological quality of the studies and quality of measurement properties per measurement property were pooled and summarised. The summary result was then rated against the criteria for good measurement properties and graded using a modified Grades of Recommendation, Assessment, Development and Evaluation (GRADE) adapted for use in systematic reviews of PROMs to form the best evidence synthesis (Mokkink et al. 2018; Prinsen et al. 2018). The quality of the evidence was graded as high, moderate, low or very low evidence according to the COSMIN procedures (Prinsen et al. 2018). All versions of a PROM were considered separately (Mokkink et al. 2018; Prinsen et al. 2018).

The GRADE approach specifies five factors to determine the quality of evidence: risk of bias (quality of the studies), inconsistency (of the results of the studies), indirectness (evidence comes from different populations, interventions or outcomes than the ones of interest in the review), imprecision (wide confidence intervals), and publication bias (Prinsen et al. 2018). The fifth factor, publication bias, is not included in the COSMIN methodology because there are no registries for studies on measurement properties. Thus, the modified GRADE approach specifying four factors developed by COSMIN was used to grade the evidence.

Generating recommendations for use of dermatology-specific PROMs

The primary outcome assessed was the recommendation for use. Each PROM was assigned to one of three standardised 'recommendation for use' categories according to the COSMIN criteria (Prinsen et al. 2018) similar to a traffic light system of Green indicating 'good to go', Amber meaning 'proceed with caution' and Red 'do not proceed':

A. PROM **can be recommended** for use (has evidence for sufficient content validity [any level] and at least low-quality evidence for sufficient internal consistency).
B. PROM **has the potential to be recommended** for use but requires further validation (cannot be categorised into A or C).

C. PROM **should not be recommended** for use (has high-quality evidence demonstrating an insufficient measurement property).

The secondary outcome was establishing the existence of dermatology-specific PROM capable of measuring impact, achieved by evaluating the domains measured in each PROM.

4.3 Results

The search identified 12,925 abstracts. An additional three articles were identified through reference lists and expert input (Augustin et al. 2000b; Schmid-Ott et al. 2003; Ofenloch et al. 2014).

Figure 11. details the full article selection process. Of the 53 dermatology-specific PROM articles identified, data were extracted from 52. One article was excluded because the psychometric testing for two separate PROMs was combined (Jobanputra and Bachmann 2000). Two articles (He et al. 2014; Chernyshov 2016) examined more than one PROM. Six articles (de Tiedra et al. 1998; Augustin et al. 1999; Jobanputra and Bachmann 2000; Hahn et al. 2001; De Korte et al. 2002b; Shikiar et al. 2005; Bronsard et al. 2010) meeting the inclusion criteria were not included in the COSMIN analysis but data were extracted: two because only interpretability information was reported (Hahn et al. 2001; Shikiar et al. 2005), and four review articles did not provide sufficient information on the methodological quality of included studies, but included information on interpretability and feasibility (de Tiedra et al. 1998; Augustin et al. 1999; De Korte et al. 2002b; Bronsard et al. 2010). In all, 36 PROMs (Table 8.), reported on in 46 articles were included in the COSMIN analysis. The characteristics of the PROMs and studies are presented in Appendices 3 and 4, respectively.

Figure 11: PRISMA flow diagram of the screening and selection process

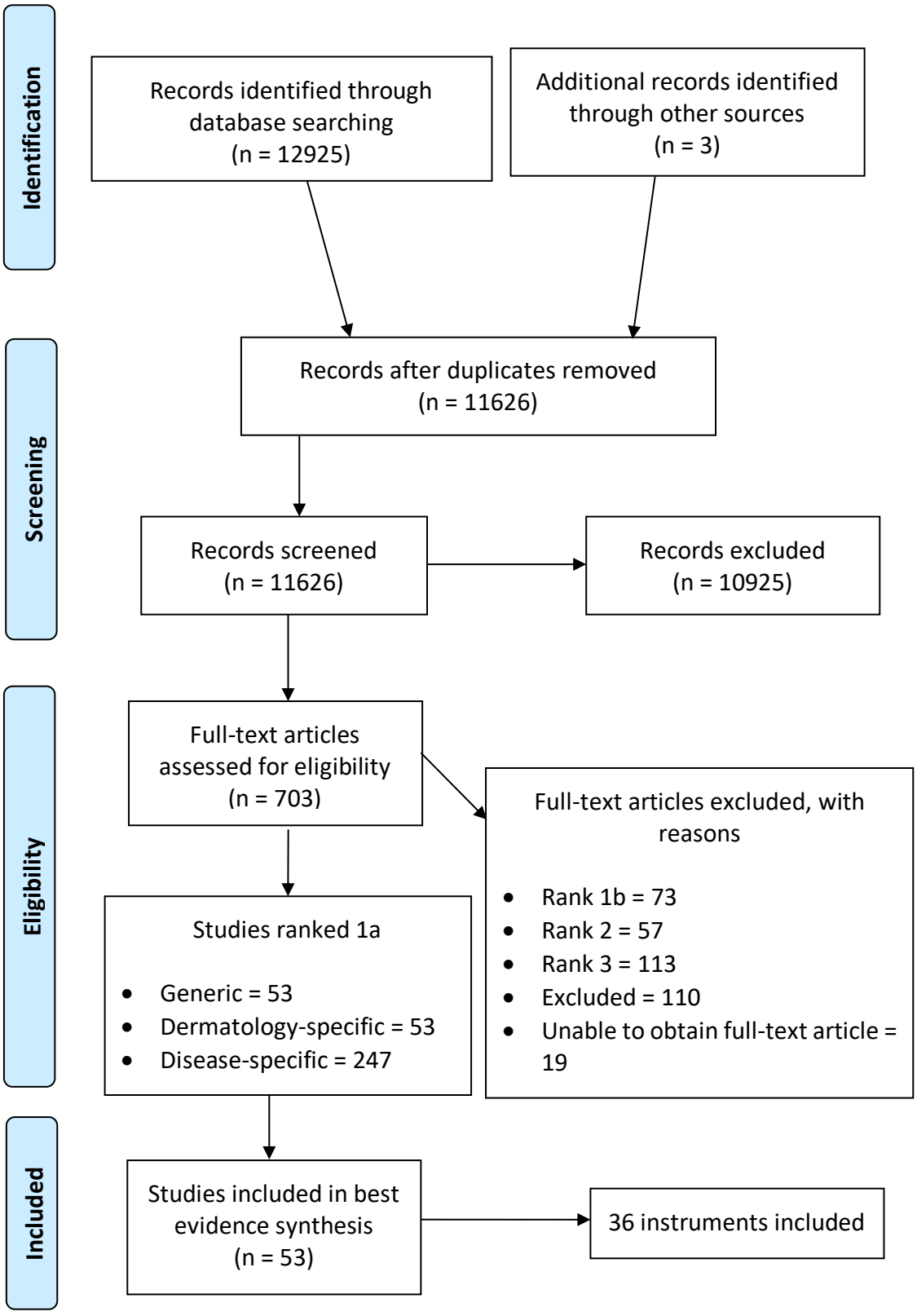


Table 8: PROMs identified (abbreviation)

1. Adjustment to Chronic Skin Diseases Questionnaire (ACSD)	2. Children's Dermatology Life Quality Index (CDLQI)
3. Children's Dermatology Life Quality Index Cantonese (CDLQI-C)	4. Consumer Quality Index Chronic Skin Disease (CQI-CSD)
5. Dermatology Intimacy Scale (DIS)	6. Dermatology Life Quality Index (DLQI)
7. Dermatology Life Quality Index Brazilian-Portuguese (DLQI-B)	8. Dermatology Life Quality Index Chinese (DLQI-C)
9. Dermatology Life Quality Index Danish (DLQI-D)	10. Dermatology Life Quality Index Italian (DLQI-I)
11. Dermatology Life Quality Index Norwegian (DLQI-N)	12. Dermatology Life Quality Index Sinhala (DLQI-S)
13. Dermatology Life Quality Index Turkish (DLQI-T)	14. Dermatology Life Quality Index Ukrainian (DLQI-U)
15. Dermatology Quality of Life scales (DQOLs)	16. Dermatology-specific Quality of Life (DSQL)
17. Freiburg Life Quality Assessment (FLQA-d)	18. Patient Benefit Index (PBI)
19. Person-Centred Dermatology Self-Care Index (PeDeSI)	20. Pictorial Representation of Illness & Self-Measure (PRISM)
21. Short-form of the Questionnaire on Experience with Skin Complaints (SF-QES)	22. Skindex
23. Skindex-29	24. Skindex-29-Chinese (S29-C)
25. Skindex-29-German (S29-G)	26. Skindex-29-Serbian (S29-S)
27. Skindex-29-Spanish (S29-Sp)	28. Skindex-16
29. Skindex-16-Arabic (S16-A)	30. Skindex-16-Brazilian-Portuguese (S16-BP)
31. Skindex-16-Chinese (S16-C)	32. Skindex-16-Japanese (S16-J)
33. Skindex-16-Moroccan-Arabic (S16-M)	34. Skindex-16-Ukrainian (S16-U)
35. Turkish Quality of Life Instrument for skin disease (TQL)	36. VQ-Dermato

4.3.1 Overview of results

The majority of the PROMs (83%) measured QoL. Of these, most of the included articles reported on the DLQI (n = 8), the three Skindex instruments (n = 4), and their translated versions. From the 46 included studies, the methodological quality of 135 measurement properties were rated. The number of studies and instruments per measurement property tested are presented in (Table 9.). No instrument was tested for all measurement properties. The number of measurement properties tested per instrument ranged between 1 and 6 (*M* = 3.7). Internal consistency was the most popular psychometric test (n = 37), measurement invariance was the least (n = 2) and measurement error was not tested at all. Evidence for content validity was based only on development and pilot-testing studies (n = 22) for most instruments as content validity studies were only conducted for one (Jones-Caballero et al. 2000).

Table 9: Number of studies and PROMs present per measurement property

	No. studies	No. PROMs
Content validity	22	21
Structural validity	23	19
Internal consistency	37	30
Reliability	20	18
Measurement error	0	0
Construct validity	35	29
Cross-cultural validity/measurement invariance	2	1
Responsiveness	13	12

4.3.2 Identification of an impact measure

A comparison of each PROM at the domain level appears in Table 10. Domains were derived based on subscales reported by the developers or through structural validity analyses. The most common domains observed were symptoms, emotional/psychological functioning, physical functioning, social functioning and daily activities. None of the PROMs included broader impact domains, such as economic impact and life course impairment and, therefore, cannot be considered a comprehensive measure of the impact of living with a dermatological condition.

Table 10: Comparison of PROMs at the domain level

PROM	Symptoms	Emotional/psychological functioning	Physical functioning	Social functioning	Daily activities	Treatment beliefs/impact	Work/school	Quality of care	Coping behaviour	Stigmatisation	Education/support needs	Intimacy
ACSD	X	X	X	X	X	X	X		X	X	X	X
CDLQI	X	X	X	X	X	X	X			X		
CQI-CSD								X				
DIS												X
DLQI	X	X	X	X	X	X	X					X
DQOLs	X	X	X	X								
DSQL	X	X		X	X		X					
FLQA-d	X	X	X	X	X	X						
PBI						X						
PeDeSI											X	
PRISM												
SF-QES		X							X	X		X

PROM	Symptoms	Emotional/psychological functioning	Physical functioning	Social functioning	Daily activities	Treatment beliefs/impact	Work/school	Quality of care	Coping behaviour	Stigmatisation	Education/support needs	Intimacy
Skindex	X	X	X	X	X					X		X
S29	X	X	X									
S16	X	X	X									
TQL	X	X		X	X							X
VQ-Dermato	X	X		X	X	X						

Abbreviations are found in **Error! Reference source not found.**.

4.3.3 Methodological quality of included studies and quality of measurement properties

As per the COSMIN methodology, content validity and other measurement properties were analysed separately. Summaries of the results are presented below and are explicated in the next section. Table 11. shows both the methodological quality of studies on content validity and the quality of the results rated against the predefined criteria for each PROM.

Evidence for content validity was based only on development and pilot-testing studies for most instruments, as a content validity study was only conducted for the Spanish version of Skindex-29 (S29-S). The majority (86%) of the development studies were of very low methodological quality. Only the Patient Benefit Index (PBI; low quality), Turkish Quality of Life Instrument (TQL; low quality), and Skindex-29 Spanish (high quality) were rated as having adequate methodological quality. The most common reason for downgrading the overall quality of evidence to very low was that a cognitive interview was not conducted or was of poor methodological quality.

The methodological quality of studies on measurement properties (Table 12.) and quality of the measurement properties (Table 13.) per instrument per study are also presented.

Table 11: Methodological quality and quality assessment of results per content validity study per PROM

	Methodological quality						Quality assessment of results					
PROM	**Design**	**Comprehensibility**	**Comprehensiveness**	**Cognitive Interview Study**	**Total development**	**Content validity study**	**Overall Relevance**	**Overall Comprehensiveness**	**Overall Comprehensibility**	**Content Validity Study**	**Overall Content validity**	**Quality of evidence**
ACSD (Stangier et al. 2003)	D	X	X	I	I	X	+	+	+		+	Very low
CDLQI (Lewis-Jones and Finlay 1995)	I	X	I	I	I	X	+	+	+		+	Very low
CDLQI-C (Chuh 2003)	I	D	I	I	I	X	+	+	+		+	Very low
CQI-CSD (van Cranenburgh et al. 2015)	A	I	I	I	I	X	±	+	+		±	Very low

	Methodological quality						Quality assessment of results					
PROM	**Design**	**Comprehensibility**	**Comprehensiveness**	**Cognitive Interview Study**	**Total development**	**Content validity study**	**Overall Relevance**	**Overall Comprehensiveness**	**Overall Comprehensibility**	**Content Validity Study**	**Overall Content validity**	**Quality of evidence**
DIS (Malakouti et al. 2017)	I	D	D	D	I	X	+	+	+		+	Very low
DLQI (Finlay and Khan 1994b)	I	D	D	D	I	X	+	+	+		+	Very low
DQOLs (Morgan et al. 1997)	I	X	X	I	I	X	?	?	?		?	Very low
DSQL (Anderson and Rajagopalan 1997)	D	I	D	I	I	X	+	+	+		+	Very low
FLQA-d (Augustin	D	D	I	I	I	X	+	+	+		+	Very low

	Methodological quality						Quality assessment of results					
PROM	**Design**	**Comprehensibility**	**Comprehensiveness**	**Cognitive Interview Study**	**Total development**	**Content validity study**	**Overall Relevance**	**Overall Comprehensiveness**	**Overall Comprehensibility**	**Content Validity Study**	**Overall Content validity**	**Quality of evidence**
et al. 2000b)												
PBI (Augustin et al. 2009)	D	D	D	D	D		±	+	±		±	Low
PeDeSi (Cowdell et al. 2012)	D	X	X	I	I	X	+	+	+		+	Very low
SF-QES (Schmid-Ott et al. 2003)	I	I	I	I	I	X	±	+	+		+	Very low
Skindex (Chren et al. 1996)	D	I	I	I	I	X	+	+	+		+	Very low
S29 (Chren et	D	I	D	I	I	X	+	+	+		+	Very low

	Methodological quality						Quality assessment of results					
PROM	**Design**	**Comprehensibility**	**Comprehensiveness**	**Cognitive Interview Study**	**Total development**	**Content validity study**	**Overall Relevance**	**Overall Comprehensiveness**	**Overall Comprehensibility**	**Content Validity Study**	**Overall Content validity**	**Quality of evidence**
al. 1997a)												
S29-S (Milutinovic et al. 2017)	D	I	I	I	I	X	-	?	?		?	Very low
S29-Sp (Jones-Caballero et al. 2000)	D	I	I	I	I	A	-	-	-	-	-	High
S29-C (He et al. 2014)	D	D	I	I	I	X	-	?	-		-	Very low
S16 (Chren et al. 2001)	D	I	D	I	I	X	+	+	+		+	Very low

	Methodological quality						Quality assessment of results					
PROM	**Design**	**Comprehensibility**	**Comprehensiveness**	**Cognitive Interview Study**	**Total development**	**Content validity study**	**Overall Relevance**	**Overall Comprehensiveness**	**Overall Comprehensibility**	**Content Validity Study**	**Overall Content validity**	**Quality of evidence**
S16-C (He et al. 2014)	D	D	I	I	I	X	-	?	-		-	Very low
S16-M (El Fakir et al. 2014)	D	I	I	I	I	X	-	?	?		?	Very low
TQL(Gurel et al. 2005)	D	D	D	D	D	X	±	?	-		±	Low
VQ-D (Grob et al. 1999)	D	D	D	D	I	X	+	+	+		+	Very low

VG = Very good; A = Adequate; D = Doubtful; I = Inadequate; X = study not performed; + = sufficient; - = insufficient; ± = inconsistent; ? = indeterminate. Abbreviations are found in **Error! Reference source not found.**.

Table 12: Methodological quality of each study per measurement property

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
ACSD	(Stangier et al. 2003)	V						
CDLQI	(Lewis-Jones and Finlay 1995)			I		D		
CDLQI-C	(Chuh 2003)		D	D		D		
CQI-CSD	(van Cranenburgh et al. 2015)	I	I			I		
DIS	(Malakouti et al. 2017)					D		
DLQI	(Twiss et al. 2012)	I	I					
	(Shikiar et al. 2006)		V			V		V
	(Lennox and Leahy 2004)	V	V					A
	(Ofenloch et al. 2014)	A	D	D				

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
	(Reilly et al. 2003)			I		I		I
	(Herd et al. 1997)					D		
	(Finlay and Khan 1994b)		D	D		V		
DLQI-B	(Ferraz et al. 2006)			I		A		
DLQI-C	(He et al. 2018)	V	D			V	I	
	(Liu et al. 2016)	A	I				I	
	(He et al. 2013)	V	V			V		
	(Liu et al. 2012)	A	A					
DLQI-D	(Zachariae et al. 2000)		I	D				
DLQI-I	(Mazzotti et al. 2005)	V	V			V		

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
DLQI-N	(Mork et al. 2002)	A	A			A		
DLQI-S	(Madarasingha et al. 2011)		V	D		D		
DLQI-T	(Balci and Inandi 2008)	A	D					
DLQI-U	(Chernyshov 2016)		I					
DQOLs	(Morgan et al. 1997)	A	I	D		D		
DSQL	(Anderson and Rajagopalan 1998)		V	D		V		V
	(Anderson and Rajagopalan 1997)	V	V	I		A		
FLQA-d	(Augustin et al. 2000b)	V				V	I	V
PBI	(Augustin et al. 2009)		D	D				A

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
PeDeSI	(Cowdell et al. 2012)	A	A					
PRISM	(Muhleisen et al. 2009)					V		D
SF-QES	(Muller et al. 2007)	V	V					D
Skindex	(Chren et al. 1996)	V	I	I		D		I
S29	(Nijsten et al. 2009)					V		
	(Chren et al. 1997a)	V	V	I		D		I
S29-C	(He et al. 2014)	A	I			V		
S29-G	(Augustin et al. 2004)	V	V			V		I
S29-S	(Milutinovic et al. 2017)		V	D		V		
S29-Sp	(Jones-Caballero et al. 2002)		V	I		A		D

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
	(Jones-Caballero et al. 2000)		V			V		
S16	(Chren et al. 2001)	A	A	I		D		D
S16-BP	(Carcano et al. 2018)		V	A		V		
S16-A	(AlGhamdi and AlShammari 2007)		V			A		
S16-C	(He et al. 2014)	V	I			V		
S16-J	(Higaki et al. 2002)		V			V		
S16-M	(El Fakir et al. 2014)		V	D		V		
S16-U	(Chernyshov 2016)		V					
TQL	(Gurel et al. 2005)	A	A	D		A		

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
VQ-Dermato	(Grob et al. 1999)	A	A	D		V		A

VG = Very good; A = Adequate; D = Doubtful; I = Inadequate. Abbreviations are found in **Error! Reference source not found.**.

Table 13: Quality assessment of measurement properties per study according to predefined criteria proposed by COSMIN

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
ACSD	(Stangier et al. 2003)	?						
CDLQI	(Lewis-Jones and Finlay 1995)			?		+		
CDLQI-C	(Chuh 2003)		+	?		?		
CQI-CSD	(van Cranenburgh et al. 2015)	?	+			?		
DIS	(Malakouti et al. 2017)					?		
DLQI	(Twiss et al. 2012)	?	?					
	(Shikiar et al. 2006)		+			?		+
	(Lennox and Leahy 2004)	?	+					?
	(Ofenloch et al. 2014)	-	?	-				
	(Reilly et al. 2003)			?		?		±

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
	(Herd et al. 1997)					+		
	(Finlay and Khan 1994b)		?	?		?		
DLQI-B	(Ferraz et al. 2006)			+		?		
DLQI-C	(He et al. 2018)	-	?				?	
	(Liu et al. 2016)	?	?				?	
	(He et al. 2013)	+	+			?		
	(Liu et al. 2012)	+	+					
DLQI-D	(Zachariae et al. 2000)		+	?		?		
DLQI-I	(Mazzotti et al. 2005)	+	+			+		
DLQI-N	(Mork et al. 2002)	?	+			?		
DLQI-S	(Madarasingha et al. 2011)		-	+		+		

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
DLQI-T	(Balci and Inandi 2008)	?	+					
DLQI-U	(Chernyshov 2016)		+					
DQOLs	(Morgan et al. 1997)	?	+	+		±		
DSQL	(Anderson and Rajagopalan 1998)		+	+		-		
	(Anderson and Rajagopalan 1997)	?	+	?		±		
FLQA-d	(Augustin et al. 2000b)		-	?		?		?
PBI	(Augustin et al. 2009)		+	?				
PeDeSI	(Cowdell et al. 2012)	?	+					
PRISM	(Muhleisen et al. 2009)					+		+

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
SF-QES	(Muller et al. 2007)	+	+					+
Skindex	(Chren et al. 1996)	?	?	?		+		?
S29	(Nijsten et al. 2009)					+		
	(Chren et al. 1997a)	?	+	?		+		+
S29-C	(He et al. 2014)	-	?			+		
S29-G	(Augustin et al. 2004)	?	+			?		?
S29-S	(Milutinovic et al. 2017)		+	-		±		
S29-Sp	(Jones-Caballero et al. 2002)		+	+		+		+
	(Jones-Caballero et al. 2000)		+			+		
S16	(Chren et al. 2001)	+	+			+		?

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/measurement invariance	Responsiveness
S16-A	(AlGhamdi and AlShammari 2007)		+			+		
S16-BP	(Carcano et al. 2018)		+	+		+		
S16-C	(He et al. 2014)	+	?			+		
S16-J	(Higaki et al. 2002)		+			+		
S16-M	(El Fakir et al. 2014)		+	+		+		
S16-U	(Chernyshov 2016)		+					
TQL	(Gurel et al. 2005)	?	+	-		?		
VQ-Dermato	(Grob et al. 1999)	?	-	?		+		+

+ = sufficient; - = insufficient; ± = inconsistent; ? = indeterminate. Abbreviations are found in **Error! Reference source not found.**.

4.3.4 Quality of PROMs: best evidence synthesis and recommendations

The results of the best evidence synthesis (Table 14.) for each PROM are described below according to the category of recommendation (A-C). Measurement properties with weak overall evidence are shown in Table 14. but are not described below. The best evidence synthesis shows the overall evidence for each measurement property per PROM expressed as one result combining both the level of evidence (high, moderate, low, very low) and the quality of the measurement property (sufficient, insufficient, indeterminate, inconsistent).

A note on nomenclature

The term ‘dermatological condition’ is used in this thesis to be inclusive of those with conditions affecting the skin, hair, nail or mucous membrane. However, when describing the target audience of the included PROMs in this chapter, the term the study authors use (e.g. ‘chronic skin disease’) is used.

This is a particular issue for AD. Some caution is required when using the term AD as there is a lack of standardised nomenclature for the condition (Berth-Jones 2010; Friedmann et al. 2010; Kantor et al. 2016). The World Allergy Organisation has suggested that 'eczema' should be used as an umbrella term and subdivided into atopic eczema and non-atopic eczema (Johansson et al. 2004); however, the clinical relevance of this classification is not confirmed (Friedmann et al. 2010). A recent meta-analysis of the most commonly used terms in the scientific literature found that AD was used most frequently and, therefore, recommended for use (Kantor et al. 2016). For this thesis, the term AD will be used and viewed synonymously with other terms, however, the term eczema will be used when describing the PROMs in this chapter, if this is what the author used.

Table 14: Best evidence synthesis and recommendations

PROM	Content validity	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Measurement invariance	Responsiveness	Recommendation
ACSDQ	W	???							B
CDLQI	W			W		+			B
CDLQI-C	W		?	W		W			B
CQI-CSD	W	W	W			W			B
DIS	W					?			B
DLQI	W	???	+++	?		+++		+++	B
DLQI-B				W		++			B
DLQI-C		+++	+++			+++	W		B
DLQI-D			W	W		???			B
DLQI-I		+++	+++			+++			B
DLQI-N		??	++			++			B
DLQI-S			---	W		+			C
DLQI-T		?	W						B

PROM	Content validity	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Measurement invariance	Responsiveness	Recommendation
DLQI-U			W						B
DQOLs	W	??	W	+		-			B
DSQL	W	???	+++	+		+++		+++	B
FLQA-d	W		+++	?		+++		+++	B
PBI	±		?	?				++	B
PeDeSI	W	??	++						B
PRISM						+++		+	B
SF-QES	W	---	++						C
Skindex	W	???	W	W		-		W	B
S29	W	???	+++	W		+++		W	B
S29-C	W	--	W			+++			B
S29-G		???	+++			+++		W	B
S29-S	W		+++	-		---			C
S29-Sp	---		+++	W		+++		W	C

PROM	Content validity	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Measurement invariance	Responsiveness	Recommendation
S16	W	++	++			+		W	B
S16-A			+++			++			B
S16-BP			+++	W		+++			B
S16-C	W	---	W			+++			C
S16-J			+++			+++			B
S16-M	W		+++	+		+++			B
S16-U			++						B
TQL	±	??	++	W		++			B
VQ-Dermato	W	??	--	?		+++		++	B

Abbreviations are found in **Error! Reference source not found.**.

+++ High-quality evidence for a sufficient measurement property

--- High-quality evidence for an insufficient measurement property

??? High-quality evidence for an indeterminate measurement property

++ Moderate evidence for a sufficient measurement property

PROM	Content validity	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Measurement invariance	Responsiveness	Recommendation

-- Moderate evidence for an insufficient measurement property

?? Moderate evidence for an indeterminate measurement property

\+ Low-quality evidence for a sufficient measurement property

\- Low-quality evidence for an insufficient measurement property

? Low-quality evidence for an indeterminate measurement property

W Very low evidence for a measurement property.

± Conflicting evidence for a measurement property

Category A

No PROMs met key requirements for immediate use as a dermatology-specific PROM.

Category B

Thirty-one PROMs are recommended for use pending further validation. A summary of each PROM is provided in alphabetical order below. Where no PROMs categorised as A are found (as here), COSMIN recommends that the PROM with the best evidence for content validity in category B could be provisionally recommended for use, until further evidence is provided (Prinsen et al. 2018). Based on the evidence for content validity across instruments in the best evidence synthesis, the PBI and TQL are provisionally recommended for use as measures of patient needs and treatment benefits, and QoL, respectively. However, it is worth noting that although both of these have content validity studies of acceptable methodological quality, their results were inconsistent.

Adjustment to Chronic Skin Diseases Questionnaire

Adjustment to Chronic Skin Diseases Questionnaire (ACSDQ; Stangier et al. 2003) is a 51-item measure that assesses problems in adapting to chronic skin disorders. The one-week recall period is within the recommended range of recall (one day to one month) for PROMs of fluctuating phenomena such as adjustment and QoL proposed in the literature (Stull et al. 2009). The overall content validity of the ACSDQ is not known due to the weak level of evidence. An inadequate cognitive interview led to an overall methodologically inadequate development study.

There was high-quality evidence for indeterminate structural validity. A principal component analysis conducted in a sample of patients with various dermatological conditions (n = 442) found six factors: social anxiety/avoidance, itch-scratch cycle, helplessness, anxious-

depressive mood, impact on QoL, and deficit in active coping. The criteria for good measurement properties of structural validity were not reported.

Children's Dermatology Life Quality Index

Children's Dermatology Life Quality Index (CDLQI; Lewis-Jones and Finlay 1995) is a 10-item QoL measure for children with a skin condition with a one-week recall period. CDLQI was developed with a sample of children aged 3 – 16 years old (n = 196). The development study was methodologically inadequate due to an inadequate cognitive interview. There was low-quality evidence for sufficient construct validity with significant differences in scores between children with skin disease and healthy controls ($p < 0.0001$), and scores for eczema, psoriasis and acne were higher than for moles and naevi ($p < 0.01$).

CDLQI-Cantonese

CDQLI-Cantonese had low-quality evidence for indeterminate internal consistency with a Cronbach's α of 0.83. Because the CLDQI-C was based on the CDLQI's development study, it was also methodologically inadequate.

Dermatologic Intimacy Scale

Dermatologic Intimacy Scale (DIS; Malakouti et al. 2017) is an 18-item measure of intimacy for patients with a skin condition with a two-week recall period. DIS showed low-quality evidence for indeterminate construct validity. Scores were significantly higher for patients with more severe psoriasis compared to those with less severe psoriasis ($p < 0.001$) and for patients with psoriasis in sensitive areas compared to those that had no involvement in those anatomical regions ($p < 0.001$).

DLQI

DLQI (Finlay and Khan 1994b) is a 10-item QoL PROM with a one-month recall period for patients with skin conditions. It appears to be acceptable with an average of 1 – 3 minutes completion time (Finlay and Khan 1994b; Hahn et al. 2001). MCID thresholds ranged between 2.34 and 5.7 (Shikiar et al. 2005; Shikiar et al. 2006). One study found an acceptable ceiling effect with 11% of patients indicating no impairment of QoL on the DLQI (Hahn et al. 2001). Floor and ceiling effects occur when a high proportion of the total population has a score at the lower or upper end of the scale, respectively (de Vet et al. 2011). The lack of large floor and ceiling effects is an indication that the instrument is comprehensive (Mokkink et al. 2010b).

Several studies evaluated the DLQI's measurement properties. A number assessed structural validity with inconsistent results. Most were of low methodological quality (e.g. Twiss et al. 2012) or did not report statistics corresponding to the COSMIN criteria (e.g. Ofenloch et al. 2014). One study of good methodological quality suggests that the DLQI is unidimensional, though relevant statistics were not reported (Lennox and Leahy 2004).

Sufficient internal consistency, construct validity and responsiveness were supported by high-quality evidence. Cronbach's α ranged between 0.89 and 0.92 (Lennox and Leahy 2004; Shikiar et al. 2006). DLQI scores were significantly correlated with the Short Form (36) Health Survey (SF-36; Ware et al. 1997), EuroQOL 5D (EQ-5D; Kind 1990), and patient- and clinician-rated severity (Herd et al. 1997; Reilly et al. 2003; Shikiar et al. 2006). Treatment success was a significant predictor of improvement in DLQI scores and significant differences between treatment responders and partial responders were found (Reilly et al. 2003; Shikiar et al. 2006). There was some evidence of indeterminate reliability in the DLQI.

DLQI-Brazilian-Portuguese (DLQI-BP)

DLQI-BP (Ferraz et al. 2006) had moderate evidence of sufficient construct validity. As hypothesised, there was no correlation between the instrument and the SF-36 subscales.

Patients with active lesions and alopecia had significantly lower scores than patients without active lesions and without alopecia, respectively.

DLQI-Chinese (DLQI-C)

Several studies evaluated the DLQI-C (Liu et al. 2012). One study sampled patients with a variety of skin disorders (n = 9845; He et al. 2018) and three had disease-specific samples: psoriasis (n = 851; He et al. 2013), chronic urticaria (n = 131; Liu et al. 2012), and neurodermatitis (n = 150; Liu et al. 2016). Some studies examined DLQI-C using Rasch analysis, others used CTT.

Although Rasch analysis does not directly map onto the COSMIN taxonomy of measurement, unidimensionality, person-separation index (PSI) and differential item functioning (DIF) analyses provide evidence for the evaluation of structural validity, internal consistency and measurement invariance, respectively. According to Rasch criteria, for a measure or subscale to be unidimensional two criteria must be met: 1) at least 50% of the total variance should be explained by the first latent dimension; and 2) < 5% of the remaining variance should be explained by any additional dimension, after removal of the first latent dimension (Smith and Miao 1994). Lui and colleagues (2016) found mixed evidence for unidimensionality as the first latent dimension accounted for 50.8% of the total variance, but the second latent dimension accounted for 7.1% of the variance. He and colleagues (2018) conducted a Rasch analysis of DLQI-C but did not provide evidence of unidimensionality as they based this on eigenvalues, rather than established criteria. Both studies met the criteria of a PSI of >2 (Linacre 2012), indicating good internal consistency. Results of the DIF analyses, however, did not support sufficient measurement invariance as significant group differences were found for some items. Unfortunately, the results of the Rasch analyses do not directly correspond to the COSMIN criteria for good structural validity, internal consistency and measurement invariance and, therefore, could not be included in the best evidence synthesis.

The best evidence synthesis was, therefore based on CTT analyses. There was high-quality evidence of a unidimensional structure and internal consistency. One study of adequate

methodological quality found two factors, though violated the criteria for good measurement properties (CFI = 0.935; Liu et al. 2012). Another study of very good methodological quality found evidence of unidimensionality that met the criteria for good measurement properties (He et al. 2013). Cronbach's α ranged between 0.82 and 0.92. One high-quality study found sufficient construct validity; DLQI-C was significantly correlated with related measures, SF-36, Psoriasis Disability Index (Finlay and Coles 1995), and PASI (Fredriksson and Pettersson 1978).

DLQI-Danish

DLQI-Danish (Zachariae et al. 2000) had high-quality evidence for indeterminate construct validity.

DLQI-Italian

DLQI-Italian had high-quality evidence for sufficient structural validity, internal consistency, and construct validity in a sample of 900 psoriasis patients (Mazzotti et al. 2005). The instrument had a unidimensional structure, a Cronbach's α of 0.83, and was moderate-to-strongly correlated with Psoriasis Disability Index and Skindex-29 (Chren et al. 1997a).

DLQI-Norwegian

DLQI-Norwegian had moderate evidence for indeterminate structural validity, and sufficient internal consistency and construct validity from a study of 230 psoriasis patients (Mork et al. 2002). The instrument may be unidimensional but results that met the COSMIN criteria for structural validity were not reported. Cronbach's α was 0.9 and scores were significantly correlated with disease severity.

DLQI-Turkish

DLQI-Turkish was tested in a sample of patients (n = 90) with lichen planus and psoriasis (Balci and Inandi 2008). It had low-quality evidence for indeterminate structural validity. A two-factor model was found though results that met the criteria for structural validity were not reported.

Dermatology Quality of Life Scales (DQOLS)

DQOLS is a 41-item QoL PROM for patients with a skin condition (Morgan et al. 1997). The content validity of the measure is unknown. The instrument was developed through qualitative research with 50 dermatology clinic outpatients, but no cognitive interview or content validity studies were completed, and the instrument was not available to be reviewed. Evidence of structural validity was moderate but indeterminate. DQOLs appears to have an eight-factor model, though results that met the COSMIN criteria were not reported. There was low-quality evidence of sufficient reliability and insufficient construct validity. The *intra*class correlation coefficients (ICC) were 0.84 for psychosocial and physical activity scores and less than 75% of hypotheses set *a priori* were met.

Dermatology-specific Quality of Life (DSQL)

DSQL is a 52-item QoL measure for patients with skin conditions that contains two SF-36 subscales of emotional distress (Anderson and Rajagopalan 1997). Two studies found floor effects for the daily activities (25.2%), social functioning (27.6%), and work/school (41.2% and 53.8%) subscales indicating that DSQL is not comprehensive or precise enough at the lower end of the scale (Anderson and Rajagopalan 1997; Anderson and Rajagopalan 1998).

Items for DSQL were identified from a review of the literature, clinical experience and a group discussion of seven patients with facial acne. The cognitive interview was methodologically

inadequate as comprehensibility was not assessed and, therefore, content validity remains unknown.

Two studies tested the psychometric properties of the DSQL (Anderson and Rajagopalan 1997; Anderson and Rajagopalan 1998). High-quality evidence for sufficient internal consistency, construct validity, and indeterminate structural validity was found. A five-factor model has been identified (Anderson and Rajagopalan 1997), though results that met the quality criteria were not reported. Cronbach's α for each subscale ranged between 0.71 and 0.91. The DSQL scores significantly correlated with patient-rated severity and the mean scores of patients with severe disease were significantly higher than for those classified as less severe. Low-quality evidence of sufficient reliability was found with an ICC of >0.82 for all subscales.

Freiburg Life Quality Assessment (FLQA-d)

The Freiburg Life Quality Assessment (FLQA) is a set of core, generic items used to assess QoL in dermatology patients that can be supplemented with additional disease-specific items. The FLQA-d is a 53-item variant of the FLQA for use with patients with long-term skin conditions (Augustin et al. 2000b).

FLQA-d was developed through qualitative research with 46 patients with AD, psoriasis and urticaria. As the cognitive interview was methodologically inadequate and there have been no content validity studies, the content validity of the instrument remains unknown.

High-quality evidence for insufficient internal consistency, sufficient construct validity and responsiveness was found. Although most FLQA-d subscales had an acceptable Cronbach's α of >0.8, the treatment scale did not meet the criteria for good internal consistency at 0.69. Correlations were found between FLQA-d and comparable QoL scales and there was significant sensitivity to change in all subscales of the instrument ($p < 0.001$). Low-quality evidence of indeterminate reliability was found as reported information did not meet the COSMIN criteria.

Patient Benefit Index (PBI)

The PBI is a 50-item measure of patient needs and treatment benefits for dermatology patients (Augustin et al. 2009). The developers found a 'major floor effect' in a cross-sectional study but the actual value was not reported. There was a low percentage of missing items indicating high feasibility.

Although the PBI showed low-quality evidence of inconsistent content validity, the overall development study was methodologically adequate and the criteria for good content validity and reviewers' rating were sufficient overall.

There was moderate evidence of sufficient responsiveness with significant correlations with patients' ratings of treatment success, efficacy of medication, recommendation of medicine, clinical improvement and QoL. Low-quality evidence of indeterminate internal consistency and reliability was found. Cronbach's α was <0.91 (though this is insufficient without information on structural validity), and reliability was tested but statistics corresponding to the COSMIN quality criteria were not reported.

Person-Centred Dermatology Self-Care Index (PeDeSI)

PeDeSI is a 10-item measure of education and support needs used to form the basis of tailored self-management programmes for patients with long-term skin conditions (Cowdell et al. 2012). The instrument was developed through qualitative research with a panel of experts, including physicians, nurses, educationalists and patients with chronic skin disease. The content validity is unknown as there have been no cognitive interviews or content validity studies.

PeDeSI has moderate evidence for indeterminate structural validity and sufficient internal consistency. It was reported to be unidimensional, though statistics were not reported. Cronbach's α was high at 0.9.

Pictorial Representation of Illness and Self Measure (PRISM)

PRISM is a visual tool to measure QoL in dermatology inpatients (Muhleisen et al. 2009). The one-item measure was highly feasible, taking less than five minutes to complete. It has high-quality evidence for sufficient construct validity and low-quality evidence of responsiveness. It was significantly correlated with Skindex-29 and DLQI and showed a significant reduction in patients' burden of illness during hospitalisation ($p < .001$).

Skindex

Skindex is a 61-item QoL PROM for patients with skin conditions (Chren et al. 1996). It had a 15-minute average completion time (Chren et al. 1996; de Tiedra et al. 1998). Items for Skindex were identified from the literature and through group discussions with dermatology patients and clinicians. Lack of a content validity study and a methodologically inadequate cognitive interview study resulted in weak evidence for content validity.

High-quality evidence for indeterminate structural validity was found. The authors hypothesised eight subscales for Skindex: four based on a conceptual framework (cognitive, social, physical discomfort and physical limitations) and four sub-dimensions of an emotional dimension (depression, fear, embarrassment and anger). A principal axes factor analysis, however, found only seven factors (negative affect, self-esteem, anxiety, physical discomfort, physical limitations, self-consciousness, intimacy), though results meeting the COSMIN quality criteria were not reported. Internal consistency was indeterminate because it was tested using the hypothesised subscales, rather than those identified by the factor analysis. Low-quality evidence for insufficient construct validity was found and less than 75% of the *a priori* hypotheses were met.

Skindex-29

Skindex-29 is a revised 29-item version of Skindex (Chren et al. 1997a). It had a completion time of 5 to 15 minutes (de Tiedra et al. 1998; De Korte et al. 2002b; Bronsard et al. 2010). Skindex underwent item analysis, reduction, and enhancement based on qualitative research (n = 591) with dermatology patients and psychometric testing to produce Skindex-29 (Chren et al. 1997a).

There was high-quality evidence for sufficient internal consistency and construct validity but also indeterminate structural validity. A principal axes factor analysis found three factors (emotions, functioning, symptoms), though relevant statistics were not reported. Cronbach's α for the emotions, functioning and symptoms subscales were 0.94, 0.96 and 0.87, respectively. Evidence for discriminative and convergent validity was found. Skindex-29 was significantly, modestly correlated with physician-rated clinical severity ($p \leq .001$; Chren et al. 1997a) and with corresponding subscales of Skindex-17 (Nijsten et al. 2009); and participants with inflammatory conditions, such as eczema and psoriasis, experienced significantly higher levels of impairment in QoL than patients with non-inflammatory conditions (Chren et al. 1997a; Nijsten et al. 2009).

Skindex-29 Chinese

Skindex-29-Chinese (He et al. 2014) had high-quality evidence for sufficient construct validity. It was moderately correlated with DLQI, and patients with inflammatory dermatosis had significantly higher scores compared to patients with isolated lesions. Moderate evidence suggested insufficient structural validity: three factors were found, though the RMSEA value reported (0.11) did not meet the COSMIN criteria for good structural validity. No floor or ceiling effects were observed.

Skindex-29 German

Skindex-29-German had high-quality evidence for indeterminate structural validity (Augustin et al. 2004). Three factors (emotions, functioning, and symptoms) were found, though relevant statistics were not reported. There was also sufficient internal consistency and construct validity. Cronbach's α was acceptable for the emotions (0.92), functioning (0.93-0.94), and symptoms (0.85-0.87) subscales. Scores were significantly correlated with other dermatology-specific QoL instruments, specifically the FLQA-d, DLQI, and Marburger Hautfragebogen (MHF; Stangier et al. 1997). No evidence of cognitive testing or content validity studies were reported.

Skindex-16

Skindex-29 underwent item analysis, reduction, elimination, refinement and psychometric testing to produce Skindex-16, a brief 16-item instrument (Chren et al. 2001). Content validity of the revised instrument was tested qualitatively in a sample of 348 dermatology patients; however, the cognitive interview was inadequate.

There was moderate evidence for sufficient structural validity and internal consistency. A principal axes factor analysis found three factors - emotions, functioning, symptoms - and Cronbach's α for each subscale was 0.93, 0.88, and 0.86, respectively. There was also low-quality evidence for sufficient construct validity. For all three subscales, mean scores of patients with inflammatory dermatoses were significantly higher than mean scores of those with isolated skin lesions ($p < 0.0001$).

Skindex-16 Arabic

Skindex-16-Arabic had high-quality evidence for sufficient internal consistency and moderate evidence for sufficient construct validity (AlGhamdi and AlShammari 2007). Cronbach's α for the emotions (0.92), functioning (0.87), and symptoms (0.81) subscales met the COSMIN

criteria. The measure was able to discriminate between patients with skin problems and healthy controls ($p < 0.02$), and between patients with inflammatory dermatoses and isolated lesions ($p < 0.001$).

Skindex-16 Brazilian-Portuguese

Skindex-16-Brazilian-Portuguese had high-quality evidence for sufficient internal consistency and construct validity (Carcano et al. 2018). Cronbach's α was 0.93, 0.89 and 0.87 for the emotions, functioning and symptoms subscales, respectively. Convergent and discriminative validity were demonstrated. All three subscales were strongly correlated with DLQI scores. As hypothesised, the emotions subscale was the most highly correlated with HADS scores and the correlations with symptoms and functioning subscales were low. There were significant differences in scores between subgroups. Patients with moderate (emotions: $p < 0.001$; symptoms: $p = 0.049$; functioning: $p < 0.001$) and severe skin disease had higher scores than those with mild disease (emotions: $p = 0.002$; symptoms: $p = 0.001$; functioning: $p = 0.002$). Patients with inflammatory dermatosis presented higher scores on emotions ($p = 0.016$) and functioning ($p = 0.056$), but not in symptoms ($p = 0.298$), when compared with patients with localised lesions.

Skindex-16 Japanese

Skindex-16-Japanese had high-quality evidence for sufficient internal consistency and construct validity (Higaki et al. 2002). Cronbach's α was 0.89, 0.83, and 0.87 for the emotions, functioning and symptoms subscales, respectively. Patients with skin disease showed significantly higher scores than healthy controls ($p < 0.001$), and patients with inflammatory dermatoses showed significantly higher scores than patients with isolated lesions ($p < 0.001$).

Skindex-16 Moroccan-Arabic

Skindex-16-Moroccan-Arabic had high-quality evidence for sufficient internal consistency and construct validity (El Fakir et al. 2014). Cronbach's α was calculated for the emotions (0.81), functioning (0.71), and symptoms (0.82) subscales. Scores correlated with EQ-5D. The ICC for the emotions (0.95), functioning (0.93), and symptoms (0.96) subscales provided low-quality evidence for sufficient reliability.

Skindex-16 Ukrainian

Skindex-16-Ukrainian had moderate evidence of sufficient internal consistency as Cronbach's α for the emotions (0.87-0.89), functioning (0.89), and symptoms (0.83-0.84) subscales met the COSMIN criteria (Chernyshov 2016).

Turkish Quality of Life instrument (TQL) for skin disease

Turkish Quality of Life Instrument (TQL) is an 11-item Turkish language QoL PROM for patients with skin conditions (Gurel et al. 2005). Items for the TQL were developed through qualitative research with 200 dermatology outpatients. The cognitive interview (n = 40) was methodologically adequate, though mixed. Compared against the criteria for good content validity, results of the relevance, comprehensiveness, and comprehensibility of the instrument were inconsistent, indeterminate and insufficient, respectively. Thus, there was low-quality evidence for inconsistent content validity.

Moderate evidence was found for sufficient internal consistency and construct validity, and indeterminate structural validity. A principal component analysis found six factors – social life, emotional, daily activity, symptom, cognitive, sexual life – though relevant statistics were not reported. Cronbach's α ranged between 0.77 and 0.84 for the six subscales. TQL demonstrated both discriminative and convergent validity: the instrument was significantly correlated to physician-ratings of severity (p = 0.001); and the mean scores of patients, severe

patients and those with inflammatory conditions were significantly higher than healthy controls, non-severe patients and those with isolated skin lesions, respectively.

VQ-Dermato

VQ-Dermato is a 28-item French language QoL PROM for patients with long-term skin conditions, which specifically excludes melanoma (Grob et al. 1999). Items were generated from a review of the literature, and qualitative research with experts and 100 patients with a single diagnosis of a wide variety of skin conditions. However, the concept elicitation study was methodologically inadequate, and no content validity study was performed.

High-quality evidence of sufficient construct validity was observed. A large number of *a priori* hypotheses were proposed and most were met; for example, there were strong correlations between VQ-Dermato and SF-36 subscales. There was moderate evidence for sufficient responsiveness, indeterminate structural validity and insufficient internal consistency. Patients considered clinically improved had significantly lower VQ-Dermato scores than stable patients. A principal component factor analysis revealed seven factors - self-perception, daily living activity, mood state, social functioning, leisure activity, treatment-induced restriction, and physical discomfort - though relevant statistics were not reported. Cronbach's α was not acceptable, ranging between 0.63 and 0.88 for the subscales. There was also low-quality evidence of indeterminate reliability with a Pearson's r of > 0.8 ($p < 0.001$).

Category C

Five PROMs had high-quality evidence for insufficient measurement properties and are therefore not recommended for use.

DLQI Sinhala

DLQI Sinhala had high-quality evidence for insufficient internal consistency (Madarasingha et al. 2011). Cronbach's alpha was calculated for each subscale - symptoms & feelings = 0.561, daily activities = 0.741, leisure = 0.687, and personal relationships = 0.442 – the majority of which did not meet the criteria for acceptable internal consistency. The measure had low-quality evidence of sufficient construct validity. It discriminated well between disease status and severity ($F=31.09$, $p<0.001$, $n=240$).

Short-form of the Questionnaire on Experience with Skin Complaints (SF-QES)

SF-QES is a 23-item German language measure of feelings of stigmatisation for patients with skin conditions (Muller et al. 2007). It had high-quality evidence for insufficient structural validity. An EFA found five factors: self-esteem, retreat, experienced refusal, concealment and composure (RMSEA = > 0.06; CFI < 0.95). There was also moderate evidence for sufficient internal consistency. Cronbach's α was .82, .76, .84, .76, and .69 for the subscales, respectively.

Skindex-29 Serbian

Skindex-29 Serbian had high-quality evidence for insufficient construct validity as less than 75% of *a priori* hypotheses were met (Milutinovic et al. 2017). The measure had high-quality evidence for sufficient internal consistency. The range of Cronbach's α was acceptable across the subscales: emotions = .89, symptoms = .75 - .92 and functioning = .9 - .92. There was also low-quality evidence of insufficient reliability with ICCs of .47, .35, .5 for the subscales, respectively.

Skindex-29 Spanish

Skindex-29 Spanish had high-quality evidence for insufficient content validity (Jones-Caballero et al. 2000). Cognitive interviews were inadequate in terms of comprehensiveness, comprehensibility and relevance. There was high-quality evidence of sufficient internal consistency and construct validity. Cronbach's α for the functions (.78 - .89), emotions (.87 - .91) and symptoms (.7 - .84) subscales were acceptable (Jones-Caballero et al. 2000; Jones-Caballero et al. 2002). Patients with skin problems and with inflammatory dermatoses had significantly higher scores than healthy controls and patients with isolated lesions, respectively.

Skindex-16 Chinese

Skindex-16 Chinese had high-quality evidence for insufficient structural validity (He et al. 2014). The emotions, symptoms and functioning subscales were found but with RMSEA = 15, CFI = 0.95, SRMR = 0.07. There was also high-quality evidence of sufficient construct validity. Patients with inflammatory dermatosis had significantly higher scores compared with patients with isolated lesions. The instrument also had a moderate-to-good correlation with Skindex-29 and DLQI.

4.4 Discussion

This is the first study to systematically evaluate published dermatology-specific PROMs following the most up-to-date standardised guidelines. Thirty-six dermatology-specific PROMs were identified, the majority of which measured QoL. Examination of the PROMs at the domain level identified a range of domains relevant to impact, however, no single PROM unified all relevant domains identified in the literature. This systematic review, therefore, supports the need to develop PRIDD.

4.4.1 Measurement properties

Based on their reported measurement properties, no single PROM met the COSMIN requirements to be recommended for immediate use (category A), 30 showed potential to be recommended for use but require further validation (category B), and six are not recommended for use (category C). Of those with the potential to be recommended for use, only the PBI and TQL can be provisionally recommended for use as measures of patient needs and treatment benefits, and QoL, respectively, as they have the best evidence for content validity (Prinsen et al. 2018).

The use of PROMs of poor or unknown quality is wasteful and unethical in part because measures that are not valid or reliable can produce misleading results (Ioannidis et al. 2014). Devellis (2017) argues that the cost of using a poor measure may outweigh any benefits gained; poor measurement imposes a limit on the validity of the conclusions that can be drawn and may lead to wrong decisions in both research and clinical practice. Although, in some situations, an imperfect PROM (beyond acceptable levels of measurement error) may be better than no PROM; it is useful to recognise the limitations of the measure so that conclusions drawn can be tempered accordingly. This is pertinent in dermatology where PROMs are used in research, including clinical trials, and in clinical practice to make individual treatment decisions. The results of this systematic review allow researchers and clinicians to recognise if and how measures used are flawed so that conclusions can be adjusted accordingly.

This review highlighted the paucity of high-quality evidence for dermatology-specific PROMs. These findings concur with another recent COSMIN systematic review in the context of eczema (Gabes et al. 2020), which found that no dermatology-specific QoL PROMs could be recommended for use, including the DLQI. This study, therefore, contributes to a growing number of systematic reviews supporting Nijsten's (2012) call "to move forward and use valuable alternatives because the DLQI's scientific limitations outweigh the practicalities of its use" (p. 11). Of the 135 measurement properties evaluated, only 26 had evidence of both adequate methodological quality *and* sufficient psychometric properties. No PROM performed well across *all* measurement properties. Evidence for measurement invariance and interpretability was lacking and measurement error was absent. Without evidence of

measurement error, it is not possible to establish how precise the measure is. Without information on interpretability, such as the 'smallest detectable change' and 'minimally (clinically) important change', it is difficult to interpret scores (both individual scores and differences between scores) in terms of their importance and magnitude.

The lack of quality evidence for content validity is particularly concerning since it is considered to be the most important measurement property (Mokkink et al. 2018; Terwee et al. 2018b). Because PROMs aim to capture information directly from patients, adequate patient input is necessary to establish content validity. However, all original PROM development studies were of low or very low methodological quality and only one PROM, the Spanish version of Skindex-29, underwent an additional content validity study. While there was evidence of *some* patient involvement in the item generation process, there was no evidence that patients were involved in the item reduction process. This suggests that the item reduction process was driven by the interests of the developers, rather than the patients. Together, this indicates a general lack of adequate patient input into the initial development of these PROMs.

The dearth of evidence for measurement invariance (or cross-cultural variance) is surprising given the number of translated PROMs identified. Four of the five PROMs not recommended for use were translated versions of other PROMs, potentially indicating an issue with current practices in cross-cultural translation. These findings cannot be generalised to all translated PROMs in dermatology, as published development and validation studies for some known translations were not found in the search. It does seem, however, that there are issues in the translation of PROMs in this area. There was a lack of measurement invariance testing for translated PROMs in any recommendation category. Measurement invariance is core to the process of validation as it provides evidence of 'construct equivalence', the assumption that items in the translated version measure the same construct in the same way as in the original version (Byrne and Campbell 1999; Beaton et al. 2000b; Hawkins et al. 2020). Evidence of construct equivalence, therefore, is required to synthesise and compare data across the language versions with obvious implications for research. There is a need to standardise cross-cultural translation studies of PROMs in terms of methods (e.g. back- and forward-translation procedures) and measurement properties tested.

Theory plays a vital role in the development of measurement instruments, but few studies reviewed here explicitly stated any theoretical basis, further reducing confidence in the validity of these PROMs. Future dermatology PROM development and validation work should focus on improving the methodological quality of studies, establishing content validity through adequate patient involvement and a theoretical understanding of the construct of interest, and addressing gaps in known measurement properties.

4.4.2 Strengths and limitations

The protocol for this systematic review was published on PROSPERO before commencing, reducing the opportunity for reporting bias by enabling comparison of the completed review with the protocol. The search strategy was developed by RP with input from a multidisciplinary team with expertise in dermatology, psychology and measurement instrument development and included a highly sensitive search filter for measurement properties validated by COSMIN. Three databases recommended by a subject librarian were searched but articles listed elsewhere may have been missed. Due to the high volume of retrieved articles in the search (n = 12925), reference lists of included studies were not searched which may explain why some translated PROMs were not found. At least three reviewers were involved in screening, data extraction and analysis to ensure quality; two of which were involved in every step to ensure consistency. Frequent discussions took place within the research team to resolve discrepancies.

A major strength of this review is that it followed the COSMIN methodology for systematic reviews of PROMs. Employing the COSMIN methodology: (i) reduced bias in the evaluation of measurement properties; (ii) allowed comparisons between PROMs; (iii) enabled standardised recommendations; and (iv) highlighted issues in the field, including poor methodological quality and reporting.

Given that no PROMs identified in the systematic review could be unreservedly recommended for use, it could be perceived that the COSMIN criteria are too strict. However, it could also be argued that the COSMIN criteria are the *minimum* methodological and quality

standards required to develop and validate a psychometrically sound PROM. For example, while evidence suggests that at least 30 participants are required to identify issues during cognitive interviews (Perneger et al. 2014), COSMIN only requires seven (Terwee et al. 2018b). In their systematic review of dermatology-specific QoL instruments, Gabes and colleagues (2020) concluded that the COSMIN guidance was "less strict and slightly more sympathetic to candidate PROMs" (p. 72) than the previously recommended OMERACT (Outcome Measures in Rheumatoid Arthritis Clinical Trials) approach (Schmitt et al. 2012). Instead of the strictness of COSMIN, the relatively recent publication of guidance on the development and validation of PROMs may better explain the lack of quality PROMs identified here. Many of the PROMs identified, for example, the DLQI, were developed before the COSMIN and FDA guidance were published. This may explain the widespread poor methodological quality of the development studies and subsequent finding that none could be recommended for use.

However, the COSMIN methodology does have some limitations. First, COSMIN conflates inadequate *reporting* of studies with poor inherent methodological quality, which reduces the validity of the best evidence synthesis. Second, the COSMIN checklist focuses on CTT and is not appropriate for use with PROMs developed using modern measurement theories such as IRT (Møller et al. 2020). Rasch analysis does not directly map onto the COSMIN taxonomy of measurement properties and the associated quality criteria do not reflect typical criteria for Rasch analysis. This may result from the lack of IRT expert input into COSMIN's development (Mokkink et al. 2010a) which was consensus-based, not evidence-based, relying on the opinion of researchers experienced in health-related QoL (McKenna and Heaney 2021). Given IRT's superiority, this approach may obstruct progress in the field of outcome measurement (McKenna and Heaney 2021). That said, the science of modern PROM development is still in an early phase and guidelines have never been evidence-based (Committee for Medicinal Products for Human Use 2005; FDA 2009; Eremenco et al. 2018; McKenna and Heaney 2021).

4.5 Summary

Conducting a systematic review of all published dermatology-specific PROMs is an important first step in the development of PRIDD. This is the first study to systematically evaluate published dermatology-specific PROMs following the COSMIN methodology. The systematic review found that no measure of impact exists, and no existing dermatology PROM can comprehensively assess the impact of dermatological conditions and, therefore, the development of PRIDD is warranted.

The review also found that no published dermatology-specific PROM can be recommended for use and there was a paucity of high-quality research in this area. No PROM had been evaluated across all of its measurement properties, reducing confidence in the conclusions that can be drawn from the measures identified. Evidence of content validity was particularly lacking. The main reason for this was poor patient engagement by researchers with both low numbers of participants recruited and data collection techniques considered suboptimal for understanding experiences employed (i.e. text-based responses rather than interviews; Terwee et al. 2018a). The development of PRIDD was designed to address these limitations.

Chapter 5: Phase 2: Concept Elicitation

5.1 Introduction

In the previous chapter, the systematic review revealed that no instrument exists that can comprehensively measure the full impact of dermatological conditions on the patient's life. In addition, the review revealed that existing dermatology-specific PROMs are psychometrically insufficient and lacked content validity, predominantly because of inadequate patient engagement during development. The systematic review justified the development of PRIDD and highlighted the importance of doing so with sufficient patient input.

The BJD states that the "robust development and content validation of dermatology-specific PROs" is a priority for the field (Apfelbacher and Nelson 2017, p. 285). Content validity is fundamental to the development of a scientifically sound instrument and is known to affect completion rates, the consequent generalisability of research findings and the appropriateness of resultant clinical decision-making (Apfelbacher and Nelson 2017).

The first crucial step in establishing content validity is to determine a conceptual framework of the construct of interest in collaboration with the target population (Apfelbacher and Nelson 2017; Terwee et al. 2018a). This is particularly important for complex or multidimensional constructs such as impact. There is no agreed conceptual framework for *impact* within dermatological conditions. Without this, we cannot gain a comprehensive understanding of impact nor judge whether a measure of impact adequately reflects the relevant concepts (Brod et al. 2009).

Brod and colleagues (2009) advocate for the development of a theoretical model of the construct, in addition to, and distinct from, the conceptual framework. The conceptual framework is used to ensure that all *relevant* items are included in the new measure, that is, only items that reflect the relevant concepts. The theoretical model serves the broader

purpose of outlining the relationship between domains, consequences and modifiers. It, therefore, provides context to aid greater understanding of the construct of impact, helps to consolidate the relevant concepts and is useful in identifying potential cofounders for future studies that include PRIDD.

There is increasing recognition of the value of qualitative research in dermatology (Nelson 2015) and PROM development (FDA 2009). Both COSMIN (2018b) and Apfelbacher and Nelson (2017) recommend that item generation is based on open-ended qualitative research with the target population. People living with dermatological conditions are experts in how their conditions impact the patients' lives and are, therefore, uniquely placed to judge impact. Since the purpose of qualitative research is to gain a rich understanding of peoples' experiences, beliefs and attitudes, and the context in which these are situated (O'Brien et al. 2014), it is the method of choice to provide an in-depth account of the impact of dermatological conditions on patients' lives. Qualitative research underpins measurement development to define constructs in a way that authentically and comprehensively reflects the patient experience (Brod et al. 2009; Apfelbacher and Nelson 2017).

Given the target population of PRIDD, qualitative research with people representing a range of dermatological conditions and geographical regions is necessary to complete the first step in the content validity phase of PRIDD development. This chapter, therefore, aims to develop a conceptual framework of impact with patients which will be used to generate concepts for PRIDD. Four objectives meet this aim:

1. To understand what 'impact of dermatological conditions' means to the people living with them and the organisations representing them.
2. To identify impacts common across dermatological conditions.
3. To develop a conceptual framework and theoretical model of impact.
4. To meet the COSMIN standards for concept elicitation studies (Terwee et al. 2018a).

5.2 Methods

5.2.1 Design

A qualitative descriptive interview study combined four face-to-face group discussions and 28 online synchronous individual interviews, providing methodological and data triangulation.

5.2.2 Data collection methods

Group and individual interviews are considered the best way to obtain information from experts about the relevant items to include in a measurement instrument (FDA 2009; Krueger and Casey 2014). Methodological triangulation - the use of multiple qualitative or quantitative approaches to study a single problem - is considered beneficial in confirming findings, providing more comprehensive data, increasing validity and enhancing the understanding of the studied phenomenon (Hastings 2010). The use of multiple qualitative methods in this thesis strengthens the study conclusions.

Group discussions have been used in mixed methods studies as a precursor to constructing questionnaires and completing psychometric analyses (Creswell and Plano Clark 2017). They facilitate the generation of concepts to include in the instrument (e.g. Howells et al. 2019) and exploration of terminology that is appropriate for the target population. The major advantage of group discussions for this study is that they facilitate discussion between groups of participants with common issues. As opposed to an individual interview, group discussions can include a diverse set of participants, perceptions, and experiences, and provide a space to share insights and actively reflect on other people's experiences (Bowling 2005; Gill et al. 2008; Krueger and Casey 2014). Participants can comment, explain, disagree and share their views, adding to the richness of the data (Krueger and Casey 2014; Tausch and Menold 2016). By sharing opinions and experiences, a collective experience may emerge that might not have surfaced during individual interviews (Tausch and Menold 2016). Group discussions also have the advantage of providing a large volume of data over a relatively short time period compared with individual interviews since multiple participants can be interviewed in a small

number of data collection sessions (Kitzinger 1995). Group discussions are ideally suited to meet the aims of this study as they allow the researcher to access a range of views - arguably making PRIDD more representative of the wider population - and confirm with participants in real-time whether the concepts discussed are specific to a particular condition or individual or are common across conditions.

Though suitable, group discussions alone are limited in their capacity to meet the aim of this study. First, the inherent group dynamics could introduce some disadvantages; some participants can dominate the discussion and the method can be less useful for obtaining input from individuals who are less comfortable speaking in a group setting. Second, logistical factors such as the practicalities of convening a group of individuals in a particular location at a particular time can make group discussions less feasible than individual interviews (Brod et al. 2009). This is pertinent to the current study where a global population was sought.

Individual interviews have the advantage of providing a more private setting for participants to share their perspectives and experiences without input from others. Participants may feel more comfortable discussing sensitive subjects in this context compared to in a group (Morgan 1988; Greenbaum 2000). Moreover, in the absence of other group members, participants in individual interviews bear a greater responsibility for explaining their views (Morgan 1988), thereby adding to the richness of the data.

Group and individual interviews can be viewed as complementary, rather than mutually exclusive, as they may provide different information and allow the investigator to support the judgment that saturation has been reached independently of interview type (Brod et al. 2009). The interview process is iterative; each interview informs the following interviews which are used to explore issues raised previously. Using a combination of group discussions followed by individual interviews provides an opportunity to test if concepts elicited by the groups are robust and to further probe potentially sensitive subjects. Therefore, employing group and individual interviews provides a richer, more robust set of data to support content validity.

5.2.3 Participants

Group discussions

To explore the target construct of PRIDD with the target population (de Vet et al. 2011), adults (aged ≥ 18 years) proficient in English (or had access to a translator), and who had a dermatological condition or were a representative of a dermatology patient organisation were recruited. The World Congress of Dermatology (WCD) is a prestigious international dermatology conference. Recruiting dermatology patient organisation representatives, many of whom are patients themselves, allowed us to gain insights from experts on many conditions from around the world in attendance for WCD. Purposive sampling helped to achieve maximum variation according to dermatological condition and demographic factors - country of residence, gender and age - to be representative of a full range of views and experiences.

Potential participants were recruited from IADPO's membership network. A PIS detailing the purpose, procedure, venue and date of the group discussion was sent to the participating patient organisations. Those who wished to participate replied to the email. Forty-five patient organisations were invited to the group discussions; 35 (78%) agreed to participate. Reasons for non-participation were primarily scheduling conflicts. Although six to eight participants are considered optimal for group discussions (Krueger and Casey 2014), recruitment was fairly high and it seemed prudent to capitalise on the diverse sample of participants from across the world. In total, 37 people participated in the group discussions.

Individual interviews

Participants were sampled purposively to address gaps in the group discussion sample. Inclusion criteria changed slightly to recruit adults (aged ≥ 18 years) with a dermatological condition and proficient in English (or have access to a translator). People who did not have a dermatological condition (i.e. patient organisation representatives, families, carers) were excluded. Dermatological conditions and geographical location remained the key drivers of

recruitment. Individuals who represented the following clinical and demographic groups were particularly welcomed:

- People with acne, alopecia, AD, psoriasis or vitiligo
- People from Africa, Asia, Oceania and South America
- Men
- People aged under 25 and over 65 years old
- People who had been living with their dermatological condition for less than one year

Because potential participants were recruited via IADPO's membership network, practical factors - whether IADPO had member organisations who could fulfil the criteria and whether those organisations were interested in participating - played a part in recruitment.

The sample size of a qualitative study cannot be determined in advance as it relies on reaching data saturation (generally defined as the point in data collection when no more new issues are identified, and data begin to repeat without adding further depth of understanding of the issues; Hennink and Kaiser 2019), though broad estimates can be made (Kerr et al. 2010; Patrick et al. 2011b). For measurement development, it is recommended that 20 to 30 participants should be interviewed (Rothman et al., 2009). We, therefore, aimed to interview 20 participants, subject to data saturation. This number allowed for the targeting of an equal number of people to represent each of the targeted dermatological conditions and geographical regions while also achieving clinical and demographic variation within those groups.

Based on IADPO's membership network and the sampling strategy, a shortlist of eight locations was identified – Kenya, South Africa, Brazil, Argentina, China, Korea, Bahrain and the USA. In the first instance, IAPDO approached patient organisations in these areas who represented the targeted conditions. IADPO emailed the leader of each relevant patient organisation with an invitation to participate letter. The email also contained background information on the study and the leader's role in the coordination of recruitment. Sixteen patient organisations were invited to participate; 14 (88%) agreed. One group cited COVID-19 as a reason for non-participation. The other declined because they were based at a

university and would require additional ethical approval to participate which could not be obtained in time.

If a patient organisation was favourable, IAPDO sent a 'patient organisation pack'. This contained a memorandum of understanding, criteria to target potential participants and an invitation to participate letter to be shared with potential participants. Fifty-three individuals responded and were sent an invitation to interview letter. This included information detailing the purpose, procedure, tentative date and time of the interview, the interviewer's name and background, URL link to the Zoom meeting and a link to the online platform containing the PIS, informed consent form and demographic questionnaire. RP monitored the online platform ensuring that each participant had completed the informed consent form before their interview was confirmed. Of those who responded, 43 completed the consent form and 28 participated in the interview. Non-participation was due to non-response to scheduling emails or not attending the scheduled interview. Recruitment ceased when data saturation was achieved (Appendix 5.); that is, when both the key sample characteristics were obtained and analysis resulted in no new or relevant information (Saumure 2008).

5.2.4 Materials

Topic guides

A topic guide was created for the group discussions (Appendix 6.) and individual interviews (Appendix 7.). It was developed based on a) extant literature (e.g. De Korte et al. 2004) and the researchers' prior knowledge of potential domains of impact, b) Wilson and Cleary's conceptual model of HRQoL; and c) the CSM. The topic guide was semi-structured to standardise the interviews while allowing the facilitators to be responsive to emergent issues. The questions were revised iteratively based on participant engagement and responses. It was continually adapted based on initial analysis of completed interviews to reflect new themes or topics that needed further probing.

The topic guide followed a 'questioning route', incorporating key open-ended questions in a planned sequence: opening, introductory, transition, key and ending questions (Krueger and

Casey 2014). The opening question introduced participants, the introductory question established impact as the subject of the discussion, the transition question linked impact to the participants, the key questions directly addressed the research question, and the ending question brought the discussion to a close. The most general questions were asked first to gain unbiased perspectives before moving on to broad domains and finally to specific probes within a domain (Brod et al. 2009). This is also considered to help participants settle into the session.

The key areas explored were the domains of life impacted by the dermatological condition, the drivers of impact, and how the range of impacts interact with other variables such as age, gender, ethnicity, socioeconomic status, and proximity to specialist medical advice.

Vignettes

Twelve vignettes were created to prompt discussion within the groups (Appendix 8). Vignettes are short stories about a hypothetical person in specified circumstances, presented to participants to glean information about their own set of beliefs about, but not limited to, the topic of interest (Gourlay et al. 2014). These served to broaden the focus from personal experiences and encourage the participants to take a wider view of the impact of dermatological conditions through perspectives different to their own. Since commenting on a story is less personal than talking about direct experience, it is often viewed by participants as less threatening, encouraging them to discuss sensitive topics, such as intimacy (Barter and Renold 1999).

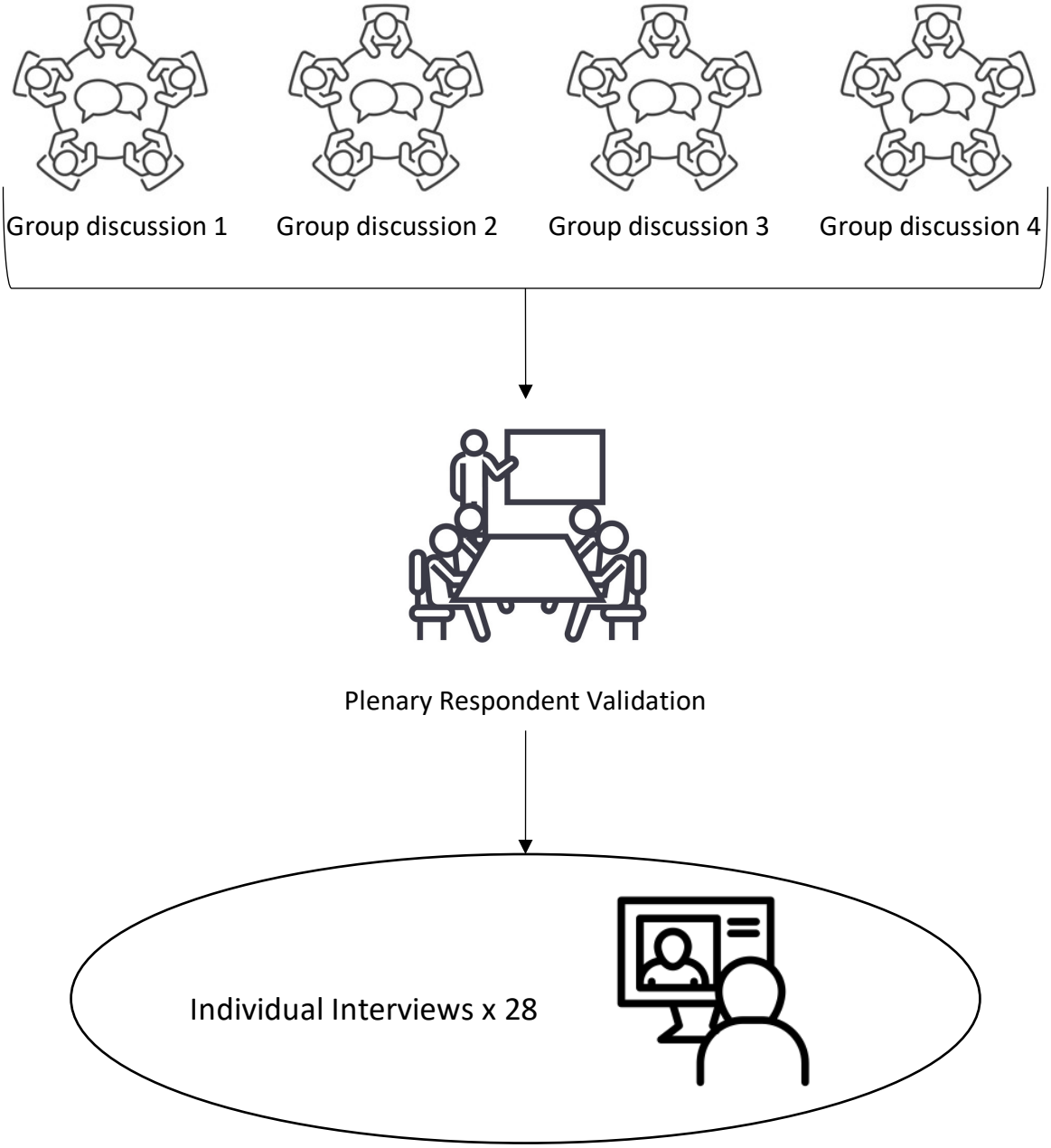
The vignettes were designed to feel plausible and real to the participants (Barter and Renold 1999). They avoided eccentric characters and disastrous events and reflected 'mundane' occurrences (Finch 1987; Hughes 1998). Some researchers have constructed their vignettes around actual experiences, either directly, for example, by using situations provided by participants in the pilot stage of the research, or indirectly, such as using agony aunt letters in teenage magazines (Harden et al. 2000). The vignettes used here were based on real patient stories from clinical practice, published literature or patient organisation websites

(Harden et al. 2000). Each vignette highlighted different impacts of dermatological diseases and they were written to represent people of different ages, genders, ethnicities, cultures and dermatological conditions.

5.2.5 Procedure

There were two stages of data collection (Figure 13.). The first stage, referred to here as 'the workshop', consisted of four concurrent group discussions (session 1) followed by a plenary respondent validation exercise (session 2). The second stage was a series of 28 individual interviews. Data were recorded with a high-quality audio recorder (OLYMPUS WS-833).

Figure 13: Concept elicitation data collection procedure



Stage 1: The workshop

The workshop took place during IADPO's patient organisation conference in Milan, Italy June 2019. It was scheduled to immediately precede the WCD The workshop was conducted in meeting rooms at a conference hotel. Hotel, transport costs and food were provided to all attendees of the conference, regardless of whether they participated in the workshop.

Session 1

The group discussions were facilitated by four researchers (RP, RH, NTS, EC) and overseen by CB. All facilitators had experience of conducting qualitative research, backgrounds in health and dermatology research and were trained by CB in facilitating group discussions. Having one person training all facilitators allowed for greater consistency among the group discussions and improved data quality (Brod et al. 2009). Facilitators began each session by stipulating the 'ground rules' (e.g. the need to respect other people's opinions and views and that the need for turn-taking were reinforced) and strategies were employed to ensure all participants were given space to talk, to prevent quieter participants from being constrained by others.

Session 2

To assess the relevance and comprehensiveness of the concepts identified during the group discussions, preliminary findings were presented during a plenary respondent validation session. First, categories and themes were summarised and presented verbally. The categories identified were physical, psychological, social, financial, coping and services. Next, group facilitators used flipcharts placed around the room to present preliminary findings (categories and their themes) in real-time with a facilitator assigned to monitor each. To illustrate, the 'social' category flip chart was titled 'Social' and listed themes such as rejection, isolation, stigma, relationships. Participants were asked to add anything they felt was missing from each category. In addition, a flip chart titled 'missing' was present to allow participants to add relevant information that they felt did not fit within any of the existing categories. To begin the process of wording constructs, facilitators asked participants whether the word listed (e.g. stigma) was understood and if it was the word they would use to label the concept. Finally, participants were asked to vote for the three categories they felt were most important to the impact of dermatological conditions using post-it notes.

Stage 2: Individual interviews

Twenty-eight individual interviews took place via Zoom from April to June 2020. Since access to video calling platforms was limited in some countries or areas, participants were able to choose an appropriate alternative method, such as a telephone call, though none did. IADPO covered WIFI/call costs for some to minimise financial barriers to participation.

The decision to conduct the interviews online was a pragmatic response to the travel and social distancing restrictions imposed by the COVID-19 pandemic. Online methods are becoming increasingly popular in healthcare research due to the widespread availability of internet access and their cost-effectiveness and convenience (Coulson 2015). Online interviews, whether synchronous or asynchronous, are typically text-based conversations between the researcher(s) and participant(s) using instant messaging, chat software, email or forums. COSMIN do not recommend relying only on written information during concept elicitation, arguing that "more valuable information is obtained by personal contact with patients because of inter-personal interaction" (Terwee et al. 2018a, p. 21). The experience of dermatological conditions is multifaceted, and many participants were not native English-speakers. A text-based interview would require a high level of reading and writing in English to convey their perspectives and experiences authentically. Therefore, it was decided to conduct the interviews synchronously using Zoom video calling software. This allowed for communication more similar to a face-to-face conversation as the researcher could use social cues to facilitate the process. The convenience of Zoom calling was considered especially important during the COVID-19 pandemic in reducing participant burden.

Following informed consent, interviewers were arranged with one of two researchers (RP and RH) at a mutually convenient time, taking into account different time zones. Interviews were scheduled for one hour, but the participant was reminded that they could choose to end the interview at any point.

5.2.6 Data analysis

Transcripts were uploaded to NVivo 12 qualitative data software package (QSR 1999 – 2018). Computer coding was used to assist the analysis by facilitating data preparation, organisation and management. This was particularly helpful for this study as a large amount of qualitative data were collected.

Data collection and analysis were interrelated and concurrent. Analysis began after the first interview to incorporate emergent themes from a) session 1 into session 2 of the workshop and b) the workshop to the individual interviews. Data from the plenary session and individual interviews served to triangulate the group discussion data, minimising uncertainty about the interpretation of the findings.

A framework analysis was conducted to develop the theoretical model and conceptual framework of impact. Framework analysis sits within the broad family of thematic analysis methods. It facilitates systematic and transparent analysis of interview data and is particularly useful for multidisciplinary research teams (Gale et al. 2013). In contrast to other methods, such as interpretative phenomenological analysis and grounded theory, thematic analysis and, by extension, framework analysis, is not wedded to any pre-existing philosophical or theoretical framework (Braun and Clarke 2006). Applying thematic analysis to PROM development closely reflects the conceptual framework, as the relationship between codes and themes are equivalent to that of the specific items and subscales of the measure. Once the conceptual framework has been created, the item pool can be generated. Wilson and Cleary's conceptual model of HRQoL and the CSM were used together as an interpretive lens to explore the impact of dermatological conditions. Since the CSM captures the emotional, cognitive and coping responses to health and illness, it ensured that usual aspects of HRQoL were supplemented. The analysis did not aim to fit the results into these existing frameworks but rather they supported the in-depth analysis of impact (Sandelowski 1993; Reeves et al. 2008). A combined inductive-deductive approach enabled the exploration of known and novel issues related to impact.

The seven-step procedure for framework analysis outlined below facilitated a systematic, yet flexible, and transparent analysis of the data (Gale et al. 2013):

1. ***Transcription***. Audio recordings were transcribed verbatim by a Cardiff University approved independent transcription provider. Transcripts were checked and anonymised by RP and participants were allocated pseudonyms.
2. ***Familiarisation with the interview***. The researchers (group discussions: RP, RH, NST and EC; individual interviews: RP and RH) familiarised themselves with the whole interview using the audio recording and/or transcript, including any contextual or reflective field notes made by the interviewer. Initial impressions were recorded.
3. ***Coding***. Analysis of the group discussions was carried out by four researchers (RP, RH, NTS and EC) with a variety of backgrounds (health psychology, clinical psychology, and public and global health). Initially, the four researchers independently coded the same transcript to check for consistency. Data were coded according to the predetermined frameworks (conceptual model of HRQoL and CSM) with open coding of relevant data that did not fit into the models.
4. ***Developing an analytical framework.*** After coding the first group discussion transcript, all four researchers met to compare codes, discuss key themes and construct an initial coding framework. Using this framework, the remaining three group discussion transcripts were divided among the researchers and coded. RP analysed all the transcripts, paired with another researcher for each. Codes were organised into themes by identifying codes that grouped together along common dimensions. Categories were developed based on the predetermined frameworks and the identification of recurrent patterns. The categories were refined and elaborated in light of incoming data and discussion between the researchers and the initial coding framework was revised accordingly. Category boundaries were tested by seeking to identify dis-confirmatory evidence within subsequent interviews and different interpretations of codes were discussed and refined until agreement was reached. The process of refining, applying and refining the coding framework was repeated until no new codes were generated. The final framework (Appendix 9.) consisted of 274 codes, clustered into categories, each with a brief definition and examples of ideas or elements that might be summarised under that code. This ensured coding consistency across the research team.
5. ***Applying the analytical framework.*** The final analytical framework was applied systematically to all transcripts using NVivo 12 for easy retrieval.

6. ***Charting data into the framework matrix.*** A Microsoft Excel spreadsheet was used to generate a matrix for each theme by abstracting, summarising and charting data for each case and each code within that theme.
7. ***Interpreting the data.*** Thematic analysis was carried out on the managed data set by reviewing the matrices, making connections within and between codes and cases, and actively identifying relationships between themes. This process was influenced by the original research objectives and by concepts generated inductively from the data.

5.3 Results

5.3.1 Participant characteristics

In total, 65 people (Table 15.) across 29 countries (

Table 16.) participated.

Table 15: Participant characteristics for the group and individual interviews

	Group interviews *n* (%)	**Individual interviews *n* (%)**	**Total *n* (%)**
Total	37 (57)	28 (43)	65 (100)
Age			
18 – 24	1 (2.8)	2 (7.4)	3 (4.7)
25 - 34	6 (16.7)	6 (22.2)	12 (19)
35 – 44	6 (16.7)	6 (22.2)	12 (19)
45 – 54	9 (25)	6 (22.2)	15 (23.8)
55 – 64	11 (30.6)	5 (18.5)	16 (25.4)
65+	3 (8.3)	2 (7.4)	5 (7.9)
Gender			
Male	3 (8.1)	18 (64.3)	21 (32.3)
Female	34 (91.9)	10 (35.7)	44 (67.7)
Dermatological condition			
Acne	0	2 (7.1)	2 (3.1)
Alopecia	2 (5.4)	5 (17.9)	7 (10.8)
Atopic dermatitis	5 (13.5)	6 (21.4)	11 (16.9)
Psoriasis	5 (13.5)	9 (32.1)	14 (21.5)
Vitiligo	0 (0)	6 (21.4)	6 (9.2)
Other*	25 (67.6)	0	25 (38.5)
Duration (years)			
Less than 1	0	1 (3.6)	1 (1.5)
1 – 5	5 (13.5)	3 (10.7)	8 (12.3)
6 - 10	0	4 (14.3)	4 (6.2)
11 - 15	0	2 (7.1)	3 (4.6)
16 - 20	1 (16.2)	7 (25)	8 (12.3)
More than 20	11 (29.7)	11 (39.3)	22 (33.8)

*Autoimmune blistering diseases, Congenital Melanocytic Nevus, Cutaneous Lymphoma, Cutis Marmorata Telangiectatica Congenita, Dermatomyositis, Epidermolysis bullosa, Erythropoietic Protoporphyria, Giant birthmark, Giant Congenital Melanocytic Nevus, Giant

Nevus, Genital Lichen Planus, Gorlin Syndrome, Hidradenitis Suppurativa, Hyperhydrosis, Ichthyosis, Keloid, Lichen Sclerosus, Lichen Simplex Chronicus, Nevus, Pemphigus and Pemphigoid diseases, Porphyria, Port wine birthmark, Port wine stain, Xeroderma pigmentosum

Table 16: Geographical locations of participants

Continent	**Group interviews, *n* (%)**	**Individual interviews, *n* (%)**	**Total, *n* (%)**	**Countries represented**
Africa	3 (8.1)	8 (28.6)	11 (16.9)	Nigeria, Kenya, South Africa, Zimbabwe
Asia	2 (5.4)	11 (39.3)	13 (20)	China, Hong Kong, Indonesia, Israel, Pakistan, Philippines, Singapore
Europe	17 (45.9)	1 (3.6)	18 (27.7)	Austria, Belgium, Denmark, France, Germany, Italy, The Netherlands, Slovenia, Spain, United Kingdom
North America	13 (35.1)	4 (14.3)	17 (26.1)	Canada, Cuba, Mexico, USA
Oceania	1 (2.7)	3 (10.7)	4 (6.5)	Australia, New Zealand
South America	1 (2.7)	1 (3.6)	2 (3)	Argentina, Colombia

5.3.2 Overarching themes

Five themes were derived (Figure 14.): 1) *Impact at the individual, organisational and societal levels*; 2) *Impact can be both point-in-time and cumulative*; and 3) *Impact is a multifaceted construct*. The final theme further divided into two subthemes: a) *Common Impacts* and c) *Psychological and social impacts are most significant*.

Figure 15. depicts the theoretical model of impact. This illustrates the relationship between themes and concepts as well as modifiers, thereby providing context and aiding greater understanding of impact. Some concepts reflect impact, some cause impact and some moderate impact.

Figure 14: Graphical illustration of the key themes

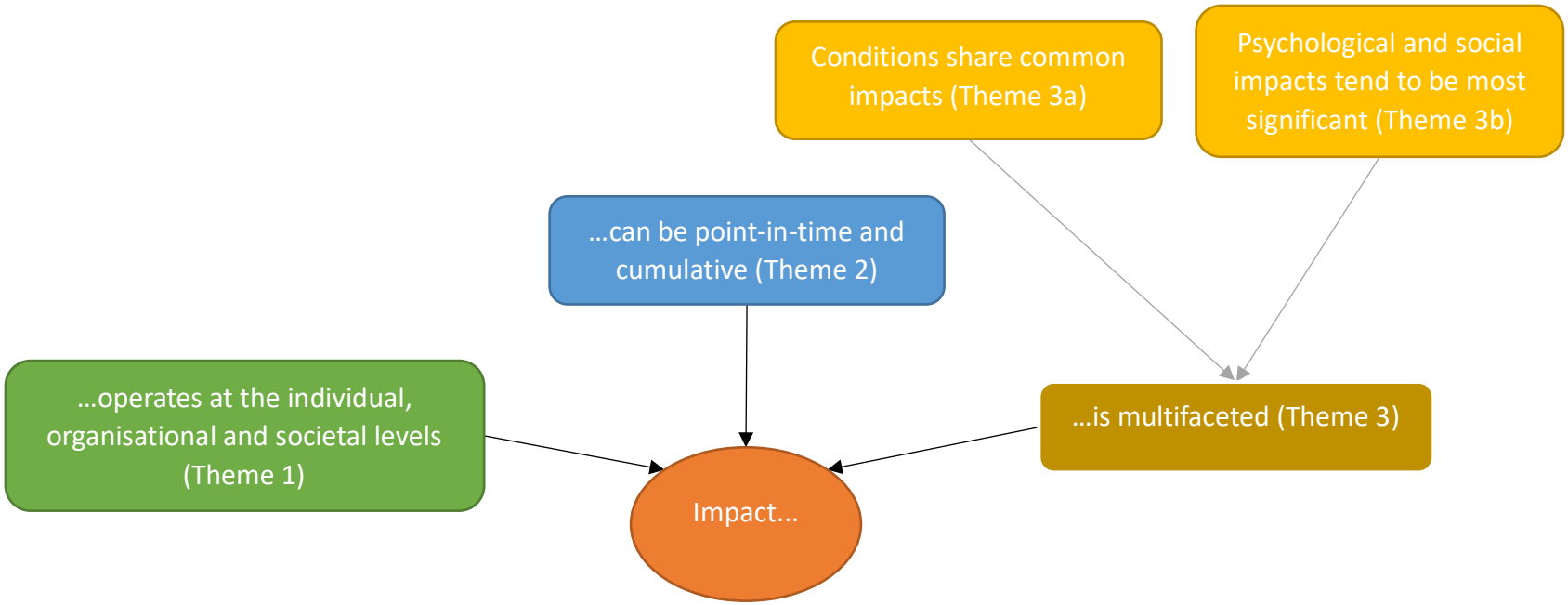
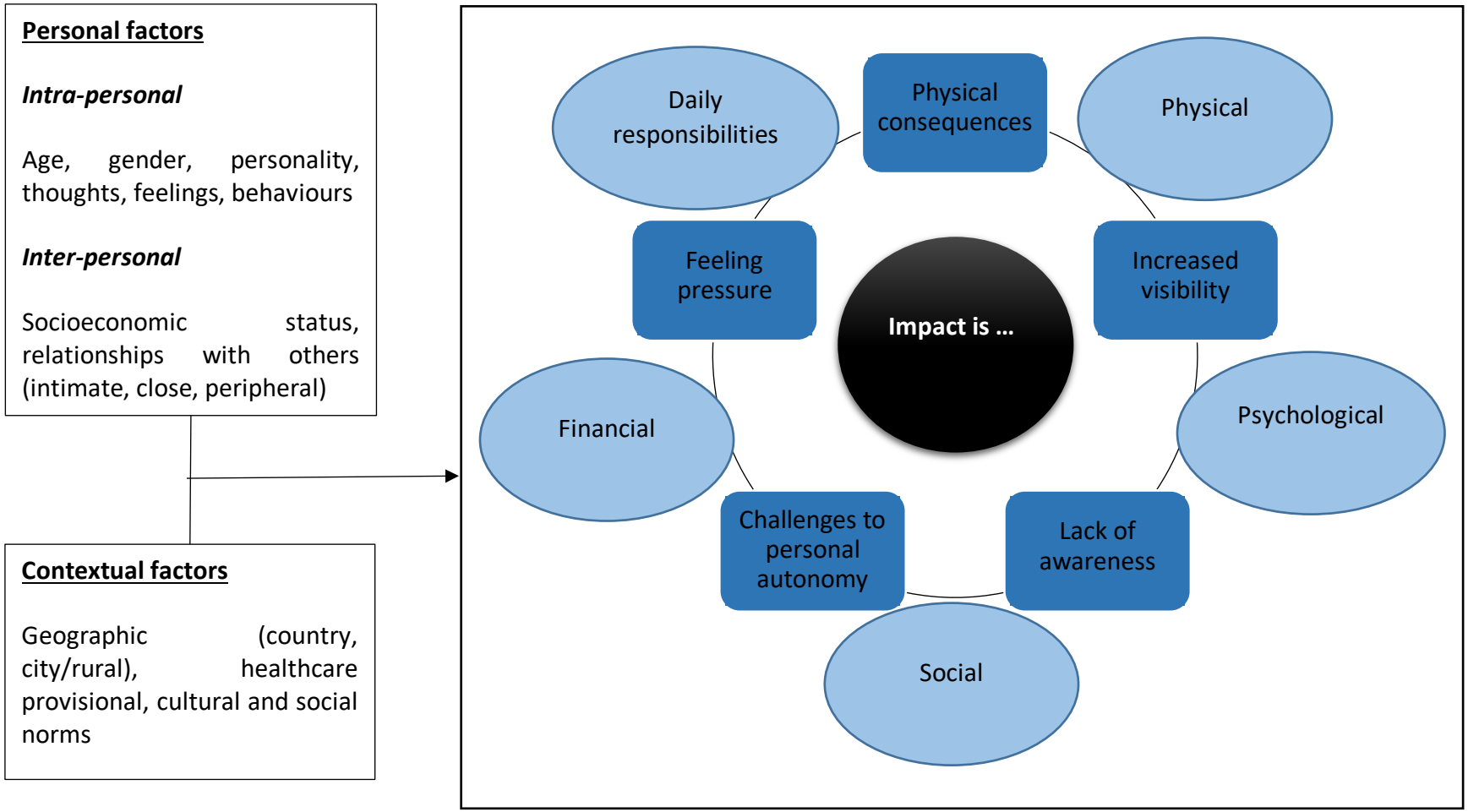


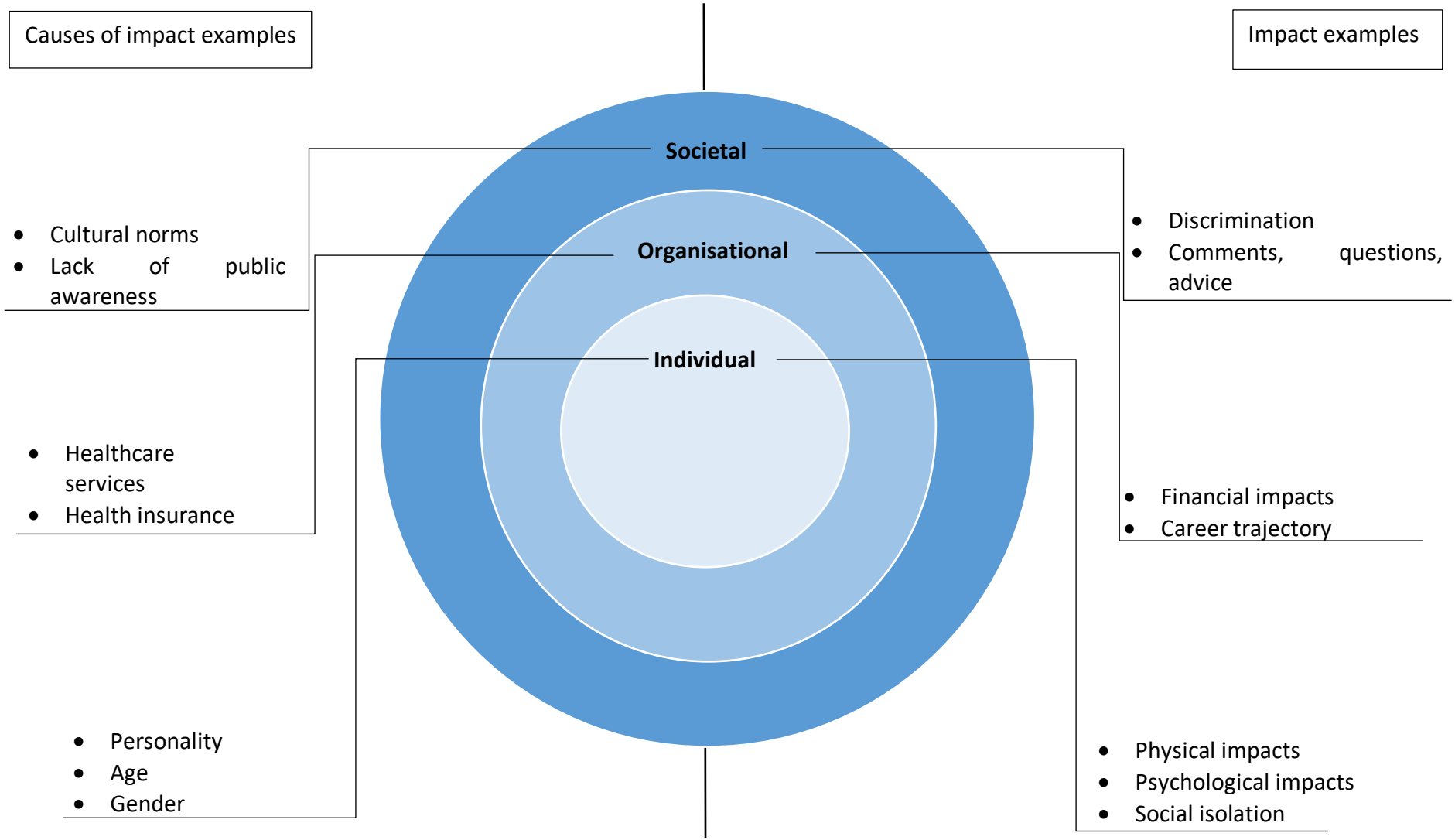
Figure 15: Theoretical model of the impact of dermatological conditions



Theme 1: Impact at the individual, organisational and societal levels

Dermatological conditions impact across three interacting levels: individual, organisational (i.e. healthcare services, employers, financial services), and societal (Figure 16.). Social and cultural factors influence how patients experience, and organisations and society interact with the condition. For example, the extent to which the symptoms (individual) impacted on the individual was influenced by the accessibility of appropriate health professionals and treatments (organisational) and public awareness (societal). This accounts for different experiences across regions, each with its cultural norms and values, which can influence healthcare service provision and equity of access.

Figure 16: Dermatological conditions impact at the individual, organisational, and societal level



Theme 2: Impact can be both point-in-time and cumulative

Two types of impact were identified: point-in-time and cumulative. Point-in-time impacts (e.g. pain and itch) were discrete and time-restricted, and, therefore, did not directly affect the life trajectory. Conversely, cumulative impacts affected the life trajectory, for example, career choices:

> I think if I don't have this … disease … I might still be working … not do the early retired thing (19) Patient with psoriasis, China

There were many examples of relatively minor point-in-time impacts, the accumulation of which could contribute to a significant overall impact. Distinguishing between the two forms of impact was complicated as point-in-time impacts contributed to impact directly *and* indirectly through their contribution to cumulative impairment. Participants, for example, explained that completing daily treatment regimens had a cumulative impact over time.

> It was, you know, some for the hands, some for the hair, you know, it's some for the genitals, so for example, you need like maybe five different ointments, you had to do this … you need to have like a manual of instructions, how, when to do, in which part of your body, very detailed things, every day you had to, well it bothers (5) Patient with psoriasis, Cuba

Theme 3: Impact is a multifaceted construct

The degree of impact varied both between individuals and across time. This was apparent in how participants described the impact of dermatological conditions on their own and other patients' lives. While some people felt that their condition had little or no impact on their lives, others experienced a significant and sometimes devastating impact.

> It's such an individual experience … the diseases are different, the variation on the disease… and the impact on someone's life may be different but it really, at the end does it matter 'cause it's the individual. (Group discussion 2)

Little or no impact was typically characterised primarily as having little or no distress or effect on daily and social functioning. Lack of symptoms was secondary. In addition, the impact of dermatological conditions was often associated with times in the lifespan and time since onset. Many participants reported the teenage years as being the most difficult for themselves and other patients.

> It was very confusing, of course, it played a part because you are going, you are at that stage of your life, where you need your looks to be really key, you're a teenager, you're in your early twenties … And you know that's the stage at which most people actually have very, very beautiful skin. So, when yours is ashy and itchy … it's a very emotional experience for a person of that age (26) Patient with alopecia, Kenya

Generally, impact appeared most severe in the years following onset. The severity of impact tended to reduce over time as individuals, their loved ones and others within the community came to understand, accept and adjust to the condition.

Though the experience of impact was individual, there were commonalities. Participants reported that at least one aspect of their life had been adversely affected:

> It just impacts every part of your life, financially, socially, psycho-socially, mentally … it's just way beyond the, the condition. And then you have the condition. (Group discussion 2)

Impact was grouped into six distinct life domains, informed by the domains identified in the systematic review (Table 10.):

- Physical
- Psychological
- Social
- Financial
- Daily life and responsibilities

- Healthcare impacts

Theme 3a: Common impacts

Impact was common across dermatological conditions:

> To hear it over and over no matter what condition's on a piece of paper … that the emotions behind it are the same, it's just really powerful. (Group discussion 2)

The volume and breadth of these common impacts are significant. For this reason, a summary of the common impacts for each of the domains identified is provided.

Physical

All dermatological conditions had physical consequences for patients, though the nature and degree of these varied both within and between conditions. Most conditions resulted in noticeable changes in appearance including differences in pigmentation, dry skin or bald patches. The visible nature of these conditions had consequences for patients; especially younger people who desired to look like and fit in with their peers. Visible alterations on the face and hands were deemed more problematic for appearance than those on the legs or back.

> I think the visibility of skin conditions … there are some, few which are not visible but most of them are really visible, so you always have to deal with people staring, people giving wonderful comments, having great advice and stuff like that, so I think this is one of the things for everyday life, in public is a big, big problem. (Group discussion 1)

Participants explained how visible changes in appearance affected their personal identity, threatened their ability to perform gender roles, and caused them distress or discomfort and

problems with social interactions. Covering symptoms (e.g. wearing wigs and long clothing) helped patients to feel like they fitted in with others:

> Vitiligo gave me a lot of stress, mentally and emotionally, and it also gave me a decline in self-confidence, because you can't meet the people who used to know you, you don't know what to tell them. Also the stigmatisation, social stigmatisation, that people staring, people running away from you, whenever they saw you (3) Patient with vitiligo, Kenya

Physical discomfort (most commonly pain and itch) was almost ubiquitous. Discomfort was characteristic of inflammatory conditions, such as acne, AD and psoriasis but was also reported by some individuals with non-inflammatory conditions such as alopecia and vitiligo.

> With a lot of patients, they say … take away my itch, I don't mind dying early if I can live without the itch and the pain (Group discussion 1)

Pain could arise from the condition itself (e.g. blisters), from wounds resulting from scratching or from comorbid conditions such as PsA. In addition, management of conditions and treatments such as creams, ointments, plasters and bandages could be uncomfortable or painful to apply, wear and remove.

> The bathing, the showering and the draining. That's tears and pain and so uncomfortable. (Group discussion 2)

Itch was also widespread. Scratching could cause wounds and bleeding and resultant pain and/or worsening of symptoms.

> When you feel like the itch is there it's hard not to scratch. It's hard not to feel like you just want to reach up and start scratching. I have found myself, subconsciously, just itching it, scratching it when it feels itchy. But then you catch yourself and you realise how long have I been scratching this, you know, it's like wow, I got to stop this, you know. And then probably within minutes, you feel the irritation because when you go back, you go back to

> itching … it's sore from being scratched for a period of time. I mean how long I was scratching it. (17) Patient with alopecia, USA

The itch sensation was described as all-encompassing by some. The resultant cognitive overload made it difficult to concentrate on anything else or cope with the condition. The dominance of itch over the individual's thoughts increased the likelihood of hypervigilance and difficulty diversifying thoughts, thereby contributing to cognitive rigidity and low mood. The consequent adverse effect on concentration made it difficult to study, complete work tasks and enjoy simple leisure activities such as watching a film. Itch and the subsequent scratching could make some individuals irritable and negatively affect their confidence, both of which impacted romantic relationships.

> Sometimes it would itch so much that, like I couldn't sit, I couldn't stand, I couldn't do anything … productive I couldn't do 'cause I was all focussed … on what part of my body am I going to rip off now … 'cause I was just scratching and scratching till, till the blood … it's a very uncomfortable situation … you can't do anything, you can't think straight … you're all focussed on what's going to happen now and what would I have to heal after this scratch is over… My parents were very careful not to tell me to stop scratching but sometimes it comes out, 'cause it's hard to see your child scratching and you can't do anything … And, and you-you're like scratching and you're all so guilty and you can't stop and, and I think that's a very hard emotion (22) Patient with AD, Israel

Participants developed coping strategies to combat itching. Some were helpful, such as taking anti-itch medication, applying creams and using self-distraction. Others were less helpful in the long term. Some individuals who were unable to control the itch may over-focus on the sensation and try to override it by knowingly engaging in behaviours that made their symptoms worse to gain short-term relief. Examples include taking hot showers and one individual with psoriasis who used lasers on their skin to turn the sensation of itch to pain, which they found more bearable:

I have another treatment but it's very dangerous, but it's helped me through. I changed my itch into pain, it's by infrared… to make it hot … you lose the itch but it's getting hot and pain. But it's better because we're not scratching, the scratching make us scars and … the blood, the open scars it makes me worse, it's getting worse. So, I don't have to scratch. (32), Patient with psoriasis, Indonesia

Sleep disturbance, while sometimes attributed to psychological factors such as stress and rumination, was mainly caused by physical discomfort. Participants reported being unable to fall asleep because of pain and itch and regularly waking during the night to scratch. This was viewed as a double-edged sword because sleep could be the only respite from the condition for some. It could also adversely affect the sleep of their partner or anyone sharing a bed or room with them and, in turn, their relationship.

It's very hard for people to sleep with you because you are, most of the night you are like this scratching and this is like it hurts really bad … so they cannot sleep … not only my boyfriend it was very hard for him to sleep but also when I was a student my roommates didn't want to sleep with me because they couldn't sleep. Of course, intimacy is the problem because not only the look, it hurts, it itches, you don't want to be touched. (Group discussion 2)

Depression because when it's hurting you it's bad … you're thinking about this all the time because it's hurting you all the time. I was like just in peace, let's say when I was sleeping. (28) Patient with acne, Israel

Physical fatigue and loss of energy were reported, independent of sleep disturbance:

I was going to say as well the psychological and financial issues there is always a certain amount of physical impairment that patients have as well, erm, depending on your condition it can cause pain, fatigue… (Group discussion 2)

I sleep so good, because I'm really, really tired. (Group discussion 4)

Comorbidities were also reported for some conditions, meaning these individuals were living with two long-term conditions. For example, asthma and allergies were associated with AD and thyroid problems and an increased risk of skin cancer were associated with vitiligo.

Dermatological conditions could also impact on general health. Health protective coping strategies included adopting healthy lifestyle behaviours such as consuming a healthy diet, exercising, avoiding alcohol, seeking information to improve self-management, planning ahead to avoid triggers and being cautiously optimistic for advances in treatment. Health threatening strategies included avoiding exercise and all situations or behaviours that might trigger a flare. Though no participants reported using alcohol or drugs to cope with their condition, they were aware of others who had. The association between alcohol and poorer disease outcomes was explicitly referenced as a deterrent from drinking alcohol. While avoiding certain foods could be a health-protective coping strategy, patient organisation leaders were aware of individuals who followed strict diets to regain a sense of control.

> I tried to control it also through my food habits, I try to eat foods and vegetables, because I think that the cure should come from inside, not from outside, from external use of medications. (46) Patient with vitiligo, Cuba

> They don't really know what to do to stop it, so there's a loss of control … they like make up for that, our patients do by controlling other aspects, like they're on extremely strict diets and it's not necessarily that the doctors telling them to do this, but they have it in their mind that like I can control this, so I feel like that's … a way that they cope with the loss of control and, in other parts of their life. (Group discussion 1)

The medications used to manage the conditions could also have physical consequences, a wide range of side effects were reported and posed a source of worry for many. A minority of participants felt that certain medications could be 'really dangerous' (5) or even life-threatening:

> The condition may not kill you, but the treatment will. (Group discussion 1)

Treatments and their side effects had physical consequences on the skin and beyond. Sometimes side effects could make the condition worse or cause another, more severe condition. Impact on the skin included dryness, itch, increased sensitivity, hair loss and a triggering or worsening of symptoms. Treatments were also reported to affect general health and, more specifically, liver and kidney function, hypertension, infertility, heart disease, pain throughout the body, immunity to antibiotics, and cancer.

Psychological

Participants reported a constant battle against the condition itself, its visibility, the lack of awareness surrounding it, as well as the poor quality and availability of health and social care provision. Despite feeling like they were fighting a losing battle, they continued to battle to avoid further suffering:

> Battling with people who don't understand and then you're battling with the authorities to get what you need … it's one big battle in all aspects … It's a constant battle, it's the 24 hours, the 365 days a year, it's like that all the time. (Group discussion 3)

People felt pressure to perform, especially at work, not just as others do, but better, and this was exhausting and not compensated. Participants described feeling physically, mentally and/or emotionally fatigued as a result of trying to keep up with other people who did not have a dermatological condition.

> It was a very tiring time to, to be trying to do what everyone else does when you're already really tired. (22) Patient with AD, Israel

> What I kept getting was in my head was exhaustion, like how there's never a time where you get relief to your point, like this is, this is the normal right, but it's additive and you never get to take a break, you don't take a vacation, right? You don't, you don't get any extra compassion or compensation for

what you have to do in a day to get to your job on time, versus someone that isn't dealing with those kinds of things (Group discussion 2)

Dermatological conditions inherently challenged personal autonomy, reduced patients' sense of control and restricted choices. Lack of control was exacerbated for those who had conditions with a relapse-and-remitting course and variable or unpredictable symptoms, further contributing to overall stress.

No control over it getting worse, no control about it getting better and regrowth … you have no control. No control. (Group discussion 4)

It's just one extra thing that, that you've kind of gotten no choice or control over… You know, I can't wake up one morning and go oh I've got my hair back, you know, it's not like you know, a broken arm or something you're gonna heal from. (33) Patient with alopecia, USA

Beliefs about the cause of their conditions could have a profound impact influencing the life course. For example, concerns about starting a family were widespread for those who believed their condition to have a genetic basis. Many worried that they would pass their condition on to their children and feared judgement by others. Some chose not to have children as a result:

You then go down that whole rabbit hole of okay, you know, here's my relationship, should I have children? If I pass this on what's the responsibility, then I'm responsible for bringing a child into the world with this condition that I am also struggling [with]. (Group discussion 2)

Participants acknowledged that there were currently no cures for their conditions; however, almost all expressed hope for a cure to be discovered reinforcing a belief that treatments are the key to successful disease control. This led to frustration with current treatment options and desperation for advancements in research and management.

Having no known any cure, there's no way I control it (1) Patient with vitiligo, Kenya

Though a cure appeared to be the ultimate goal, participants acknowledged the need for some form of control in its absence. The extent to which participants felt they could control their condition was heterogeneous, with perceptions ranging from full control to no control. In keeping with the CSM, two forms of control beliefs were discerned - personal (whether they could control the condition) and treatment (whether treatments could control the condition).

Treatment control beliefs were most prominent, with many participants believing that treatments were the key to managing their condition. Treatments had varying degrees of success across the people sampled and while they could improve control and physical outcomes, they had costs in terms of side effects and damage to surroundings (including homes and clothing). Thus, whilst treatments had the potential to increase participants' sense of control, they could also introduce some issues that challenged it.

A lack of perceived personal control and/or effective treatment options were associated with feelings of helplessness or hopelessness where the individual was at the whim of their condition. This created feelings of desperation, particularly for a cure, better treatment options and improved disease outcomes, and fostered low mood and depression.

> Helpless would be probably the best description I have, it's just you know, when they say there's nothing, they, they can do. (33) Patient with alopecia, USA

The avoidance of triggers was a major source of choice restriction across the sample, particularly for people with AD who often have allergies. To avoid triggers, individuals would restrict the clothes they wore, the food and drink they consumed, the bedding and products they used, and the places they travelled.

> It burns my skin when I put on makeup. Whatever makeup it was, like I couldn't, I got red, once I tried after maybe two weeks of the antibiotics, I tried to put makeup on and my skin just gets red and I was like crying, I couldn't wear anything I washed really, really fast because my skin was really

> sensitive with the cream that I was putting and the antibiotics I was taking. So I think that's why, so I stopped makeup. (28) Patient with acne, Israel

The increased 'mental load' was described as tiring or draining. Many said their condition preoccupied them and prevented them from having 'mind space' (Group discussion 2) or the mental break they needed. For some, this resulted in hypervigilance or constant planning ahead. Feeling the need to hide the condition further increased mental load. This involved constantly checking the visibility of symptoms and planning strategies to hide, if necessary.

> It makes me very uncomfortable, emotionally and you feel, you feel tired of it, because I'm conscious of everything you know. (26) Patient with AD, Kenya

Distress (anxiety and depression) was common. Some people found these conditions all-consuming, with widespread appearance-related concerns and anticipatory worry about social situations, as well as pressure to complete treatment regimens. Preoccupation with the condition was generally perceived as unnecessary, though it was acknowledged that it would continue until the condition was cured. The SARS-CoV-2 pandemic caused additional anxiety as people worried how the virus would affect them and their condition.

> I actually, for a bit of anxiety a few years ago, I went to see someone, and she said what's going on with you at the moment, 'cause I was in a bit of a low spot and I explained a few things and she stopped me halfway through 'cause I mentioned my skin condition and she said … you can't speak so quickly over it because it's a full-time job to mentally always think. I mean even just coming to this conference. I didn't sign up for GRIDD because I have to think, I have to keep some space for my body to recover from the flight, so it's constantly thinking about things all the time that other people don't think about. (Group discussion 2)

People felt overloaded with issues: their condition was long-term, it could prevent them from doing what they needed or wanted to do, and the itch and pain were relentless. Seeing the condition deteriorate or realising treatment was ineffective was disheartening and frustrating

for participants. Low mood and depression were extreme in some participants: some had contemplated suicide because of their condition.

> With hyperhidrosis, we get so many emails from patients who are just crying for help saying they're considering suicide and how many people have we lost to skin conditions, beyond depression, people who have that was their last resort. (Group discussion 4)

Participants explained how they came to terms with their condition over time; some resigned themselves to living with their condition, whereas others chose to adopt a positive perspective towards their condition and felt happier about their life as a result.

> I've started to accept it. I think its impact on my life … the negative part becomes smaller … I can also consider the impact it can be positive. I started to treasure my, my life and also treasure my relationship … with those close to me and I don't want to spend time with unnecessary things … A person with normal skin is a very very lucky. (10) Patient with psoriasis, China

Acceptance of the condition and being resilient were seen as key to coping with a dermatological condition. Many participants felt that they had become more resilient or 'strong' as a person as a result of meeting the challenges of their condition and its broad consequences. A characteristic of resilience was that the opinions of others mattered less, and their internal sense of self became more important in establishing their identity. In addition, the ability to use positive reframing as a coping strategy demonstrated resilience. Other people could facilitate resilience through social support such as supporting the patient through negative comments. Resilience also played an important role in managing the condition and manoeuvring the healthcare system.

Social

Many participants believed that awareness of dermatological conditions, although increased over time, was still lacking at the individual, organisational, and societal levels. Some lacked

awareness and understanding of their own conditions, such as their long-term and cyclical nature:

> What caused it, why did it happen, you know. Is there going to be a cure? You know when is it going to get to the point where I can't cover the tracks anymore? ... when do I get to the point where I have to make a decision of whether to shave it off or not?... So the worry, the actual part that's always in the back of your mind is the present and the future, where it's going to lead to, or what it's going to lead to. (17) Patient with alopecia, USA

Lack of awareness and understanding of dermatological conditions across societies profoundly impacted patients' psychological and social wellbeing. Public attitudes towards appearance and a poor general understanding of dermatological conditions negatively impacted on their self-esteem and heightened feelings of anxiety and fear of other people's thoughts and behaviour towards them:

> I'm stressed because not a lot of people know about this disease … I'm stressed, because the way people treat me, I'm stressed because the way how people when I socialise with them, they often question because they don't have the knowledge. (29) Patient with psoriasis, Indonesia

Negative comments, questions and assumptions from others were a common experience for this group. Universally, participants reported being expected to explain their condition to others. This caused additional pressure when in public spaces, was stressful and had repercussions beyond the encounter itself, with participants variously reporting anxiety, low mood and anger, in anticipation of, during and after the event.

> It is quite annoying you know that every time, every new people they will ask oh why your skin like this. Even they just concerned about my condition, they are not afraid of me, but they will, friendly asking you oh why your skin like that. Then have to explain how it is not infectious, don't worry about it, something like that blah-blah-blah. (8) Patient with psoriasis, China

> Having to give an explanation leaves me low (29) Patient with psoriasis, Indonesia

Preconceived ideas about dermatological conditions being dirty, contagious or a curse increased stigma and led to social exclusion. Experiences of discrimination and bullying in the workplace, schools and public places, particularly swimming pools, were common for most. Stigma was seen to fuel avoidance coping, for example, social withdrawal, which exacerbated low mood and further increased social isolation.

> The community we are raised up to has its own culture and beliefs, so you find it difficult to mingle with other people cos you will find some of the people in your community has that mentality that maybe it's a curse … So it gives you problem to cope with people and explain to people what is happening (3) Patient with vitiligo, Kenya

> I say social relationship is not easy to build, because other people do not understand your skin condition, what is your skin problem, they think, most of them misunderstood it is contagious … some people say is it because you go to some dirty place, not good hygiene, or even have sexually transmitted disease from someone else … they misunderstood the situation and I have to explain to them that … the skin problem is inherited from my parents … so understanding of psoriasis is not very deep actually. Yeah, but when I … tell them it is similar to or eczema, they understand more. (7) Patient with psoriasis, China

Trigger avoidance also had social consequences; individuals faced peer pressure and social exclusion when they could not participate in social or cultural events or activities.

> From my life, are things that we love having here … African setting, we love having parties, or meetings where everybody you know, is having tea, lots of tea with milk and … just a lot of snacks … made of wheat and everything else, so you can't … participate in that, and some people will ask you, why don't you want to have this? Are you trying to watch your weight? Why, why aren't

you taking this? And you don't want to have to explain to everybody. (26) Patient with AD, Kenya

I didn't get out there much, I didn't go clubbing, I didn't go sort of social event… I didn't go to parties, you know, my friend's parties' sort of came and went. (42) Patient with alopecia, Australia

Financial

Significant economic pressures were reported and were perceived to not be appreciated by those without dermatological conditions.

It's illness for rich people. (23) Patient with psoriasis, Israel

You wouldn't think that defaulting on a credit card would have anything in the world to do with a, with a skin condition. (Group discussion 2)

The costs associated with dermatological conditions reduced financial resources and, in turn, personal choice. High medical costs prevented individuals from saving money needed for important and expensive purchases, for example:

Consequences is I cannot buy a bigger house … normally I can do my, saving for investment or improve my life but now I need to use my savings to buy medicines or doctor consultations … it takes a very big proportion of my savings every year I would say. Yes, it's quite a big burden for me. (8) Patient with psoriasis, China

Three main costs were reported: medical costs, non-medical costs and loss of earnings. Medical costs included the cost of appointments, prescriptions and medications. The extent and impact of medical costs varied by country of residence and, in turn, whether the costs were covered by the healthcare system and/or health insurance. For some there were no medical costs; for others, this accounted for a relatively large proportion of their salary with serious financial consequences such as bankruptcy.

> Dealing with the disease and when I finally got that under control then it took me another ten years to deal with the financial impact of it … almost filing for bankruptcy and I couldn't because I didn't owe enough money and … I made too much money in my job and getting served with papers for defaults on credit cards, like it was traumatic … it was like are you kidding me, like I just came through, I almost died, I managed to get through this and now I have to deal with the financial like, how much more do you want, need, and, and being ashamed … and not wanting to ask people for help because I felt like I didn't want anybody to feel sorry for me, or that I couldn't do it, or that I couldn't manage it, or anyone in my employer to think that I was not capable. (Group discussion 2)

The expense of treatments in these countries was also an issue and contributed to health inequalities. Some people chose to forgo or limit their treatments to offset the expense but by not taking the therapeutic dose they threatened their disease control. Others felt there was no choice but to pay for expensive treatments.

> You don't think about the expense too much because there's no choice, you will get the medication either way. (23) Patient with psoriasis, Israel

> The right treatment is really important … but the Biologic treatment is not free, it's very expensive, it takes at least eight thousand Hong Kong dollars payments on average which equivalent to thirty per cent of my salary at least. … it works, but it cannot have an effect for too long, only one or two years … is the most I can afford … I cannot afford this amount of money for too long. (7) Patient with psoriasis, China

Trigger avoidance could also be costly as, for some, it was necessary to purchase particular foods (e.g. gluten-free bread) or products (e.g. makeup, soaps, cosmetics) which were typically more expensive than generic alternatives.

> There are other incidental costs like very expensive shoes because we keep trying different kinds, fabrics that have to be specific and seamless and

> textures should not rub or tear off the skin, linen, prams, you know, baby prams etc, everything has to be customised. (Group discussion 1)

Daily life and responsibilities

The impact on people's daily routines dictated their everyday choices and the time spent on meaningful activities (e.g. work, school, hobbies and holidays). Many patients had to alter the structure of their day to manage their condition; those with photosensitive conditions, such as vitiligo and erythropoietic protoporphyria, often completed outdoor activities in the early morning or evening to avoid sun exposure. This was challenging, indeed impossible for people who worked outdoors, leading to reduced independence and contributed to a loss of autonomy and experiences of social isolation.

> If I'm going out, like if I have to stay in the sun, I really have to ensure that I'm in a place where there's shade. So sometimes I can't do everything physically. (11) Patient with AD, Kenya

> For coming here I needed to, my boyfriend come with me because for me drive the car is impossible because I have the sun in my direction and the hands start to burn. (Group discussion 1)

While individuals with specific dermatological conditions had their own treatment strategies, the use of treatments, whether prescribed or not, was almost ubiquitous. Some spent little to no time on treatments, whereas others could spend several hours each day completing complex, painful treatment regimens. Treatments regimens reported included one or more of the following: bathing/showering, performing checks, tending to wounds, applying topical agents, applying plasters and bandages, or self-injecting biologics.

> It's four hours for dystrophic [Epidermolysis bullosa (EB)] and then they can only do the top part of the body and then the next day they do the bottom part of the body. They can never do the … the whole body at the same time. (Group discussion 3)

Adherence to treatment regimens interfered with people's daily routines and required compensation, for example, sacrificing sleep. People with conditions that caused skin flaking and bleeding, or that required topical treatments, spent extra time on daily chores, such as cleaning and doing laundry. Even with less arduous treatments, participants described the cumulative impact of having to plan and complete regimens every day.

> [I] remember once we did a campaign on psoriasis, the people with psoriasis had to wake up an hour before the rest of them, one hour before just for psoriasis, imaging for epidermolysis. (Group discussion 3)

> My skin will peel off on the floor, very, very dirty, touch it, it's very rubbish so you need to clean up every day. (9) Patient with psoriasis, China

Both the psychological impact of dermatological conditions and the avoidance of triggers affected how individuals chose to spend their already reduced free time. Avoiding triggers, such as chlorine or sweat, influenced the individual's choice of exercise, and in some cases, deterred them from exercising at all. Instead, people with these conditions tended to participate in individual activities like reading and cycling. Thus, dermatological conditions are limiting in nature and can feed social isolation and prevent individuals from participating in their preferred hobbies.

> It's being treated like I'm a contagious disease and I think that's that a big, big downer for, for four or five, six years old and like she, she grows in a way that she's not beautiful and she's … unlovable and, and why wouldn't they like, jump rope with her, why wouldn't they play with her, hopscotch it doesn't matter, it's anything I would be a lot … in the corner, like in the playground. I would sit in the corner with a book, or maybe just staring into space. … I was very dumpy at home, and I like bicycle, I roller skate and I'm not the type that would sit and read even today … I think I read only comics, you know, I like to say I read, I'm more like playing games with my friends, even now … so that was a big battle for such a girl to be in that a corner and, and to be alone. (22) Patient with AD, Israel

Career choices were constrained by the perceived limitations of dermatological conditions and by people's level of confidence in applying for jobs and participating in certain work activities.

> Because of this disease, maybe I have to consider some job that would be no need to go on a trip, I mean no need for travelling, that would be better for me. (19) Patient with psoriasis, China

The time that people spent attending hospital appointments affected the time available to work with some employers being intolerant; whilst some participants opted for early retirement, others were persuaded or even forced to leave. People in the sample reported workplace discrimination and being refused jobs, which prevented them from moving on in their career:

> I remember that I tried to change my job once … I was about to face the job interview. But before I had to fill out papers you know, one of the requirements was not having any visible marks on the skin … So then, I didn't go to the interview because I realised that that job was not for me … Even when I had all the qualities you know, the qualifications to do the job. (48) Patient with vitiligo, Cuba

Finding work that did not aggravate dermatological conditions was challenging. These people often relied on their job for their health insurance putting them in a 'catch-22' situation where their job may not suit or worsen their condition, but they could not receive healthcare without it. Participants reported, for example, quitting their job because their skin could not tolerate the air conditioning in their office. People with dermatological conditions were therefore under pressure to find work that did not worsen their symptoms. People were forced to decide whether to prioritise their health or their financial security, exacerbating pressure on those with lower incomes. It was often felt that there was no choice but to take any work. This put people from countries without free medical care at the point of delivery under particular pressure.

> It's the fear, I needed my health insurance, I needed my job. I couldn't be seen as being unable to do my job because of my condition … this in the mid-90s, so I could have easily been fired … the pressure of having to pretend and to do what you're doing in order to make sure that I could financially deal (Group discussion 2)

Physical symptoms and fatigue made it difficult for some participants to perform caregiving or childcare duties. Sometimes participants prioritised caring for their children at the expense of following their own treatment routines, which was especially difficult when the child also had a dermatological condition:

> My daughter … when I was suffering, and she was suffering it was crazy because I was always taking care of her first … That's the instinct of a mother and I … would bathe her, and put her clothes and maybe the bandages, I would put her to sleep, then I would fall asleep. … I wouldn't have the energy to take care of myself too ... so I'd ask someone to help us get things done and today both of our … situations are much better, so I have the strength to take care of both of us (22) Patient with AD, Israel

Impact of healthcare

Lack of medical awareness affected the quality of dermatological care provided. Not everyone had access to specialist care, particularly those in low-income countries and rural areas. People with access to dermatology services reported that some specialists lacked expertise in dermatological conditions and awareness of their wider impacts, evidenced by stories of inaccurate and delayed diagnoses. Nevertheless, participants were hopeful that more dermatology research would increase medical awareness and improve condition management and service provision in the long term.

> I met five doctors, and the last doctor, confirmed that I have the Psoriasis (29) Patient with psoriasis, Indonesia

Diagnosis is almost impossible and where it's available it's very exorbitant. (Group discussion 1)

Only a minority of participants expressed satisfaction with their healthcare. These people usually received whole-person care or effective medication. Dissatisfaction was partly due to factors beyond their individual healthcare, such as the perceived lack of evidence-based and effective treatments available for their condition. Factors relevant to their individual care included inaccurate or delayed diagnosis, poor clinician communication, and a disintegrated, biomedical approach to condition management.

Some people with dermatological conditions were prescribed medication by their clinician and conducted research into more effective medications and other strategies to improve their condition. Others had not been prescribed any medication, typically because they had not been able to access a clinician with sufficient expertise or because no adequate treatments existed. Participants variously reported researching and trialling medications, psychological therapies and holistic/natural remedies.

Many participants felt that clinicians preferred to manage dermatological conditions with medication alone and did not consider or provide information on other important environmental and lifestyle factors. This led some to be cynical of clinicians who they saw as predominantly motivated by profit.

I'd like to raise the issue of doctors recommending medication as … they make patients feel like it's the only solution, probably because that contributes to the patients giving them their paycheque, but I think from what I've been studying, I think there's another whole lot of information that, I don't know if it's been deliberately hidden … or doctors don't know genuinely. (11) Patient with AD, Kenya

In Africa, and I believe in many parts of the world … the doctors … just tell you to not take this, use this cream come back after a week or two weeks. If it doesn't work in three or four days come back. They won't tell you that it's

> because of such fabric in your house, or what you're wearing or what your baby is wearing. (12) Patient with AD, Kenya

As a result, individuals felt let down and spent considerable time and effort using a trial-and-error approach to self-management. Some found that the information they found through the internet led to better disease control than that provided by clinicians.

> Different doctors were giving you different advice … you don't know which one to follow, and … after series of times, I work out my own, own ways to, to treat, to deal with my diet (10) Patient with psoriasis, China

More advanced treatments could relieve some pressure as they were usually more effective, less time consuming and required less planning. Biological medications emerged as a key example, though some patients found self-injecting to be traumatic.

> Now with Biologics, you forget about everything, it's just once every two weeks and forget about anything else and it works. So forget about all the other things. (5) Patient with psoriasis, Cuba

As well as research to supplement their healthcare, participants also spent extra time and effort researching and obtaining alternative products that would not trigger their condition.

> That company got out of business and … we had to go all around the country to the, all shops and so on to try and pick the last few of those lotions as I figured out what to use. (12) Patient with AD, Kenya

Although conducting research could improve disease control and encourage participants to engage in healthy lifestyle behaviours, it could also be a source of misinformation and anxiety, inducing a fear of comorbidities and treatment consequences. By far the most common mode of research was the internet/google, though patients also obtained information by attending conferences, joining patient organisations, subscribing to newsletters and magazines, reading books and joining forums or other forms of peer-to-peer information sharing.

Theme 3b: Psychological and social impacts are most significant

While the physical impact of dermatological conditions was important and could be profound, the general consensus was that the psychological and social impacts were the most significant and often underappreciated:

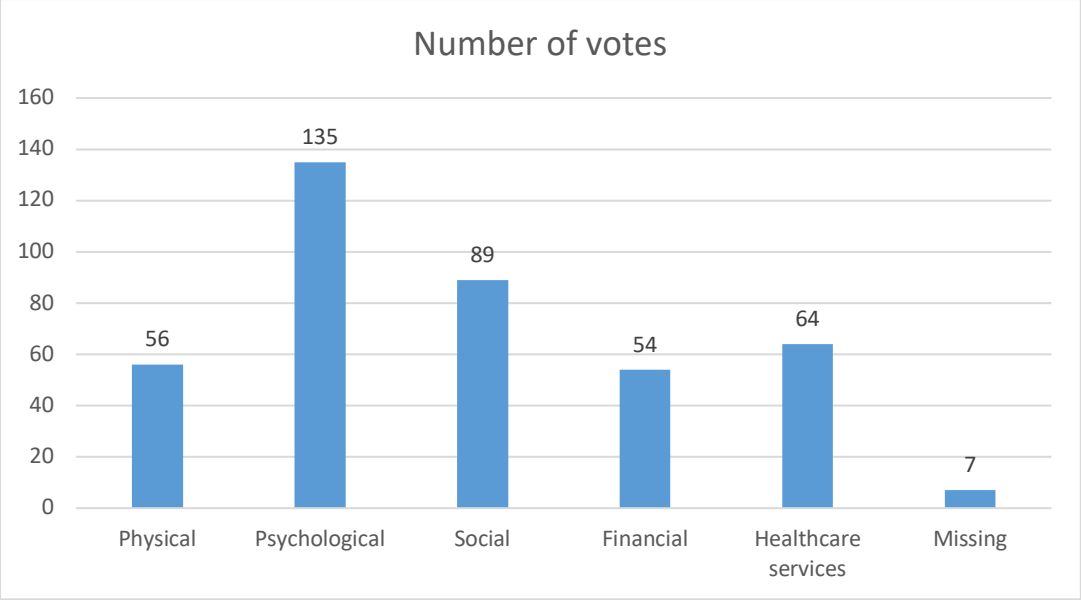
> Even if EB was cured tomorrow that will always be in your head. We seem to think of a lot of the physical strain that it does, the skin conditions on people, but we forget that mentally it'll never leave, and I think there's very little that people do for that. There's no magic pill that you can take and you're going to forget. I think that the mental implications involved into skin, it's not just physical, it's very mental as well … So there's an internal scar that doesn't go away. (Group discussion 2)

> It doesn't hurt me physically, it's just emotionally and psychologically. (38) Patient with alopecia, Australia

> Alopecia, it's more … a mental disease for me. (42) Patient with alopecia, Australia

This assertion was strengthened in the voting in the plenary session where the psychological and social categories obtained the most votes (Figure 17.).

Figure 17: Number of votes for each category in the plenary session



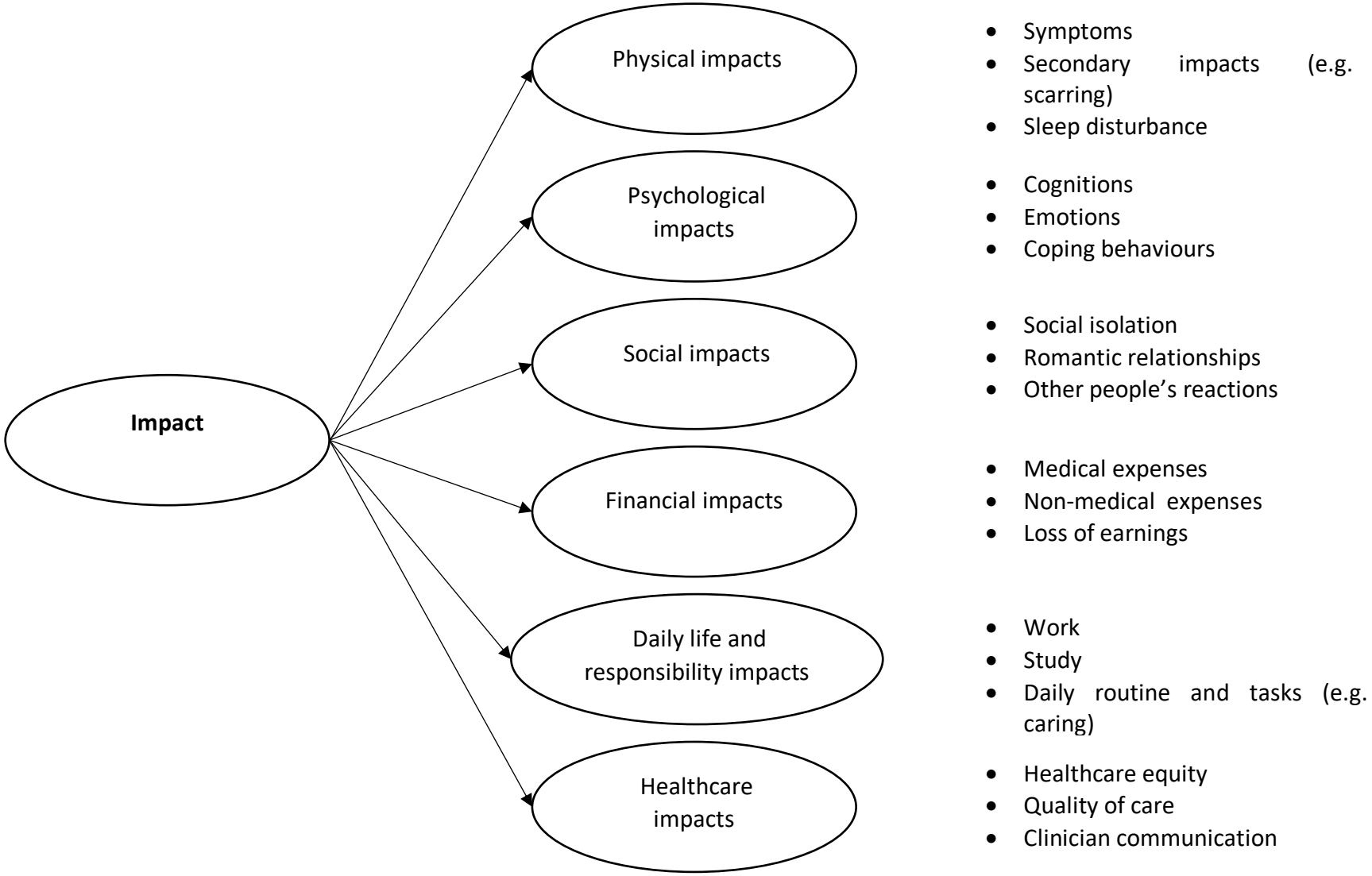
5.3.3 Themes and their implications for PRIDD

The themes presented in the previous section inform the content and structure of PRIDD. Table 17. summarises the implications of each overarching theme on measuring the impact of dermatological conditions. Figure 18. depicts the conceptual framework of the impact of dermatological conditions. Together, Table 17. and Figure 18. serve as the basis of the item generation process documented in the next chapter.

Table 17: Themes and their implications for PRIDD

Theme	Measure
1. Impact at the individual, organisational and societal level	As a *patient-reported* measure, PRIDD must focus on the impacts acting at the individual level, in the context of the organisational and societal levels.
2. Impact can be both point-in-time and cumulative	To comprehensively capture the impact of dermatological conditions, PRIDD must include items that reflect both the incidental and cumulative impacts.
3. Impact is a multifaceted construct	A range of subscales are required to measure impact: • Physical impacts • Psychological impacts • Social impacts • Financial impacts • Daily life and responsibilities • Impact of healthcare The final domain appeared to *influence* rather than reflect impact, so it may not be suitable to include in the conceptual framework. This need to be tested further. As a dermatology-specific measure, PRIDD should consist of concepts common across conditions. The common impacts identified in this study will form the basis of the items of each subscale.

Figure 18: Conceptual framework of the impact of dermatological conditions with example concepts



5.4 Discussion

5.4.1 Main findings

This concept elicitation study marks the first step in the content validity phase of PRIDD development. It aimed to explore how patients and patient organisation leaders conceptualise the impact of dermatological conditions, especially across conditions.

The construct of impact involves physical, psychological, social, financial and daily life and responsibilities (and potentially healthcare) impacts. Many experiences of living with a dermatological condition were common across conditions indicating that a dermatology-specific measure is appropriate. The data gathered resulted in the development of a conceptual framework (Figure 18.) which formed the basis of item generation.

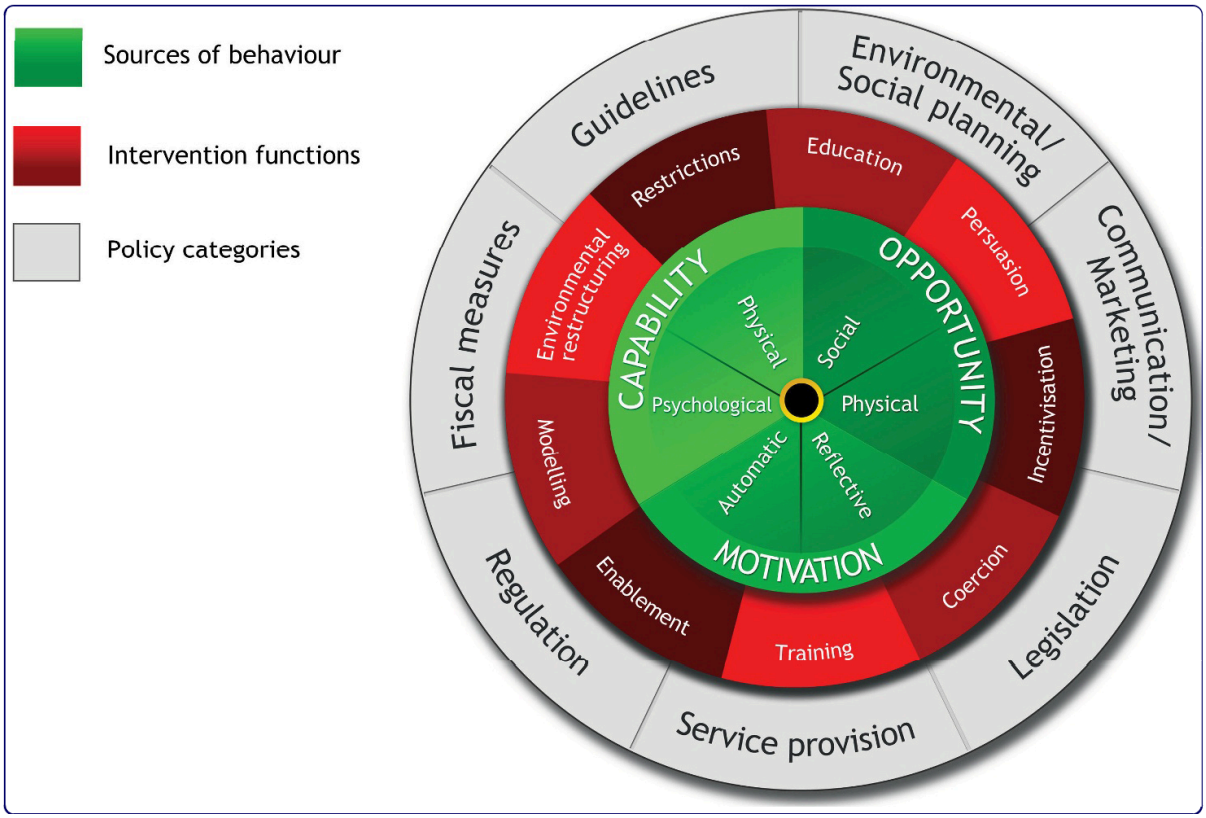
5.4.2 Interpretation of findings

The results indicate that impact operates across individual, organisational and societal levels. Issues affect and were caused at each of these levels, which interact in the experience of impact. The levels, along with the life domains identified, support the position proposed in this thesis that dermatological conditions are best understood and managed according to a biopsychosocial model. Many of the impacts identified were modifiable; patient self-management and clinician communication skills, for example, were identified as important determinants of impact.

Conceptualising impact as operating across three levels is congruent with the Behaviour Change Wheel (BCW; Figure 18.; Michie et al. 2011). The BCW provides a systematic way of identifying relevant interventions and policies to change for a particular target behaviour. It uses an overarching model of behaviour, the COM-B model, to link interventions to potential behavioural targets. These interventions can then be linked to specific behaviour change techniques. Use of both the three levels of impact and the BCW together can identify the most promising interventions for modifiable determinants of impact leading to the more efficient design of interventions to reduce the impact of dermatological conditions on

patients' lives. Multi-level interventions targeted at policy makers, clinicians and patients themselves will be key to improving dermatology patient outcomes. To illustrate, the lack of high-quality clinician communication experienced by patients indicates a need to target clinicians with behaviour change techniques (i.e. education, training and modelling) to improve their communication skills and this will require policy changes such as those to service provision and guidelines. The behaviour change wheel can also be used to identify interventions aimed at patients to improve outcomes for example by reducing distress and improving self-management.

Figure 19: The Behaviour Change Wheel reproduced from Michie et al. (2011, p. 7)



While patient behaviour change may be appropriate in some cases, interventions to reduce distress may be more appropriate in many cases. This study provides qualitative evidence in support of research suggesting that people with dermatological conditions experience significant levels of distress. There is, therefore, a clear and urgent need for access to

evidence-based psychological interventions. Though there is limited research into the effectiveness of psychological interventions for dermatology patients (Montgomery and Thompson 2018), the APPG on Skin (2020) recommends a range of potential interventions to be used in a stepped provision of support including peer support, mindfulness, habit reversal and cognitive behavioural therapy.

The importance of psychological processes on distress regulation and self-management behaviour outlined by cognitive behavioural models such as the CSM suggest CBT interventions as a promising potential intervention. CBT has been widely applied to improve distress and self-management in long-term conditions (Graham et al. 2016) and has some evidence of efficacy for dermatological conditions (Lavda et al. 2012). Acceptance and Commitment Therapy (ACT; Hayes et al. 2006), a third wave treatment of CBT, emphasises the influence of language on behaviour and improving psychological flexibility. Given that negative illness beliefs and distress may be realistic at certain times in certain conditions, ACT's focus on encouraging acceptance may be particularly efficacious for improving distress and self-management in people with long-term conditions. Indeed, several systematic reviews and meta-analyses have found it to be efficacious in improving outcomes in long-term conditions (Öst 2014; Graham et al. 2016) and reducing anxiety (Bai et al. 2020) and depression.

The life domains identified here are congruent with and expand upon the domains identified in the systematic review (Table 10.) which, in turn, are consistent with Wilson and Cleary's conceptual model of HRQoL. While the life domains are broadly similar to those identified previously, they have not been unified before, nor has such an in-depth understanding of each domain and their relationships been provided. This richness of data attests to the value of engaging patients in high-quality qualitative research during measure development, rather than relying predominantly on clinician or researcher knowledge, theory or text-based methods.

Research on the impact of dermatological conditions on patients' lives is limited and is often unidimensional and/or condition- or impact- specific. Not only does this study consolidate and extend existing knowledge, but two novel findings of the impact of dermatological conditions that were previously hidden are identified. The data show that many people with

dermatological conditions report employment discrimination and hesitate to or are against having children, highlighting further inequalities faced by patients.

Assessment of the impact of dermatological conditions on patients' lives has largely been based on repeated point-in-time evaluation, thereby potentially missing major aspects of impact. The cumulative impacts identified here add further support to the concepts of CLCI and MLCDP in dermatology. The similarities between the results of this study, CLCI and MLCDP are somewhat unsurprising given that they all conceptually overlap with HRQoL. The scope of the current study was broader than the development of CLCI and MLCDP as it was interested in a) both point-in-time *and* cumulative impacts and b) all dermatological conditions, not just psoriasis. Both forms of impact significantly affected participants. The results, therefore, suggest that PRIDD must include both point-in-time and cumulative impacts to comprehensively capture the impact of dermatological conditions, though this will need to be considered carefully in relation to responsiveness.

Though dermatological conditions tend to negatively affect people's lives, some positive impacts were reported. Theories of coping may be able to provide context for these. Most theories of coping emphasise a person's desire to establish equilibrium with effective coping, defined as that which enables adjustment to the illness and a return to normality (Ogden 2012). A positive psychology approach to health threats, on the other hand, highlights the positive rather than the negative consequences of illness. Research indicates that some people perceive benefits from ill-health. In their development of the Silver Lining Questionnaire, for example, Sodergren and colleagues (2002) concluded that the positive consequences of illness are varied and more common than is often realised. The self-regulatory model of 'post-traumatic growth' developed by Tedeschi and Calhoun (2004) draws together existing literature on trauma and coping and highlights five main areas of positive growth: perceived changes in self, closer family relationships, changed philosophy in life, a better perspective on life, and a strengthened belief system (Tedeschi and Calhoun 2004,2006). Each of these was observed in the current study. The authors note the role of factors including personality, optimism, social support and meaning-making in positive growth which were also identified as determinants of positive impacts in this study. From their synthesis of the literature, Tedeschi and Calhoun concluded that positive growth was a

more progressed form of positive adjustment than either just resilience or optimism and involved a process of transformation. This was demonstrated in the data with people with dermatological conditions experiencing 'stages of coping' which described the process of moving from initial distress following the onset of symptoms to acceptance of and adjustment to the condition later.

Research has found that several factors play a role in predicting positive growth. These include symptom severity, the time elapsed since the event, age, gender, social support, a clear cause (Tedeschi and Calhoun 2004), available support for recovery (McMillen 2004), the positive and negative responses of others (Harvey et al. 2004), the role of spirituality (Cole et al. 2008), talking about and assigning meaning to the experience, and financial stability (Cordova et al. 2001). Each of these factors influenced the impact of dermatological conditions. For example, the negative responses of others and uncertainty regarding the cause, triggers and disease course were key sources of distress. Participants advocated for improvements in healthcare provision (including clinician communication, availability of healthcare and effective treatments) and raising awareness of dermatological conditions among the public and health professionals. The post-traumatic growth literature gives weight to the patients' advocacy agenda as evidence-based actions that may not only negate the negative impacts of dermatological conditions but also promote positive growth.

The data gathered here demonstrate that cognitions such as negative thoughts about one's self contribute significantly to the overall impact of dermatological conditions. While negative self-concept could be thought of as a consequence within the CSM, it is better explained by the concept of illness identity. Illness identity refers to the degree to which a long-term condition becomes integrated into one's personal sense of self (Charmaz 1995). It is based on the notion that, when confronted with a long-term condition, individuals must understand what this means for their identity and try to create or regain a coherent sense of self (Leventhal et al. 1999). Four different illness identity states have been distinguished: rejection, engulfment, acceptance and enrichment (Oris et al. 2016). The first two capture a lack of illness integration. Engulfment refers to the degree to which a condition dominates a person's sense of self. Rejection refers to the degree to which the condition is rejected as part of one's identity and is viewed as a threat or as unacceptable to the self. This illness identity

state may explain why some individuals in the current study held a negative view of themselves because of their dermatological condition and is clinically important as it can lead to neglecting self-management (Tilden et al. 2005). In contrast, acceptance and enrichment capture more adaptive illness integration. Acceptance refers to the degree to which individuals accept their condition as one part of their identity, alongside other social roles and identity assets. Evidence shows that individuals who have accepted their condition do not feel overwhelmed by it (Evers et al. 2001; Morea et al. 2008) and try to lead as normal a life as possible, without neglecting their self-management (Adams et al. 1997). Enriching refers to the degree to which having a long-term condition results in positive life changes, benefits one's identity, and enables one to grow as a person. As such, the concept of illness identity may explain why some individuals experience post-traumatic growth while others do not. Similarly, the stages of coping described above could be explained as moving from engulfment or rejection of an individual's dermatological condition to acceptance or enrichment. When developing the Illness Identity Questionnaire, Oris and colleagues (2016) demonstrated the criterion validity of these illness identity states and found that each was uniquely related to psychological and disease-specific functioning. The concept of illness identity, therefore, clearly has implications for dermatological care. Since individuals appear to benefit from accepting their illness as part of their identity without it dominating their lives, multidisciplinary teams can support the patient by, for example, challenging their illness beliefs (e.g. negative thoughts about their dermatological condition) or supporting people to reduce avoidance behaviour. The CSM is an ideal framework to provide specific interventions within.

Overall, the sample tended towards treatment rather than personal control. Personal control demonstrates an internal locus of control whereas treatment control sits further towards the external end of the locus of control continuum. Since it is very unlikely that locus of control causes dermatological conditions, it seems that having a dermatological condition may undermine internal locus of control and strength external locus of control. Thus, dermatological conditions may affect an individual's sense of agency and autonomy, beyond the condition itself.

5.4.3 Implications for measuring the impact of dermatological conditions

The results of this study provide a working definition of impact and inform how it should be measured and, subsequently, inform clinical and treatment decision-making. The finding that participants primarily assess the impact of their condition in terms of their psychological, social and daily functioning, rather than physical functioning or symptoms, supports the need to assess the impact of these conditions more widely, and by extension the need for PRIDD.

Patient-reported method of measurement

The choice to make PRIDD a patient-reported measurement was driven by the conceptualisation of impact as a construct reflecting patients' sensations, experiences and perceptions (de Vet et al. 2011).

Reflective measurement model

How impact was conceptualised has implications for choosing the most appropriate measurement model to use when developing PRIDD. While some items could be viewed as causal, namely those of the 'healthcare impacts' domain, overall the conceptual framework is consistent with a reflective measurement model as each of the items *reflect* impact. Researchers have some freedom to choose between a reflective and formative model; where a construct lends itself to be measured with a formative model, it is usually also possible to identify items that reflect the construct too (de Vet et al. 2011). Given the advantages of following a reflective model listed previously – i.e. the acceptability of missing items and presence of well-developed measurement theories for development and evaluation – PRIDD will be developed and validated accordingly. Although there is uncertainty regarding the relationship between the 'healthcare impacts' domain and impact, this domain has been included in the conceptual model to be further tested with patients in the next phase of the research.

No existing measures cover all important concepts or forms of impact

The systematic review reported in Chapter 4 found that existing dermatology-specific PROMs have captured *some* of the individual sub-domains of impact that are important to patients and have focused almost exclusively on point-in-time impacts. The multiple aspects of impact identified in this study have not previously been captured as a unified construct using a single measurement instrument. Likewise, previous measures have focused on either point-in-time or cumulative impact instead of presenting a single measure that unifies these two distinct impacts in order to capture a comprehensive understanding of the overall impact of living with a dermatological condition.

Variations in the experience of impact present challenges for measurement

Impact varies both for an individual over time and between individuals and, likewise, for a condition over time and between conditions. This variability across individuals, conditions and time presents numerous challenges to the measurement of the impact of dermatological conditions.

The variation suggests that the full scale of impact ranges from 'no impact' to 'devastating impact'. While the decision regarding the measurement scale is relatively straightforward, decisions regarding the items will be more difficult. There was a general consensus that psychological and social impacts were the most important to patients. However, the way these were experienced varied across the sample and some felt other life domains were more important. Therefore, the items in PRIDD must be specific enough to capture the underlying concepts but broad enough to be relevant across individuals and conditions.

5.4.4 Strengths and limitations

Study design

This study met the standards for concept elicitation studies outlined by COSMIN (Appendix 10.). Designing the study according to the COSMIN criteria strengthened the content validity of PRIDD and increased the transparency and quality of reporting.

Data were collected using a mixture of in-person group discussions and online individual interviews. The counting procedures employed during the respondent validation exercise demonstrated that the qualitative analysis represented the impact of dermatological conditions well. Many researchers perceive face-to-face interviews as the 'gold standard' of qualitative data collection, with online methods viewed as inferior (McCoyd and Kerson 2012). However, much like a traditional interview, online interviews using video-conferencing software such as Zoom allow real-time communication with both audio and video with the exception that the researcher and participant are in different locations (Mann and Stewart 2000). In addition, the Zoom chat feature was useful where there were language barriers, for example, to confirm the words spoken, and meaning, where there was uncertainty.

The study methods constituted a pragmatic approach to the complications presented by the SARS-CoV-2 pandemic, allowing the study to continue and improving access to a representative sample of patients worldwide with minimal respondent burden. Furthermore, the resultant methodological and data triangulation provided a rich and robust dataset to support content validity and strengthened the study conclusions by removing uncertainty about the interpretation of the findings.

Sample

Unlike the PROM development studies identified in the systematic review, PRIDD received high levels of patient and patient organisation input by recruiting through the unique global membership network of IADPO. Scheduling the group discussions immediately before the WCD 2019, a prestigious international dermatology conference, provided a rare opportunity

to convene a large group of dermatology patient organisation representatives from around the world. Participants were sampled purposively to include a diverse range of people representing both inflammatory and non-inflammatory dermatological conditions of variable rarity (common, uncommon, rare) across the six populated continents as well as other clinical (e.g. time since onset) and demographic groups (e.g. age and gender).

The GBD estimates the prevalence of acne at 9.4%, ranking it as the eighth most prevalent disease worldwide (Vos et al. 2012; Hay et al. 2014). However, only two people with acne participated in the current study. Later recruitment efforts focused on people with acne, but the paucity of acne patient organisations hindered this. To achieve good content validity, future work must include people with this common dermatological condition. Other conditions were better represented, ensuring that concepts for PRIDD were elicited from across the target population.

Employing IADPO's member network enabled access to a relatively large and representative sample efficiently. Patient participants were experts on the impact of living with a dermatological condition. Furthermore, patient organisation members may generally be more knowledgeable about dermatological conditions and may have more opportunities to interact with other people living with their condition meaning that they can provide both a personal and wider view of impact. Patient organisation leaders do not necessarily have personal experience of the conditions they represent, though many of those who participated in this study did. Even so, patient organisation leaders have a high-level overview of the issues faced by their patient members. The fact that almost all of the issues raised by the patient leaders during the group discussions were also reported in the individual interviews with patients is a testament to their expertise.

Nevertheless, because IAPDO is a global alliance of patient organisations focused on research, advocacy and support, these participants may not represent the experiences of non-members. This is demonstrated by the finding that a significant number of participants engaged in advocacy work to combat and cope with the impact of their condition. This is unlikely to be representative of the experience of non-members. People using problem-focused coping, such as advocacy work, may be overrepresented in this study. This may explain why none of the sample reported personal experience of particular emotion-focussed

coping strategies such as drinking alcohol and using recreational drugs, though these strategies are reported in the literature (Zink et al. 2017). Qualitative researchers have also noted that women are often more likely to participate in qualitative research than men (Robinson 2013). This was true of our sample with women accounting for 92% of participants in the group discussions. The female bias was counteracted by purposely sampling for the individual interviews, resulting in a more acceptable ratio of men (32%) overall.

Ethical research requires that participation is voluntary, however, this introduces self-selection bias because those that consent to participate may differ from those that do not in ways that are not related to the sampling criteria (Costigan and Cox 2001). The interview methods employed in this study may be particularly vulnerable to self-selection bias as participants were required to disclose personal information and discuss sensitive topics. Individuals who participated in the study may have been more open, patient and interested in the impact of dermatological conditions than others who also met the inclusion criteria and, therefore, may not well represent the entire target population (Robinson 2013). In addition to being more interested in the topic, arguably people who join patient organisations differ from those who do not. Prummer et al. (2019), for example, found that as well as being slightly younger and female, members of the Acoustic Neuroma Association, a national, non-profit organisation, experienced greater severity and lower QoL compared to non-members.

Role of theory

The results indicate that use of the CSM along with aspects of the conceptual model of HRQoL provides an appropriate framework for exploring the impact of dermatological conditions on patients' lives. While the conceptual model of HRQoL suggested the exploration of micro, meso and macro impacts and influences, the CSM provided item content. As a result of this approach, this study found that personal and contextual factors operating at the individual (e.g. beliefs about distress and behaviour), organisational (e.g. impact of healthcare services) and societal levels (e.g. lack of public awareness) influence the experience and degree of the impact of dermatological conditions. Previous dermatology-specific QoL PROMs have focused on the emotional and, to a lesser extent, coping aspects of psychological functioning, while

largely ignoring cognitions. The data demonstrate that beliefs about the condition contribute significantly to the overall impact of dermatological conditions. This study demonstrates that theoretically informed, patient-driven measure development increases understanding of the construct of interest and therefore strengthens content validity.

A potential limitation introduced by the use of theory was the inductive-deductive, as opposed to a purely inductive, approach to data analysis. This approach is arguably theory-driven rather than patient-driven. A deductive approach increases the risk of overlooking important information regarding the impact of dermatological conditions that do not fit with pre-existing frameworks. Arguably a truly inductive analysis is difficult to achieve as researchers cannot entirely free themselves from the influence of their preconceptions, epistemology, and knowledge of the relevant literature and theories (Malterud 2001; Braun and Clarke 2006). The theoretical structure provided a way of managing a relatively large amount of data by qualitative standards. The use of an inductive-deductive approach limited the risk of missing important information as all data were coded whether or not it appeared explicitly relevant to the frameworks. This allowed the development of a conceptual framework that was meaningful to the participants. Ultimately, the use of an inductive-deductive analysis arguably broadened, rather than narrowed, the conceptualisation of impact. For example, the topic guide did not specifically address the influence of healthcare delivery on the overall impact of dermatological conditions, yet this was discussed by the majority of participants. In this way, the inductive-deductive approach, along with the semi-structured interview format, provided participants with the opportunity to discuss topics of importance and central to the topic to them. As a result of these elements, the conceptual framework of impact also encompassed a range of domains, including the cognitive impact. Thus, the inductive-deductive approach facilitated transparency regarding the researcher's prior knowledge of relevant literature and theory while achieving a richer conceptual framework.

Team science

This study demonstrates the value of multidisciplinary teams in healthcare research. The study was designed and analysed by RP with input from the wider team who were a mix of clinicians and researchers and all had expertise in dermatology, health psychology, clinical psychology and/or public and global health. While having multiple interviewers can be viewed as a limitation as it may reduce consistency, there were methodological and practical advantages. The team science approach facilitated a broader conceptualisation of impact and increased the trustworthiness of the analysis since perspectives across multiple relevant disciplines were obtained (Henwood and Pidgeon 1992; Gale et al. 2013). Furthermore, without multiple interviewers, it would not have been possible to conduct the four group discussions simultaneously and the opportunity to capitalise on the patient organisation leaders in attendance from around the world would have been missed. To maintain consistency, all interviewers followed the topic guide and were trained by one expert (CB) in facilitating group discussions.

5.4.5 Implications for clinical practice

The WHO recognises that health is a fundamental human right and health inequalities can affect QoL (WHO 1948). This position was borne out in this study as inadequate healthcare emerged as an important determinant of impact. The WHO also promotes the concept of people-centred health care, emphasising the need for fair access to health care for the right patient at the right time (WHO 2007). This study revealed global inequities in dermatological care. Accessibility and quality of dermatological care varied according to geographical location (both in terms of countries and whether an individual lived in a city or rural area) and socioeconomic status. In addition, participants felt that people with other conditions received a higher standard of care; one participant, for example, noted that in the US healthcare system people with alopecia and hair loss were not entitled to a wig whereas people experiencing cancer were. Resource allocation to dermatology that reflects the burden of these conditions may go some way to improving dermatological care and reduce their impact on the patient.

According to the CSM, illness beliefs are known to influence individuals' cognitions, emotions and coping behaviours, and predict outcomes for a range of long-term conditions (Leventhal et al. 1984). For example, beliefs about psoriasis are better predictors of outcomes than disease severity (Fortune et al. 1998,2000; Fortune et al. 2002) and are closely linked with medication adherence (Thorneloe et al. 2018). Participants in this study held a variety of beliefs about their dermatological conditions and treatment side effects including liver and kidney dysfunction, hypertension, infertility, heart disease, pain, immunity to antibiotics, and cancer. These beliefs affected how they understood, reacted to and managed their condition and influenced major decisions. For example, individuals who validly or erroneously believed their condition had a genetic cause chose not to have children and anticipated side effects deterred some from using potentially effective medication.

Patient beliefs are partly shaped by the information they receive from their healthcare providers as well as from other, arguably less reliable, sources (Gallagher and Updegraff 2012). Kahneman and Tversky (1979, 1981) demonstrated that individuals do not appraise information purely rationally and objectively but are influenced by how that information is presented. Subsequently, research in the field of side effect framing – how information about the likelihood or significance of side effects is presented (e.g. negative frame: 30% *will* experience headache vs. positive frame: 70% *will not* experience headache) – has revealed that positive framing side effect information could foster a therapeutic placebo effect and diminish nocebo effects. Alongside the use of appropriate diagnostic tests and treatments, message framing is an intervention that can influence patient health outcomes. In addition, clinician beliefs about psoriasis also drive clinician behaviour (Chisholm et al. 2016) and may be partly responsible for how patients use their medication (Hewitt et al. 2021a). Clinician expectations, along with other important mechanisms such as emotional reactions to health messages, are a potential mechanism that may influence message effectiveness. Overall, the literature on beliefs and message framing indicates the need to improve clinicians' communication skills through further education and training in order to improve patient health outcomes and QoL. PRIDD may serve as a useful device to facilitate related discussions.

Research on the emotional impact of dermatological conditions has mostly focused on low mood and anxiety, though there is some evidence of increased anger (Conrad et al. 2008; Gulec et al. 2009; Sampogna et al. 2012; Aydin et al. 2017). This study adds to the sparse literature with data showing that patients report feeling angry, frustrated and irritated with their condition, healthcare provision and other people. Anger is a universal feeling which develops when an individuals' wishes and requirements are not fulfilled, their plans do not come to fruition or they perceive a personal threat (Tatlılıoğlu and Karaca 2013). In addition, this study and others indicate that anger may arise, in part, due to loss of function and control and low self-esteem (Aydin et al. 2017). This is the first study to provide qualitative data that some participants felt hostile towards their healthcare professionals and healthcare systems more generally, usually as a result of poor access to healthcare, lack of awareness of dermatological conditions and poor communication, especially in terms of information giving. Patient anger is clinically significant as it is associated with depression and anxiety (Posternak and Zimmerman 2002; Dougherty et al. 2004; Fraguas et al. 2006), hostility and aggression (Siegman and Smith) as well as some evidence of poorer health outcomes (Staicu and Cuţov 2010) and information processing (McKasy 2020). This further highlights the need for training in psychological support and communication skills for dermatology clinicians, particularly in light of the vast literature suggesting a therapeutic effect of good doctor-patient relationships (Blasi et al. 2001).

Dermatological care is currently lacking a systematic approach to management. Perceived inadequate healthcare, including lack of specialists, effective medication and poor clinician information provision and communication, creates pressure on patients who are left to try to understand their condition alone. This work shows that people with dermatological conditions clearly want to understand their condition. Clinicians are ideally positioned to provide accurate, evidence-based information to patients in a way that does not increase anxiety, but they require training to do so effectively. The data here show that when this is not provided, patients will find this information elsewhere, where they may be met with anxiety-inducing misinformation. This particular source of pressure is modifiable; high-quality dermatological care may improve disease outcomes and reduce some of the pressure on people with these conditions.

Participants in this study recognised the value of psychological support in the management of their condition. However, many were not able to access this support as it was not integrated with their routine care and was too expensive to access privately. The PsoWell™ training programme and clinical initiative was introduced in Chapter 1 and suggested as a means of improving clinicians' skills and confidence to address the psychological aspects of psoriasis and health behaviour change with patients during standard dermatology consultations (Chisholm et al. 2017). The conceptual framework developed here is suitable for identifying common experiences within an inherently heterogeneous population. A PsoWell-type training programme that draws on information on the common impacts across dermatological conditions identified in this study may provide a cost-effective way of training clinicians to provide psychological support to people with dermatological conditions. Furthermore, the profound psychological impact demonstrated here reinforces the need for dedicated psychological support provided by psychologists *in addition to* that provided by dermatologists. Additionally, clinicians should be aware that young people and those with recent disease onset may be particularly vulnerable to psychological distress.

The results of this research reinforce the understanding of dermatological conditions as complex long-term conditions that have impacts beyond the skin and supports existing research indicating that dermatology management does not meet the expressed needs of patients (Nelson et al. 2013a). To address these needs, dermatology clinicians need to recognise the physical, psychological and social demands of these conditions and improve their knowledge and skills in its assessment, management and communication. Multidisciplinary services that focus on the long-term impacts of dermatological conditions on well-being and QoL could address the deficits in care reported. Specialist psychological support should be available and integrated with the wider care of patients with dermatological conditions and, where possible, free at the point of entry.

5.4.6 Implications for research

This study demonstrated that dermatological conditions have many and varied consequences for the people living with them. Some of these impacts are shared across conditions whereas

others are disease-specific. The data provide a basis for developing PRIDD and other disease-specific measures. The study design provides a model for the development of other speciality-specific measures. The large number of concepts discerned demonstrate that the full impact has been underestimated by existing, often widely used measures, but it is not feasible to include all concepts, or items that capture all concepts, in PRIDD. As a *patient-reported* measure, patients should be involved in the item reduction process. Further research is needed to prioritise items from the conceptual framework. To maintain the high level of content validity achieved in this study, future work should consult a wider group of people with dermatological conditions to endorse the impacts identified here, check whether any relevant impacts are missing, and identify which items to prioritise for inclusion in PRIDD.

Consistent with previous research (Carr et al. 2014; Suseł et al. 2014), pain and itch emerged as significant components of the experience of dermatological conditions in this study and as a key driver of their overall impact. There has been considerable interest in pain and itch recently, not only in terms of pharmacological interventions and their physical consequences but also in terms of the psychological impact (Ingram and Ahluwalia 2019). Transcutaneous electrical nerve stimulation (TENS) is a non-pharmacological intervention that relieves pain by activating descending inhibitory systems in the central nervous system to reduce hyperalgesia (Vance et al. 2014). Because TENS is effective, non-invasive, low-cost and can relieve chronic itch as well as pain, it is valuable and growing in use in dermatology (Visconti et al. 2020). Though small-scale studies have shown multiple benefits of TENs in dermatology, better-designed studies – i.e. blinded RCTs with sufficient sample sizes – are needed before its application can be recommended. The biopsychosocial model of itch considers psychological factors that exacerbate or trigger itch (Verhoeven et al. 2008). Daily hassles, perceived stress, negative life events and certain personality traits have been associated with itch intensity in both the general population and people with itch-related dermatological conditions (Yamamoto et al. 2009; Lien et al. 2011; Chrostowska-Plak et al. 2013; Schut et al. 2014; Schut et al. 2015). It follows, therefore, that a biopsychosocial approach that takes psychological factors into account is necessary for adequate pain and itch treatment. Reviews have demonstrated that psychological interventions such as habit reversal training, arousal reduction and CBT have positive effects on wellbeing and itch in different dermatological conditions (Chida et al. 2007; Lavda et al. 2012). In their review of psychological itch

interventions, Schut and colleagues (2016) suggest that new psychological techniques such as acceptance and commitment therapy and mindfulness-based stress reduction that have been helpful in the treatment of chronic pain may also be useful for chronic itch. They conclude by advocating for psychological interventions in chronic itch treatment. RCTs should be conducted to establish the effectiveness of non-pharmacological, including psychological, interventions. Future research should focus on translating effective pain and itch interventions into clinical practice as one way to reduce the impact of dermatological conditions on patients' lives.

5.5 Summary

This concept elicitation study marked the first step in the content validity phase of PRIDD development. The findings reinforced and broadened the understanding of dermatological conditions as complex long-term conditions that have impacts beyond the skin. The first conceptual framework of the impact of dermatological conditions on patients' lives was developed. The conceptual framework demonstrated that the impact of dermatological disease is multifaceted; this has not previously been captured as a unified construct using a single measurement instrument. It will be tested in future work and form the basis of PRIDD item generation.

Chapter 6: Phase 3: Item generation and reduction

6.1 Introduction

Our new conceptual framework of the impact of dermatological conditions on the patient's life indicated a reflective measurement model of impact operating across six domains: physical, psychological, social, financial, daily life and responsibilities, and healthcare impacts.

The next step in the content validity phase of PRIDD development is the generation of items that relate to the conceptual framework (Apfelbacher and Nelson 2017). These items reflect the essence of each domain and form the first draft of the measure (Brod et al. 2009). To maintain good content validity, there is also a need to check whether the concepts identified in the concept elicitation study are recognised and endorsed by a wider group of people with dermatological conditions. During this process, the aim is to generate as many items as possible to be reduced later using item reduction techniques (de Vet et al. 2011). This chapter describes both the item generation and reduction process of PRIDD.

6.1.1 Seeking consensus on the final item pool

Item reduction is customarily achieved through statistical techniques (i.e. factor analysis and examination of item characteristics) but can also involve participatory methods (i.e. consensus-seeking methods and cognitive interviews; de Vet et al. 2011). Statistical techniques, such as factor analysis, examine whether the patients' responses correspond with the conceptual framework but are more closely aligned with researcher and clinician interests than the patients'. Our systematic review (Chapter 4) revealed a distinct lack of patient involvement during the item reduction process of existing dermatology-specific PROMs. Consequently, it is not clear whether the included items (and therefore the measure as a whole) accurately reflect concepts that are most important to patients. Participatory methods

enable participants to have greater input into the final item pool than purely statistical methods allow and, therefore, offer additional evidence of content validity. This study will involve participatory methods of item reduction, followed by statistical methods during the psychometric testing phase (beyond the scope of this thesis).

Consensus group methods are widely used in healthcare research as a systematic means for measuring and developing consensus between experts regarding domains of uncertainty (Bourrée et al. 2008; Humphrey-Murto et al. 2017), such as the most important items to include in a new PROM. These methods are founded on the involvement of a group of experts who are not necessarily scientific authorities on the topic area, but rather any person with good practical, legal or administrative knowledge of the subject and with sufficient legitimacy to express a representative opinion of the group to which they belong (Bourrée et al. 2008). People with dermatological conditions, therefore, are considered experts on the impact of dermatological conditions.

Consensus group methods can engage a relatively large number of experts and have a set of common features - anonymity, iteration, controlled feedback, statistical group response and structured interaction (Lewis‐Jones and Finlay 1995; Murphy et al. 1998; Vernon 2009) – which, together, offset some of the limitations of the concept elicitation study including the small sample size and biases inherent in group decision-making exercises such as conformity to the dominant view.

The Delphi survey, the most commonly used consensus-seeking method in healthcare, is popular across many disciplines. It is referred to as a 'study', 'method', 'group', 'survey' or 'technique' interchangeably throughout the literature. The Delphi method uses surveys across a series of sequential stages, known as rounds, to collect information from participants. The starting point is usually an initial qualitative, open-ended 'idea generation' stage, with the primary function of exploring the range of salient issues that go beyond the currently known (Iqbal and Pipon-Young 2009). The 'ideas' that emerge in Round 1 are collated to construct a survey instrument to be distributed at subsequent rounds.

The Delphi method has a number of advantages over other consensus methods, the most notable of which is the nominal group technique (Gallagher et al. 1993). Unlike the nominal

group technique, Delphi surveys facilitate group communication without imposing geographical or temporal restraints on participation, making it ideally suited to PRIDD's global target population. The structure of the Delphi method enables researchers to access the helpful aspects of interacting groups (e.g. obtaining ideas and knowledge from a range of sources) whilst pre-empting some of their unhelpful attributes (e.g. personal conflicts; Rowe and Wright 1999). It also ensures that all panellists have anonymity and an equal voice in the proceedings, thereby reducing the influence of dominant individuals. In addition, it is relatively low cost, requires less time to participate and panellists have asserted the appeal and efficacy of online surveys (Iqbal and Pipon-Young 2009).

In the context of healthcare, the Delphi method is most often used to gain consensus during the development of guidelines or treatment protocols when there is limited, insufficient, or conflicting available evidence. The Delphi method has occasionally been used to obtain consensus on items for inclusion during the development of dermatology PROMs. McLellan and colleagues (2018), for example, conducted a Delphi study to identify domains and generate items for an acne-specific QoL PROM. Developing consensus across disease groups on the shared important issues to include in PRIDD is a necessary step in establishing content validity.

Aims

This chapter examines the research question "what items do patients think are most important to include in PRIDD?" There are two aims:

1. To reduce the item list to form the first draft of PRIDD.
2. To further strengthen content validity, by a) determining whether the concepts identified in the previous study are endorsed by a wider group of people with dermatological conditions and b) exploring whether any important items are missing from the item pool.

6.2 Methods

6.2.1 Design

We conducted a modified, two-round Delphi study to elicit expert consensus on the most important items to include in PRIDD. That is, in lieu of an idea generation round, the survey was developed based on the outcomes from the concept elicitation study. It incorporated both quantitative and qualitative methods to facilitate and provide a more complete understanding of the item reduction process (Iqbal and Pipon-Young 2009). Quantitative data were collected using Likert-type ranking scales. Qualitative data were collected using open-ended free-text responses that provided participants with an opportunity to provide additional feedback.

6.2.2 Sampling and recruitment

We employed convenience sampling. IADPO invited all their member organisations to direct their respective patient members to the Delphi survey via a secure online platform which also included the PIS and an electronic consent form. Participants met the inclusion criteria if a) they had a dermatological condition and b) were aged 18 or over. Clinicians and proxies, such as family members or carers, were excluded a) because evidence of content validity must come from the target population and b) to maintain patient-centredness in the item reduction process.

There is no set standard sample size for a Delphi study but it is generally agreed that the more members the greater reliability of the group judgement (Murphy et al. 1998). The appropriate sample size varies according to the topic area and diversity of the target population as well as the time and resources available. Delphi studies have included between seven and 1,000 participants (Iqbal and Pipon-Young 2009), but a minimum of 30 participants are required to provide rigour for statistical analyses (Chuenjitwongsa 2017). Because of the diversity of PRIDD's target population along with the fact that Delphi studies often suffer from attrition (Chuenjitwongsa 2017), we aimed to recruit up to 2,000 participants but no less than 30.

6.2.3 Materials

The study was conducted using an online platform developed by information technologists with expertise in Delphi surveys. A specific platform was required in order to track participants data across both rounds and to send reminder and invitation to participate in Round 2 emails. Conducing the survey online enabled the recruitment of a sample that was geographically dispersed around the globe. As opposed to post or email, the online survey had the advantage of maintaining participant anonymity, reducing the time required for data delivery and ensuring the readability of participant responses (Hsu and Sandford 2010).

We also provided PDF copies of the survey to participants who had issues accessing the online survey. These participants were located in China and Kenya because of the internet firewall and poor internet connection, respectively. Patient organisation leaders distributed and collected the completed anonymous PDFs and send them to the information technologists who incorporated responses into the Delphi dataset.

Demographic questionnaire

The online platform included a brief demographic questionnaire that gathered information regarding the participant's primary (most impacting) dermatological condition, time since onset, age, gender, country of residence, native language and to which patient organisation they belonged, if any.

Delphi items

This section describes the development of the Delphi items, their response options and translations.

Item generation

An initial list of working items was produced guided by the conceptual (Figure 18.) and analytical frameworks (Appendix 9.). The conceptual framework determined the domains to be included. The analytical framework was used to identify codes relevant to each domain as a basis for each corresponding item. At least one working item was proposed for each code. These were refined through discussions with CB, RH, and NTS to ensure that the underlying concept was captured and good item principles were followed. This process was documented in an Excel spreadsheet (Appendix 11.).

Item wording

To support the assertion that the items have good content validity, they were generated to directly reflect the content of the qualitative statements made and the language used by participants in the concept elicitation study. In the absence of specific guidance on generating Delphi items, general guidance on measurement item generation was followed to ensure that that the items were simple, clear, avoided biased language and followed a common structure (Appendix 11.; DeCoster 2000).

Item pool

After checking for duplicates in the item pool, 263 items remained. The OMERACT group recommends including a maximum of 70 items in the first quantitative round of a Delphi (Humphrey-Murto et al. 2019); however, there is no literature to support this recommendation. A systematic review of 80 Delphi studies found that the initial number of items ranged from 11 to 767 (Boulkedid et al. 2011). Prior research suggests that the relevance of survey content is more predictive of attrition than overall survey length (McCambridge et al. 2011; Hochheimer et al. 2016). Given that the items were highly relevant to the target population and that item reduction prior to the Delphi would defeat the purpose of the study by losing patient insight on the items, all 263 items were retained.

Item mapping

During the development stage, all codes in the analytical framework were compared against relevant items from measures identified in the systematic review. Where existing items met the item generation guidance, they were used as a basis for item wording. For example, the item 'my skin condition causes me to fear social interactions with men and/or women of interest to me' from the DIS provided a useful example of how to word an item reflecting issues initiating romantic interactions without being heteronormative.

Scoring issues

Researchers have a considerable amount of freedom to choose the level of measurement of response options but certain considerations such as the application of the measure guide this (de Vet et al. 2011). The Delphi item response options operate at the ordinal level and it was anticipated that PRIDD will too. It was possible to choose a lower level of measurement, for example, ordinal level response option with three categories of mild, moderate and severe impact, but information would be lost. On the other hand, a ratio level of measurement was not possible since there is not an absolute true zero point for impact. While an interval scale appears to provide more information than an ordinal scale, it is unlikely that respondents will be able to grade the impact of their dermatological condition in such detail (i.e. reliably distinguish between a score of 50 and 55 on an impact scale of 0 – 100). Visual analogue scales are an example of a widely used measurement method operating at the interval level. However, these are limited to measuring unidimensional constructs, commonly pain intensity (Carlsson 1983), and therefore are not appropriate for measuring the multidimensional construct impact.

The number of response categories on an ordinal scale depends both on how many degrees of the characteristic can be distinguished by respondents, and how many categories are relevant. Dichotomous categories appear where only two options exist (e.g. 'treatment' or 'no treatment', 'yes' or 'no'; de Vet et al. 2011). More options that can provide more detailed

distinctions are necessary to gain a deeper understanding of the impact of dermatological conditions. In one of the most highly cited papers in psychology, Miller (1994) proposed that humans can effectively process no more than seven units of information (plus or minus two). This is supported in the psychometric literature with numerous studies finding that four to seven response options provide validity and reliability while maintaining enough points of discrimination (Preston and Colman 2000; Lozano et al. 2008).

Likert-type scales are one of the most common ordinal level response options and are widely used in instruments measuring opinions, beliefs, and attitudes (DeVellis 2017). When using a Likert-type scale, the item is usually presented as a declarative sentence such as 'I often feel anxious', followed by response options that indicate varying degrees of agreement with or endorsement of the statement. Response options should be worded to have roughly equal intervals in terms of agreement. Conventionally, the response options are bipolar and consist of three, five, or seven categories forming a continuum from 'strongly disagree', 'moderately disagree' and 'mildly disagree' on the left-hand side to 'mildly agree', 'moderately agree' and 'strongly agree' on the right-hand side. The middle category is usually neutral (commonly 'neither agree nor disagree') but researchers can force respondents to choose positive or negative answers by removing this category. To maintain good psychometrics and discrimination a five-point Likert-type scale was used to examine how important each Delphi item was to patients. Response options ranged ‘not at all’, ‘somewhat’, ‘moderately’, ‘quite a lot’ to ‘very much’. Statistical analysis during the psychometric testing phase of development can determine the number of categories required by PRIDD by examining how informative each category is.

Cross-cultural translation

Given PRIDD’s global target population, the survey was translated from the original English into five languages – German, Spanish, French, Arabic and Chinese – by a professional translation service. Including non-English speakers: a) allowed participants to consider the concepts in their own language, b) increased the likelihood of meeting the target sample size, and c) maximised the representativeness of the sample. The five languages chosen for

translation were primarily prioritised based on the languages spoken in the countries where IADPO had member organisations and secondarily because they were some of the most widely spoken languages in the world (Ghosh 2020).

Core to the process of validation is 'construct equivalence', the assumption that items in the translated language measure the same construct in the same way as in the original language (Byrne and Campbell 1999; Beaton et al. 2000a; Hawkins et al. 2020). Construct equivalence is necessary to confidently synthesise and compare data across different versions of a PROM. Back-translation methods were employed to qualitatively maximise construct equivalence. This involved translating the target language items back to English which were then checked by a native English speaker (RP) for construct equivalence. An Excel spreadsheet was used to track the process. The code descriptions in the analytical framework were used to describe the target concept for each item and check the back-translated items against. Incorrect translations were highlighted, explanations as to why the item was wrong were given and sent back to the translators for corrections. To illustrate, the item 'I have developed a related condition' (physical impacts) back-translated from the Arabic version translated as 'Something similar happened to me'. It was explained that the item was designed to assess whether the respondent has developed a comorbid condition.

6.2.4 Study procedure

The Delphi study was conducted over two rounds. Iqbal and Pipon-Young (2009) assert that Delphi studies that aim to generate consensus should consist of at least three rounds. However, a two-round Delphi is considered most suitable where there is clear literature or primary data (e.g. interviews) from which to establish the survey instrument. Since the concept elicitation study provided rich, qualitative data to develop the conceptual framework, the initial 'idea generation' round was considered redundant.

Prior to launch, the Delphi surveys for both rounds were pilot-tested with Public and Patient Involvement (PPI) by 14 individuals who provided feedback and suggestions on the structure and readability of the statements, as well as the usability of the online platform. All members

were either patients or patient organisation representatives. Suggestions for additional statements were not accepted at this point since this data would be collected systematically during the study. To quality check the different language versions at least one native speaker for each of the survey languages pilot-tested the survey. Some changes were made to the survey based on the PPI feedback including correction of typos and change of font colour to enhance readability.

Round 1 (from 14 December 2020 to 15 February 2021) aimed to a) reduce the number of items generated and b) ensure that any missing but relevant items were captured. The results from Round 1 were used to proceed from the longlist of 263 items to a shortlist for further ranking in Round 2. Item reduction was driven by participant consensus rather than a target number of items. Round 2 (12 May to 3 June 2021) aimed to further reduce the item pool. The results from Round 2 formed the first draft of PRIDD.

Potential participants received an email inviting them to take part in the study with a link to the online platform. For both rounds, participants were given at least four weeks to respond and the surveys took approximately 30 and 10 minutes to complete for Rounds 1 and 2, respectively. A reminder email was sent two weeks after the initial invitation email.

After reading the PIS and giving consent, participants were asked to register an account on the online platform to ensure that only those who participated in Round 1 participated in Round 2. This enabled tracking of participants' data across rounds and allowed an email prompt to complete Round 2 to be sent.

The survey for both rounds was split into three sections: 1) Demographic questionnaire; 2) Instructions; and 3) Delphi items. In the third section, participants were asked to rank the importance of each item to them using the Likert-type scale. Items were presented within their domains. In Round 1, participants could provide additional qualitative comments using free-text space in each of the domains to identify any important relevant concepts that were missing. This qualitative feedback was translated into English by the partnership professional transcription service.

6.2.5 Data analysis

Data management

Quantitative data were uploaded to SPSS version 26. Qualitative data were exported to NVivo 12 qualitative data software package.

Participant data

Sample characteristics were summarised for demographic (age, gender, country of residence, native language, patient organisation membership) and clinical variables (dermatological condition and time since onset). Response rates for each round were calculated.

Item-specific statistics

At the end of each round, simple item-specific descriptive statistics regarding the number of items retained (without alteration), removed, edited or added based on the consensus criteria and free-text responses were reported.

An *a priori* definition of consensus is important because it cannot be assumed that consensus is an automatic outcome at the conclusion of a Delphi study (Diamond et al. 2014) and prevents data mining (Grant et al. 2018). Following their systematic review of Delphi consensus criteria, Diamond and colleagues (2014) suggest the following definition of consensus regarding the prioritisation and exclusion of items: if ≥70% of participants score the item as 'critical' (options 'quite a lot' and 'very much') and if <15% of participants scored the same item as 'not important' (options 'not at all', 'not applicable' and 'somewhat'), the item should be prioritised. Items should be considered for removal if ≥70% of participants scored the item as 'not important' (options 'not at all/not applicable' and 'somewhat') and <15% of participants scored the same item as 'critical' (options 'quite a lot' and 'very much').

With the ICD-10 (2004) classifying over 1,000 dermatological conditions, the target population of PRIDD and this study is heterogeneous and, therefore, 70% consensus may be unrealistic. For this reason, Diamond and colleagues' definition of consensus was adapted for this study as follows: if ≥50% of participants scored the item as 'critical' (options 'quite a lot' and 'very much') and if <50% of participants scored the same item as 'not important' (options 'not at all', 'not applicable' and 'somewhat') the item was prioritised. Items were considered for removal if ≥50% of participants scored the item as 'not important' (options 'not at all', 'not applicable' and 'somewhat') and <50% of participants scored the same item as 'critical' (options 'quite a lot' and 'very much'). All other scoring patterns were taken to indicate non-consensus. The 50% consensus threshold, therefore, represents an agreement that all participants can accept as a 'working arrangement' (Humphrey-Murto et al. 2019, p. 1042).

One of the limitations of *a priori* specification is that certain items may fall just below the threshold of a fundamentally arbitrary cut-off. For this reason, items believed to be theoretically important that fell just below the consensus threshold were retained if there was sufficient justification for doing i.e. if an impact was reported frequently or strongly in the qualitative data, literature or clinical practice. In this way, the definition of consensus *guided* rather than *dictated* the development of the first draft of PRIDD.

Items were removed, retained, edited or added according to both the consensus criteria *and* the qualitative results. Items were retained if they met the consensus criteria and removed if they did not meet both the consensus criteria for prioritisation *and* did not receive sufficient support from the free-text responses. Items were added where impacts, discerned from the qualitative data, were not captured by an existing item. Items were edited if they did not meet the criteria for prioritisation but were important concepts according to the qualitative data.

Subgroup analyses were conducted using Mann-Whitney U tests to determine whether over-represented conditions (AD, PRP, psoriasis) differed on the items compared to other conditions overall. The prioritisation or removal of items where significant differences were found but the consensus criteria category was the same remained unchanged. Items where significant differences were found and the consensus from the sample overall had changed were prioritised for inclusion or removed according to the change in consensus.

Qualitative feedback

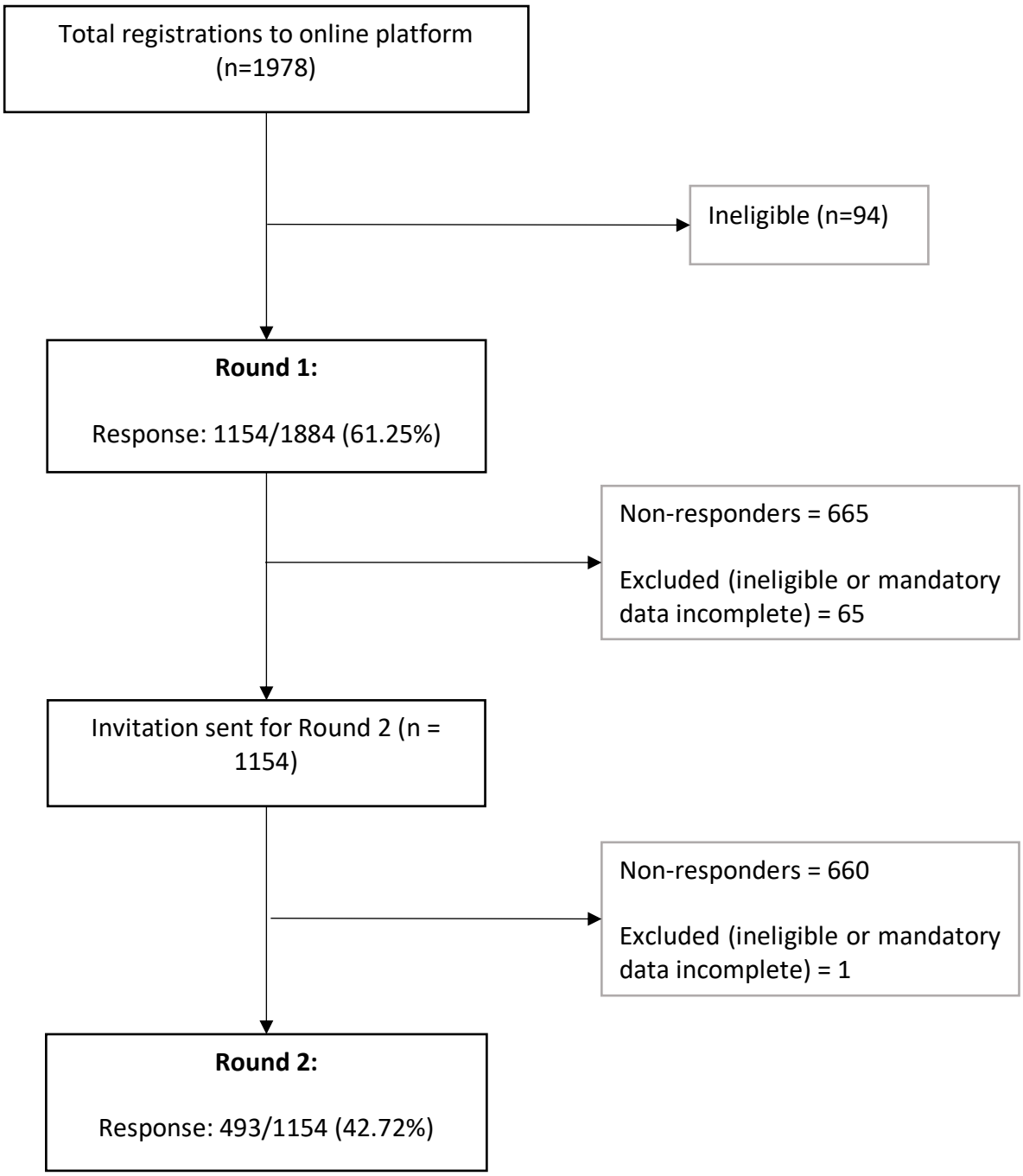
Thematic analysis was conducted on the free-text responses following an inductive-deductive approach using the conceptual framework. This approach enabled the exploration of both existing domains and items as well as emergent impacts. The data for each domain and item were summarised.

6.3 Results

6.3.1 Response rate

In total, 1978 people registered to the Delphi online platform. Of these, 1154 completed Round 1 and 493 Round 2 (42.72% response rate). 824 were excluded from Round 1 either because they did not meet the inclusion criteria (n = 665) or did not complete the minimum data required (age, gender, dermatological condition and at least one Delphi survey item; n = 65). One participant was excluded from Round 2 because they had not participated in Round 1. Figure 20. shows the recruitment process.

Figure 20: Flowchart showing responses to Delphi survey


Total registrations to online platform (n=1978)
Ineligible (n=94)
Round 1:
Response: 1154/1884 (61.25%)
Non-responders = 665
Excluded (ineligible or mandatory data incomplete) = 65
Invitation sent for Round 2 (n = 1154)
Non-responders = 660
Excluded (ineligible or mandatory data incomplete) = 1
Round 2:
Response: 493/1154 (42.72%)

6.3.2 Participant characteristics

All demographic data collected from the first round and tracked through the study are provided in Table 18. In total, 90 dermatological conditions (Table 19.) and 65 countries (Table 20.) were represented. The numbers presented refer to the participant's primary dermatological condition; 158 (13.69%) had multiple dermatological conditions.

Table 18: Participant characteristics of Delphi Rounds 1 and 2

	Round 1, *n* (%)	**Round 2, *n* (%)**
Total	1154	493
Gender		
Male	332 (29.2)	160 (32.5)
Female	802 (70.5)	325 (65.9)
Other	3 (0.3)	1 (0.2)
Age		
Overall	*M* = 49.34 (SD = 15.61, range = 18-94)	*M* = 52.27 (SD = 14.91, range = 18-85)
18 - 29	156 (13.5)	44 (8.9)
30 -39	186 (16.1)	13.2 (13.2)
40 - 49	208 (18)	81 (16.4)
50 - 59	274 (23.7)	133 (27)
60 - 69	204 (17.7)	107 (21.7)
70 - 79	117 (10.1)	57 (11.6)
80 - 89	8 (0.7)	6 (1.2)
90+	1 (0.1)	0
Member of a patient organisation		
Yes	584 (50)	260 (54.2)
No	584 (50)	220 (44.6)

Table 19: Dermatological conditions represented

Dermatological condition	**Round 1, *n* (%)**	**Round 2, *n* (%)**
Psoriasis	247 (21.4)	113 (22.9)
Atopic Dermatitis	207 (17.9)	86 (17.4)
Pityriasis Rubra Pilaris	199 (17.2)	94 (19.1)
Alopecia Areata	95 (8.2)	33 (6.7)
Pemphigus Vulgaris	65 (5.6)	34 (6.9)
Vitiligo	38 (3.3)	16 (3.2)
Acne	34 (2.9)	12 (2.4)
Bullous Pemphigoid	32 (2.8)	15 (3)
Lichen Sclerosus	32 (2.8)	9 (1.8)
Cicatricial Pemphigoid	22 (1.9)	0
Pemphigus Foliaceus	15 (1.3)	5 (1)
Other	168 (14.6)*	76 (15.6)

*Actinic Keratosis (Solar Keratosis), Albinism, Alopecia, Alopecia Areata, Alopecia Totalis, Alopecia Universalis, Androgenetic Alopecia, Angioedema, Autoimmune Skin Diseases, Basal Cell Carcinoma, Birthmarks, Burn Injuries, Candidiasis, Corticosteroid Addiction Skin, Cutaneous Lymphomas, Cutis Laxa, Dermatitis Herpetiformis, Dermatitis Hypomelanosis, Dermatitis Seborrheic, Dermatomyositis, Dyshidrotic Eczema, Ectodermal Dysplasias, Epidermolysis Bullosa, Erythema Nodosum, Erythropoietic Protoporphyria, Frontal Fibrosing Alopecia, Generalized Pustular Psoriasis, Genital Herpes, Haemangioma, Herpes Simplex Types 1 And 2 Infection, Hidradenitis Suppurativa, Hirsutism, HIV-Associated Skin Diseases, Hyperhidrosis, Ichthyoses, Keloid, Keratosis Pilaris, Lichen Planopilaris, Lichen Planus, Lichen Simplex, Lipoma, Lupus Erythematosus, Malignant Melanoma, Melanocytic Naevus, Melasma, Miliaria, Mycosis Fungoides, Nevus Flammeus, Pemphigus Superficial, Pityriasis Lichenoides, Pityriasis Rubra Pilaris, Porphyria Cutanea Tarda, Pressure Sore, Psoriasis Arthritis, Psoriatic Spondylitis, Pyoderma Gangrenosum, Raynaud's, Rosacea, Sarcoidosis, Scalp Folliculitis, Scarring Alopecia, Sebaceous Hyperplasia Epidermal Cyst, Sjögren Syndrome, Skin Allergy, Squamous Cell Carcinoma, Tinea Pedis, Chronic Topical Steroid Withdrawal Syndrome, Urticaria, Wells Syndrome

Table 20: Geographical spread of participants according to WHO regions

WHO region	Countries represented	Round 1, *n* (%)	Round 2, *n* (%)
African region	Cameroon, Ghana, Kenya, Nigeria, Uganda	12 (1)	2 (0.4)
Region of the Americas	Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Honduras, Mexico, Nicaragua, Panama, Peru, Puerto Rico, Trinidad and Tobago, Uruguay, US, Venezuela	565 (49)	237 (48.1)
South-East Asian region	Bangladesh, India, Indonesia, Nepal	8 (0.7)	2 (0.4)
European region	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Israel, Italy, Kyrgyzstan, Liechtenstein, Netherlands, North Macedonia, Norway, Poland, Portugal, Serbia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom	439 (38.1)	192 (38.9)
Eastern Mediterranean region	Lebanon, Pakistan, Qatar, Saudi Arabia	4 (0.3)	1 (0.2)
Western Pacific	Australia, China, Japan, New Zealand, Singapore	124 (10.8)	59 (12)

6.3.3 Round 1

Qualitative feedback

515 (44.6%) participants made at least one free-text comment. Two overarching themes were discerned: 1) *General feedback* and 2) *Feedback on items and domains*. These themes contributed to both shortlisting items and edits to the survey instructions. However, it was impossible to implement all of the feedback as some of it negated the purpose of PRIDD by, for example, suggesting disease-specific items.

Theme 1: General feedback

There was general praise from participants for the survey and how well it captured the impact of living with a dermatological condition, triangulating the results of the concept elicitation study. However, some felt it was too long or not relevant enough to their condition.

> Thank you for putting this research project together and for trying to understand the mental impact of dermatological conditions on patients and caregivers. It is very important work! (298) Patient with alopecia areata, USA

> The survey is very comprehensive. (303) Patient with AD, Portugal

Participants expressed confusion concerning the period of time the items referred to, which influenced responses. They recommended providing either a specific recall period or indicating whether the items should be answered according to a particular time period (i.e. acute or remission phase, present or past, or on or off effective treatment). The survey instructions were edited to make it clearer that participants should respond based on a time when their condition was most impactful.

> I wonder if it would be worth considering adding a time dimension to the questions you ask throughout this survey e.g. for each question you could ask respondents to answer for the present time and also for 'any time over the past x number of years'? (101) Patient with psoriasis, Ireland

> I'm past the acute stage so my answers are not so high scoring. If I'd filled this in a year ago most answers would rate badly. (302) Patient with pityriasis rubra pilaris, UK

People with conditions that affect the mucous membrane felt that the term 'skin' was not relevant to them. The survey instructions were edited to indicate that 'skin' included the mucous membrane.

> Do you consider mucus membranes in the mouth the same as "skin"? If so, I would need to change some of my answers. (459) Patient with mucous membrane pemphigoid, USA

A small number of people struggled to separate their responses regarding their dermatological condition and the impact of associated comorbidities or COVID-19. The survey instructions were amended to make this distinction clearer.

> On many of these questions, it would be hard to distinguish between my skin conditions and my diabetes. (117) Patient with malignant melanoma, USA

A small number of comments highlighted issues with the online platform. These were collated and passed on to the I.T. consultants to address, for example:

> I am trying to do this on an iPad and the buttons in the survey don't work (481) Patient with AD, USA

Theme 2: Items and domains

In general, the free-text responses supported the conceptual framework. No additional domains were identified, and the responses primarily served to confirm or clarify concepts, for example, physical discomfort emerged again as a common and significant impact.

> I have managed my condition by hiding it from sight. In the past, I always wore clothes to cover my arms and legs if I had a rash. As a child that was difficult at school, but I tended to be criticised for being smaller rather than for any skin problems. My eczema got worse in adult life and impacted on relationships. I was reluctant to go on dates or get close to anyone. I decided in my twenties I did not want to have children as I did not want to pass on my condition to anyone else. When I finally got married at the age of 40, my partner had two children already. Now in my mid-60s I am a grandpa to two children and greatly enjoy that role and am accepted as I am. (255) Patient with AD, Australia

> The pain and blood from the lesions in my mouth, throat, sinuses, colon really impacted my mind. I never ever want to hurt that much again. (336) Patient with pemphigus vulgaris, USA

While the concept of ‘mobility’ was important, participants felt that it was not adequately captured by the item ‘I struggle to walk’:

> The statement “I struggle to walk". The issue was having lesions in my private area made walking 'awkward' and uncomfortable, as well as concerned about rubbing and making this worse such as getting more lesions or infection. I word struggle I think implies lack of energy or muscle coordination. (244) Patient with pemphigus foliaceus, USA

Very few concepts not already captured were suggested. Of those that were, some were disease-specific, but others, such as ‘disgust’, were experienced across conditions.

> I would like you to be able to include questions associated with Nail Psoriasis, that is, Psoriasis of the Nails, which is why you noticed that my answers are "Not at all or not applicable". Consequently, you should take the following questions: 1.- He has a nail plate on his fingers, a few do not have it, they are all.2.- He has spots on his nails or thickening of the fingers, reddish colour, swollen, 3.- Has pain, pricks, burning, in your nails or fingers. Focus a little on the disease of Nail Psoriasis. (342) Patient with psoriasis, Colombia

> I cannot stand being seen because I am ashamed or disgusted with myself. (363) Patient with psoriasis, Argentina

People who had retired felt that the ‘work’ and ‘study’ items were not relevant to them:

> Please note that I had retired early (not because of PRP) and work or study was not relevant (446) Patient with pityriasis rubra pilaris, UK

It emerged that, though important, the ‘impact of healthcare’ domain had a causal rather than reflective relationship with impact and, therefore, was not consistent with the reflective measurement model of PRIDD. The underlying construct of this domain appeared to be ‘quality of dermatological care’ rather than ‘impact of dermatological conditions’, meaning that, for PRIDD to remain unidimensional, it was necessary to remove this domain.

I had to become sick enough and become poor enough to qualify for free healthcare in California. It was only after getting so low that I was able to access the care that actually helped mitigate my debilitating symptoms. (497) Patient with pemphigus vulgaris, USA

Item-specific descriptive statistics

The decision to retain, remove, add or edit items was made on a case-by-case basis according to the consensus criteria and free-text responses (Table 21.). Edited items include both single items that were reworded and the collapsing of one or more items.

Table 21: Item-specific descriptive statistics regarding the number of items retained (without alteration), removed, edited or added (Round 1)

	N	Examples
Retained	5	'My sleep is disturbed' (Physical) 'I am anxious' (Psychological)
Removed	79	'I struggle to save money' (Financial)
Edited	179	'I structure my day around my condition' (Daily) 'I have medical expenses such as prescriptions' (Financial)
Added	2	'I often feel disgusting' (Psychological) 'My ability to be the person I want to be with others is affected' (Social)

From these findings, the Round 2 survey was created; the shortlist resulted in five domains with 76 items and edited instructions.

6.3.4 Round 2

The top 20 most important impacts of dermatological conditions are shown in Table 22.

Table 22: Top 20 most important impacts to participants according to item means

Rank	Item	Impact domain	Mean
1	My skin is sensitive	Physical	2.81
2	The quality, look and feel of my nails, skin, hair bothers me	Physical	2.76
3	I experience physical discomfort, soreness or irritation	Physical	2.52
4	I feel dismissed or abandoned by the healthcare system	Psychological	2.46
5	I cope by living a healthy lifestyle	Psychological	2.46
6	My leisure time/activities are affected	Daily life and responsibilities	2.35
7	I have been affected financially	Financial	2.34
8	My life choices are affected (e.g. choice to have children)	Psychological	2.33
9	I rely on others to help me cope	Psychological	2.32
10	My daily routine has had to accommodate my condition	Daily life and responsibilities	2.29
11	My education has been affected	Daily life and responsibilities	2.22
12	I worry about other health consequences	Psychological	2.22
13	I worry about social situations	Psychological	2.21
14	I am tired, fatigued or lack energy	Physical	2.09
15	My everyday choices are affected (e.g. clothes, food, drink, products)	Psychological	2.02
16	I cope by avoiding challenges	Psychological	2.02
17	I often feel unsure or uncertain	Psychological	2.01
18	My general health has been affected	Physical	1.96
19	I am stressed	Psychological	1.95
20	My sleep is disturbed	Physical	1.94

Consensus

Of the 76 items, 29 (38%) met the criteria to be prioritised for inclusion (Table 23.) and 13 (17%) to be considered for removal. There was at least one item prioritised for inclusion in each of the five domains of impact, providing further support for the conceptual framework.

Table 23: Items that met the criteria to be prioritised for inclusion and the percentage that deemed them 'critical'

Item	%
Physical impact	
The quality, look and feel of my nails, skin, hair bothers me	78.9
I experience physical discomfort, soreness or irritation	72.4
My skin is sensitive	80.7
My sleep is disturbed	55.4
I am tired, fatigued or lack energy	58
My general health has been affected	56.5
The treatment for my condition causes me problems	54
Daily life and responsibilities	
My daily routine has had to accommodate my condition	65.3
My leisure time/activities are affected	68.8
Psychological	
I am stressed	63
I feel emotional pain or turmoil	56.5
I feel anxious	53.4
I am often worrying or feel nervous	52
I worry about social situations	55
I worry about other health consequences	65.6
I am always thinking about my skin, hair or nails	62.3
I often feel frustrated	49.4
I am self-conscious	51.8
I think that I'm unattractive	51.3
The course of my life has been affected	49.3

Item	%
My everyday choices are affected (e.g. clothes, food, drink, products)	64.3
I have changed my appearance or how I chose to style myself (e.g. clothes, hair, makeup)	55.5
I am expected or expect myself to perform or function as though I don't have a dermatological condition	55.9
I cope by focusing on the positive	72.1
I cope by living a healthy lifestyle	68.8
I control all the things that I can	73.7
Social	
My social life has been affected	56.5
I tend to avoid social events or situations	50.6
Financial	
I have extra out-of-pocket expenses (e.g. medical appointments and prescriptions, wigs, creams and ointments)	66.2

Subgroup analysis

During the concept elicitation study, it emerged that dermatological conditions could have a substantial impact on individuals' occupations, work choice or ability to perform work tasks. However, the qualitative feedback gathered in Round 1 indicated that this impact was not relevant to people who were retired. A Mann-Whitney U test was run to determine if there were differences in the item 'my career has been affected' between those at retirement age (70 and above) and those not. Distributions of the item scores for both groups were similar, as assessed by visual inspection. Item scores were statistically significantly lower for those at retirement age compared to those that were not, $U = 9526$, $z = -4.494$, $p = .001$, suggesting that this item was less important to people of retirement age.

To control for the influence of disease groups disproportionately captured in the Delphi, subgroup analyses were conducted to test whether such groups were skewing the overall items prioritised for inclusion in PRIDD. Mann-Whitney U tests were performed to determine

whether there were any differences across the items between the two most dominant conditions, psoriasis and AD, and the sample overall. Statistical differences were found between the psoriasis and AD groups compared with the sample overall on 24 (32%) and 15 (20%) items, respectively. Of these, only two items – 'my life choices are affected (e.g. choice to have children)', U = 13763, z = -3, p = .003, and 'I feel dismissed or abandoned by the healthcare system', U = 25096, z = 3.394 p = .001 – met the criteria to be prioritised for inclusion when AD and psoriasis and AD were controlled for, respectively.

Similarly, Mann-Whitney U tests were run to determine whether there were any differences across the items between those with PRP (who were overrepresented) and the sample overall. Statistical differences were found between the groups on 63 (82.9%) items. Of these, six items reached the threshold to be prioritised for inclusion and eight no longer met this threshold when PRP was controlled for. Those six items prioritised were:

- 'I have been treated differently by others regarding employment', U = 15491.5, z = -3.085, p = .002
- 'I feel anxious', U = 22382.5, z = 3.544, p < .001
- 'I feel like I have lost some control', U = 23067, z = 4.321, p < .001
- 'I cope by focusing on the positive', U = 22940, z = 4.035, p < .001
- 'I cope by avoiding thinking about my condition', U = 21202.5, z = 3.063, p = .002
- 'I struggle to perform roles important to me, for example, as a caregiver or as a man', U = 20359, z = 2.29, p = .023

Based on the consensus criteria and subgroup analyses, the list of items prioritised for inclusion was created (Table 24.).

Table 24: List of items prioritised for inclusion in PRIDD

Domain	Item
Physical	The quality, look and feel of my nails, skin, hair bothers me
	I experience physical discomfort, soreness or irritation
	My skin is sensitive
	I am tired, fatigued or lack energy
	My general health has been affected
	The treatment for my condition causes me problems
Daily life and responsibilities	My daily routine has had to accommodate my condition
	I have been treated differently by others regarding employment.
Psychological	I feel anxious
	I am often worrying or feel nervous
	I worry about social situations
	I am always thinking about my skin, hair or nails
	I often feel frustrated
	I am self-conscious
	I think that I'm unattractive
	my life choices are affected (e.g. choice to have children)
	I feel dismissed or abandoned by the healthcare system
	I control all the things that I can
	I feel like I have lost some control
	I cope by avoiding thinking about my condition
	I cope by focusing on the positive
	I struggle to perform roles important to me, for example, as a caregiver or as a man
Social	My social life has been affected
	I tend to avoid social events or situations
Financial	I have extra out-of-pocket expenses (e.g. medical appointments and prescriptions, wigs, creams and ointments)

This list formed the basis of the first draft of PRIDD (Appendix 13.), containing five domains and 27 items. The decision to retain, remove, add or edit items (Table 25.) here was primarily driven by the item concepts. To reduce the number of items, items that tapped the same underlying concept were collapsed. Again, edited items included both single items that were reworded and the collapsing of one or more items.

Table 25: Item-specific descriptive statistics regarding the number of items retained (without alteration), removed or edited (Round 2)

	N	Examples
Retained	23	'The quality, look and feel of my nails, skin, hair bothers me' (Physical)
Removed	37	'I am concerned that people only see me as my condition' (Social)
Edited	16	'I have found it hard to work or study' (Daily life and responsibilities)

6.4 Discussion

6.4.1 Main findings

This Delphi study represents the second of three steps in the content validity phase of PRIDD development. It aimed to achieve consensus with patients on the most important impacts of living with a dermatological condition and subsequently develop a list of items to prioritise for inclusion in PRIDD. The results generated the first draft of PRIDD, consisting of 27 items across five domains, ready for pilot-testing in the next phase of development.

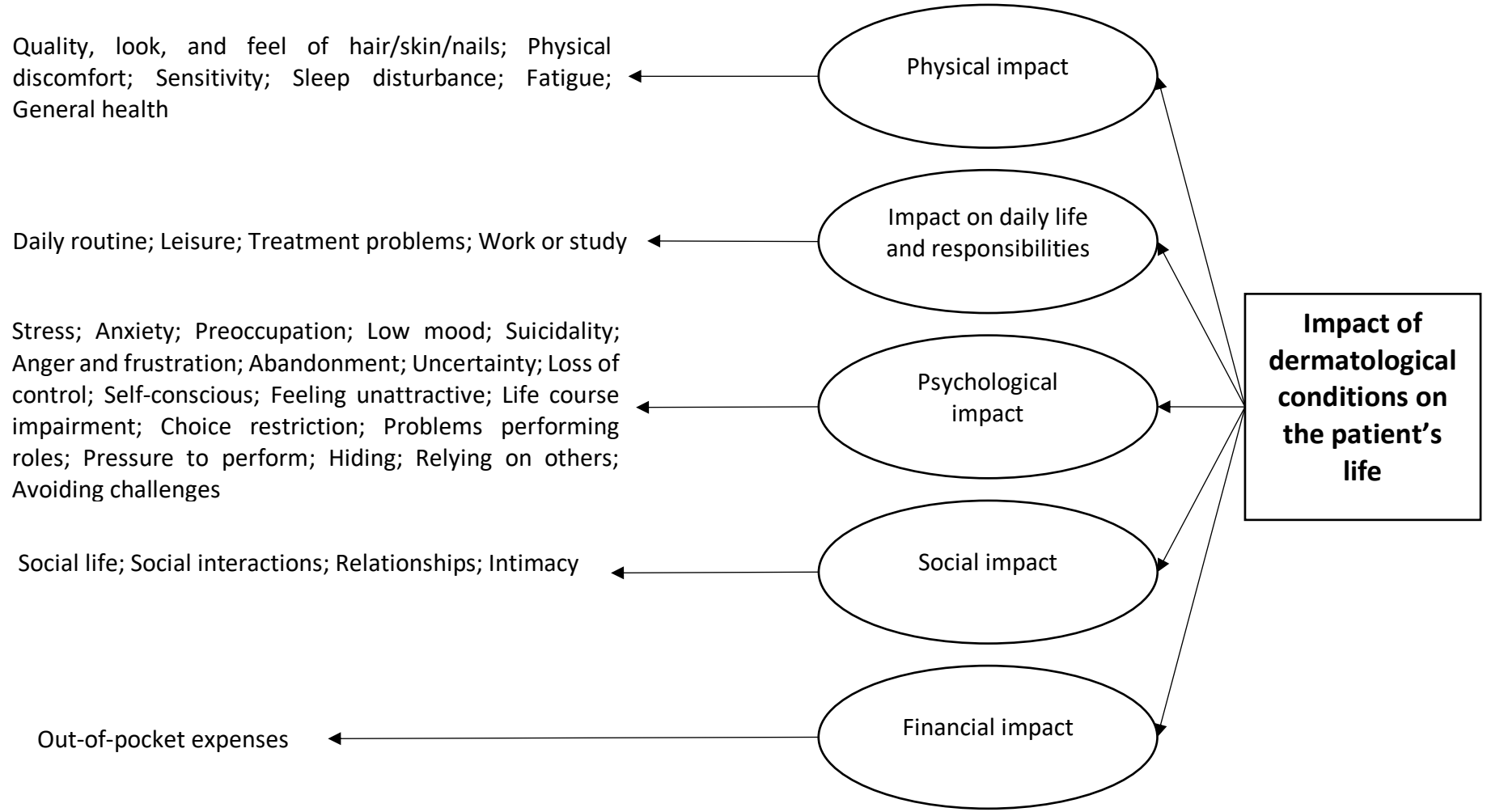
6.4.2 Implications for measuring the impact of dermatological conditions

Refining the conceptual framework

Data gathered from the free-text responses supported the conceptual framework of impact generated in the previous chapter as no new domains were suggested. The previous chapter

noted the uncertainty regarding the relationship between the 'impact of healthcare' domain and the construct of impact. While the impact of healthcare on the patient's life remains important, it was clear that healthcare *contributed to* rather than *reflected* impact. This relationship is consistent with a formative rather than reflective measurement model of impact. To meet the assumption of uni-dimensionality, the impact of healthcare domain was removed from the conceptual framework (Figure 21.). It remains in the theoretical model, however, to aid a greater understanding of impact. Given the obvious importance of the impact of healthcare domain to patients, the data gathered thus far could form the basis of a separate, new measure of the 'quality of dermatology services', which could be used to target quality improvement efforts at the local, national and global level.

Figure 21: Conceptual framework of the impact of dermatological conditions on the patient's life (version 2)



PRIDD makes a unique contribution to dermatology PROMs

The first draft of PRIDD was mapped onto the PROMs identified in the systematic review (Appendix 14.). This exercise revealed that not one of the existing PROMs captured *all* of the impacts the study participants considered most important. Furthermore, PRIDD includes three impact concepts – abandonment, problems performing roles and pressure to perform - not captured in any of the existing measures. This demonstrates that, as the first PROM to capture all aspects of the conceptual framework as a unified construct (Figure 21.), PRIDD advances knowledge in and makes a unique contribution to dermatology.

The challenge of developing a dermatology-specific PROM

The data gathered reflect the challenges inherent in developing a dermatology-specific PROM compared to a disease-specific or even other speciality-specific PROMs. With the ICD-10 (2004) classifying over 1,000 dermatological conditions, dermatology patients are a particularly heterogeneous group in relation to age and condition type, relative to other medical specialities, so finding issues shared across most conditions may be more challenging. Related to this was the difficulty of implementing all of the qualitative feedback provided as some participants sought to capture impacts specific to their condition (e.g. items specific to nail psoriasis). The advantage of a large number of participants across conditions outweighs the issue of heterogeneity in that the data gathered have low specificity but high sensitivity. Recruiting a global sample is likely to have further exacerbated this heterogeneity and, therefore, it was unlikely that high levels of consensus would be found. Recognising this, along with the importance of an *a priori* definition of consensus, Diamond and colleagues (2014) recommended definition of consensus was adapted by lowering the threshold from 70% to 50%. In this way, consensus was viewed as a 'working agreement' for the target population and, by not forcing consensus, will likely improve the longer-term acceptance of PRIDD. Despite the heterogeneity of the sample, these consensus thresholds were able to prioritise items for inclusion in PRIDD. This study demonstrates that while each dermatological condition may have a unique impact profile, there are also similarities and, therefore, a dermatology-specific measure is appropriate.

6.4.3 Strengths and limitations

Study design

The use of the Delphi method to prioritise items for inclusion in PRIDD is a major strength of this study and the overall PRIDD development process. The Delphi survey provided a systematic and transparent means of reducing the items with high levels of patient input while offsetting some of the limitations of the concept elicitation study. First, helpful aspects of group decision-making (e.g. obtaining expert input) were accessed while limiting their unhelpful attributes (e.g. conformity to the dominant view). Unlike the group discussions and individual interviews, where participants were identifiable to the other participants and/or researchers, in the Delphi survey participants remained anonymous. The ability to anonymously and confidentially respond to sensitive topics may have reduced social response bias and increased the validity of the results. Finally, the online nature of the Delphi survey facilitated group communication without imposing geographical or temporal constraints on participation. This enabled the recruitment of a large global sample to test and prioritise the concepts elicited in the previous study. However, limitations were evident, for example access to the internet was limited in some regions. In particular, there were issues recruiting and collecting data from Chinese participants because of the internet firewall. To overcome this, PDF copies of the survey were provided to participants who had issues accessing the online survey. With this in mind, the online survey ultimately allowed us to reach more participants and diversity much more efficiently than paper-based methods would allow. Future survey studies, especially those of a global population, should consider mixed-mode (paper and web-based) surveys as this increases response rates (Greenlaw and Brown-Welty 2009).

At the same time, the Delphi method built on the strengths of the previous study. An exploratory (qualitative) first Delphi round is recommended so that an initial group of experts produces the items, thereby increasing reliability and validity (Iqbal and Pipon-Young 2009). This Delphi study consisted of two rounds using the results of the concept elicitation study in place of an initial qualitative round. By relying on the in-depth qualitative research outlined in the previous chapter, an arguably more rigorous approach to Delphi item generation was followed than the text-based approach used in initial qualitative rounds. This also served to

offset the critique of quantitative research that it is focused on the interests of the researcher (Bryman 2006) by ensuring that the items were of interest and importance to patients.

The Delphi survey was designed and conducted to ensure the highest levels of quality and patient recruitment. The online platform was developed by colleagues with expertise in Delphi surveys to ensure the best participant experience, track participants across the rounds and facilitate data entry. A particular strength of the survey is that it was translated from the original English language version into five other languages - German, Spanish, French, Arabic and Chinese - thereby recruiting from the global target population. In doing so, we worked with a professional translation company following standard cross-cultural translation procedures (i.e. forward- and back-translation) to ensure construct equivalence. Not only did this permit data synthesis and comparison across languages, but it also strengthened validity by allowing participants to consider the concepts in their own language. The Delphi survey was pilot-tested with PPI by a group of patients and/or patient organisation representatives who provided feedback and suggestions on the structure and readability of the statements, as well as the usability of the online platform. To check the quality of the different language versions, at least one native speaker for each of the survey language versions took part in pilot-testing. We took a pragmatic approach to selecting the languages for translation by prioritising those spoken in the countries where IADPO had member organisations and the most commonly spoken languages in the world. Though some languages - and therefore populations - were missing, the variety of languages increased the validity and robustness of the data compared to an English version alone. Despite the Arabic language versions availability, only one Arabic speaker participated. In the future, a content validity study should be conducted to test the content validity of the final version of PRIDD with a greater number of Arabic speakers.

Although the Delphi method has many benefits for the development of a PROM, there is a notable limitation, albeit one that can be offset later on in the process. Because PRIDD items were prioritised for inclusion based on consensus thresholds, the first draft of PRIDD is unlikely to capture the more severe or extreme impacts that are very important but to relatively few people, for example, suicidality. This means that by relying only on the results of the Delphi, it is unlikely that PRIDD would capture the full range of impact, potentially

resulting in floor and ceiling effects. In Rasch terms, this would mean that PRIDD would not be well-targeted and, therefore, lack precision. Further testing is required in the psychometric phase of PRIDD development to ensure it captures the full range of impact. Item refinements may be required to ensure PRIDD has precision.

Similarly, psychometric testing will be useful in selecting a definitive list of items for each domain. To illustrate, while fatigue emerged as a physical and psychological aspect of living with a dermatological condition in the previous chapter, it was presented within the physical domain during the Delphi survey. This is because fatigue is a common symptom of long-term conditions (Whitehead 2009), including dermatological conditions (Tarazi et al. 2019), and experienced physically, though strong correlations with psychological and social factors such as low mood, anxiety, poor sleep quality and chronic pain are noted (Omdal et al. 2003). (Omdal et al., 2003). One conception of the experience of fatigue is that it is the difference between the current and normal expected amount of effort required to complete a task (Ackerman, 2011). This understanding of fatigue acknowledges it as a centrally driven phenomena that is most closely aligned with the physical domain of impact. A factor analysis conducted during the psychometric testing phase will be invaluable in determining whether fatigue is more suitably listed under the physical and psychological domain.

Sample

Unlike many PROM development studies, there was a high level of patient involvement in the item reduction process. A large and diverse sample of 1154 people with dermatological conditions was recruited, far exceeding the typical Delphi sample size of 11 to 30 members (Dalkey 1969; Akins et al. 2005) and the minimum sample size of 30 required for statistical analyses (Chuenjitwongsa 2017), by recruiting through IADPO's membership network. In total, 90 dermatological conditions and 65 countries (across all WHO regions) were represented, with participants with an array of disease types (i.e. common, rare, inflammatory, autoimmune etc.). Moreover, there was an acceptable split across age groups and genders (females 71%) for survey research. The sample, therefore, provided high-quality evidence of content validity from the target population.

Despite this, the general limitations of non-probability sampling apply. Specifically, it is impossible to know how well the sample represents the target population, reducing the generalisability of the study findings. Indeed, there was evidence that the sample was not representative of the global population of people with dermatological conditions. Firstly, as noted above, only one Arabic speaker participated. Secondly, conditions were over- and under-represented in relation to their prevalence. PRP, an ultra-rare condition – the exact prevalence and incidence is unknown, but the incidence of PRP was approximately 1 in 5000 among patients presenting to a specialist dermatology centre (Burns et al. 2010) - was especially overrepresented. This was because a PRP patient organisation enthusiastically promoted the study to their members. The overrepresented groups (PRP, AD, psoriasis) were prevented from exerting undue influence on the items prioritised for inclusion by checking for significant statistical differences between these groups and the sample overall.

Conversely, people with acne were under-represented, accounting for less than 3% of the study sample. Nevertheless, the study findings are broadly consistent with a recent Delphi survey conducted to determine the most prominent impacts of acne identified by patients and clinicians in Canada, the USA and the UK (Tan et al. 2020). The study found that impacts could be categorised into three domains: psychological, social and treatment-related. Similar to the current study and past findings (Aktan et al. 2000; Martin et al. 2001; Ng et al. 2002; Rapp et al. 2004), Tan and colleagues identified cognitive (e.g. self-concept) and mood-related (e.g. feeling stressed, sad or depressed) psychological factors. They also found discrepancies between patients and clinicians regarding the impact of acne, demonstrating the importance of PROMs.

The same limitations of recruiting through IADPO as noted in the previous chapter apply. Namely, participants may not represent the experiences of those who are not members of a patient organisation. The risk of this is reduced in the current study because half of the participants were not members of a patient organisation. Furthermore, unlike in the previous study, in this study patient members were not personally chosen to participate by their organisation leader. Together, these factors provide evidence that the results of the concept elicitation study have been confirmed by a wider group of patients who are likely to be more representative of the target population.

Response rate

The response rate for the survey (43%) was good compared to the average figures (29%) reported by survey companies (FluidSurveys Team 2014). Based on the feedback from participants, we acknowledge that the length of Round 1, which took up to 30 minutes to complete, contributed to non-response and dropout. This corresponds to evidence indicating an inverse relationship between response rates and survey length (Hoerger 2010). In this context, the response rate is respectable. However, a dropout rate of any size carries the risk of non-responder bias. Attrition was minimised by sending up to three email reminders including the closing date of the survey. In the email reminders for Round 2, we indicated that the survey would take only 5 to 10 minutes to complete.

6.4.4 Implications for clinical practice

This study provides quantitative data from the patients' perspective in support of the proposed thesis that the psychological aspects of dermatological conditions result in significant additional impact and, therefore, a biopsychosocial approach to assessment and management is necessary. This is exemplified in the first draft of PRIDD in which the psychological impact domain alone accounts for almost a third of the total items.

Beyond its role in the development of PRIDD, the Delphi survey provides insight into what people with dermatological conditions consider important issues impacting on their lives (Table 22.). As with the approach to the WHO's QoL measure WHOQOL (1998) development, two levels of data are provided – whether an impact is important and, if so, how much. Clinicians can use this knowledge to guide their discussion of the impact of dermatological conditions with patients during consultations and to target interventions to improve QoL. In the previous chapter, we recommended PsoWell-type training for dermatology-specialist staff to improve knowledge of dermatological conditions, consultation skills and confidence to address the psychological aspects of these conditions and health behaviour change with patients during standard dermatology consultations. The results of this study indicate which impacts this training package should focus on.

6.4.5 Implications for research

The James Lind Alliance Priority Setting Partnership (PSP) is a research initiative designed to address the imbalance between researcher interests and patient, clinician and carer needs in the way research is designed and funded. PSPs enable equal collaboration between patients, clinicians and carers to identify and prioritise research questions that are of direct relevance and potential benefit to patients and clinicians. James Lind Alliance PSPs have been conducted for acne (Layton et al. 2015), alopecia (Macbeth et al. 2017), eczema (Batchelor et al. 2013), hidradenitis suppurativa (Ingram et al. 2014), psoriasis (Majeed-Ariss et al. 2019) and vitiligo (Eleftheriadou et al. 2011), but none have been conducted for the global dermatology population as a whole. In its absence, the top-ranked impact concepts (Table 22.) in this Delphi study could stand in by representing what patients think are the most important impacts of their condition and developing corresponding research questions and initiatives. The Delphi findings are broadly consistent with the existing PSPs in that the top 10 priorities across the conditions acknowledge the need for research on psychological interventions and lifestyle factors as well as traditionally biomedical aspects such as pharmacological interventions.

Involving the target population during development is deemed a necessary part of creating a high-quality measurement instrument. Typically, item reduction is achieved through statistical techniques (i.e. factor analysis and examination of item characteristics). Consensus-seeking methods, such as Delphi surveys, are being increasingly employed to develop PROMs as they provide patient insight into each item (e.g. Hepworth and Rowe 2018). The large reduction in number between the item pool (263 items) and the first draft of PRIDD (27 items) here highlights the utility of Delphi surveys in PROM development and therefore we recommend this approach.

Patient insight during item reduction may be especially useful when developing speciality-specific measures like PRIDD, where the item pool is likely to be broader than disease-specific measures, so a working agreement across disease groups on items prioritised for inclusion must be attained. Building this collaboration into the development of PRIDD potentially

improves the quality of the final product. However, while consensus-seeking methods allow participants to have greater input into the final item pool than purely statistical methods, ideally, they would not be the sole method of item reduction. Statistical item reduction techniques will be employed during the (post-doctoral) psychometric phase of PRIDD development. A concept can be expressed in different ways by different people and the 'best fit' can be tested in the pilot test and psychometric phase. The combination of these methods serves to enhance content validity and establish the psychometric properties of the scale. As such, measure developers should consider employing participatory methods of item reduction *in addition to* the conventional processes (e.g. Apfelbacher and Nelson 2017; de Vet et al. 2011).

The outcome of this study was the production of the first draft of PRIDD. To complete the next and final step in the content validity phase of development, PRIDD should be pilot-tested with people with dermatological conditions to evaluate the measure's comprehensiveness, comprehensibility, relevance, acceptability and feasibility and make refinements accordingly in preparation for the final psychometric phase.

6.4.6 Summary

This Delphi study provided patient input into the item reduction process and resulted in the first draft of PRIDD, ready for pilot-testing. The data triangulated and refined the conceptual framework of impact and strengthened the evidence for the content validity of PRIDD. The results provide insight into what people with dermatological conditions from around the world consider to be the most important issues impacting their lives.

Chapter 7: Phase 4: Pilot-testing

7.1 Introduction

Based on the concept elicitation and Delphi studies, the first draft of PRIDD was created (Appendix 13.). This version has 27 items across five domains. The previous two chapters ensured that PRIDD's items are comprehensive and relevant to people with dermatological conditions.

PROMs such as PRIDD make high demands on the motivation and skills of respondents which may cause problems with data quality in terms of validity, reliability and completeness (Jansen and Hak 2005). To minimise problems with the data quality of PRIDD, motivational and cognitive conditions should be met; that is, respondents must a) positively identify with PRIDD and/or the research aims of the study it is used in and its completion should be perceived as worthwhile and b) understand PRIDD's items and response options.

The first draft of a measurement instrument should undergo pilot-testing with a small sample of individuals from the target population, after which adaptations are made (de Vet et al. 2011; Terwee et al. 2018a). The purpose of the pilot is to rigorously test three aspects of content validity: comprehensiveness (all key aspects of impact are present), comprehensibility (items are understood by respondents as intended) and relevance (all items are relevant to the impact of dermatological conditions from the patients' perspective; Terwee et al. 2018a). The acceptability (whether patients are willing to complete the instrument) and feasibility (whether patients are able to complete the instrument) are also tested.

Pilot-testing typically consists of asking patients about their experience of completing the questionnaire; this is described as cognitive interviewing. Apfelbacher and Nelson (2017)

identify cognitive interviewing as the final step in the content validity phase of measure development (

Figure 6.). As with concept elicitation, people with dermatological conditions must be involved in pilot-testing because only they can judge the comprehensiveness, comprehensibility and relevance of PRIDD (de Vet et al. 2011). This chapter will describe how PRIDD was pilot-tested and subsequently refined through cognitive interviewing.

7.1.1 Cognitive interviewing

Measurement instrument development involves formulating items that are clear, unambiguous, understandable and permit respondents to answer the question as intended (Drennan 2003). The process of answering PROMs can be viewed as an interaction between the respondent and the measure (Bode and Jansen 2013). While researchers can observe the measure and completed measure, the process of completion is not observable. The most widely used cognitive theory underpinning cognitive interviewing is Tourangeau's (1984; 2000) four-stage model of question response, an amalgamation of information processing theories and survey methodology. The model explores how respondents approach the task of answering items and identifies problematic items by considering their storage, retrieval, and organisation of information (Drennan 2003; Streiner 2015). The model explicates the response process in four main cognitive steps: 1) comprehension of the question; 2) memory retrieval of necessary information; 3) deciding which information is needed; and 4) responding to the question or choosing the adequate response option.

Cognitive interviews use a semi-structured topic guide to direct the interview according to Tourangeau's model. Qualitative interviewing provides direct information about how participants interpret questions and choose their answers. Whereas the purpose of the interviews in Chapter 5 was to generate concepts for PRIDD, the purpose of the cognitive interviews is to reach consensus on PRIDD's format and structure by confirming that the items, instructions and response options are unambiguous, inoffensive, relevant and appropriate to the target population.

Cognitive interviews can be an efficient way to gather high-quality feedback on a wide variety of aspects of PRIDD. The depth of feedback is greater than alternative feedback collection methods such as surveys while providing a more systematic framework for collecting the feedback than unstructured conversations with respondents. This method highlights misunderstandings that may otherwise be overlooked (DeVellis 2017). It therefore provides additional assurance that the researcher and respondent have a common understanding of the meaning of each item, consequently enhancing the validity of PRIDD.

Approaches to cognitive interviewing

Although there are a variety of approaches, cognitive interviewing is generally an iterative process whereby interviewers identify issues with the measure's items, structure, instructions or recall period (e.g. unclear questions, unfamiliar words, ambiguous syntax, missing time-frame, lack of an appropriate answer), the measure is modified accordingly, and the revised measure is used in subsequent cognitive interviews. This process continues until consensus is reached that the measure is acceptable, resulting in a validation-ready version of the measure.

The two most well-known and commonly used approaches to cognitive interviewing are the 'think-aloud' and 'probing' techniques. The think-aloud method is used to gain insight into the respondents thinking or decision-making process while completing the measure (Someren 1994). Participants are asked to explain how they arrive at their answers to each question. Brod (2009) argues that because the role of the interviewer is usually limited to reading the items, the think-aloud method has the advantage of reducing the influence of the interviewer's biases and standardising the interview administration across participants. Participant responses may more accurately reflect their thought processes with this method compared with post hoc interviewing such as probing which relies on recall (Beatty and Willis 2007). However, some participants may experience difficulty verbalising their thought processes and the act of doing so may affect their responses. The think-aloud method, therefore, is an imperfect technique but the best approximation of an observation of the response process (Hak et al. 2008).

In contrast, probing is used to gain insight into how respondents perceive the content and interpret the items and occurs *after* they have responded (Brod et al. 2009; de Vet et al. 2011). Participants are asked to explain their interpretation of the item, along with how difficult it was to answer and how they arrived at their answer, with follow-up questions to assess recall time frames and vocabulary comprehension (Brod et al. 2009). The probing method has two main advantages. First, it prevents the interview process from affecting the participant's answers since probes occur after they have answered the items. Second, the structure and guidance provided by the interviewer during probing may pose less of a burden on participants and help them to stay focused.

The think-aloud and probing methods each offer a set of advantages and drawbacks. Both are designed to reveal possible sources of misunderstanding and facilitate responses that provide new information or insights that the participant would not offer without being specifically asked to do so. However, when used alone, each method may not be sufficient to completely cover all aspects of PRIDD's content from the patient's perspective. De Vet and colleagues (2011) recommend the Three-Step Test-Interview (TSTI; Jansen and Hak 2005; Hak et al. 2008) method of cognitive interviewing as this combines both the think-aloud and probing methods and can, therefore, offset the weakness of each and provide a deeper understanding of how questions are interpreted and answered.

The TSTI assesses the quality of PROMs by observing actual instances of interaction between the measure and a respondent (the response process) before exploring reasons for their response behaviour (Hak et al. 2008). Jansen and Hak (2005) empirically evaluated the productivity of the TSTI against an expert review on the same measure of alcohol consumption and found that the TSTI confirmed most problems identified in the expert review along with many others. The authors concluded that "the TSTI is a powerful test tool with a high ecological validity" (p. 103). In addition, whereas other methods tend to assess each question separately, the TSTI also considers the overall measure making it more sensitive to routing errors and interaction effects between items.

7.1.2 Aims

This chapter concludes the content validity phase of PRIDD development. It aims to pilot-test PRIDD by qualitatively exploring whether the measure (items, structure, response options and recall period) is comprehensive, comprehensible, relevant, feasible and acceptable to people with dermatological conditions through cognitive interviews.

7.2 Methods

7.2.1 Design

A qualitative study using the TSTI method of cognitive interviewing was conducted to pilot test PRIDD.

7.2.2 Sample and recruitment

As in phases 2 and 3, participants were drawn from PRIDD's target population using purposive sampling to achieve a sample with maximum variation according to participants' dermatological condition and demographic factors (age, gender, and country of residence). Participants met the inclusion criteria if they were an adult (aged ≥ 18 years) with a dermatological condition and spoke English sufficient to take part in the interview and complete PRIDD independently (without a translator). Patients who required translation to complete PRIDD were excluded as construct equivalence could not be determined and, therefore, confidence in the evidence of content validity would be lacking. Children and proxies, such as family members or carers, were also excluded.

Sample size requirements for cognitive interviews vary. The number of cognitive interviews needed is a function of the complexity of the measure's construct of interest, items and instructions and the diversity of the target population (Patrick et al. 2011a; Terwee et al. 2018b) along with the scope of the research question and 'information power' in the sample (Malterud et al. 2016). Willis (2005) has suggested that 7 to 10 interviews are sufficient.

However, others have found that much larger samples are required to achieve an acceptable likelihood that even common problems are detected (Blair and Conrad 2011; Perneger et al. 2014). Perneger and colleagues (2014) concluded their review of cognitive interview sample sizes by recommending a default sample size of 30 participants. Given the complexity of PRIDD's construct of interest and the large number and diversity of dermatological conditions, we aimed for a sample size of 30. However, recruitment ceased at the point of data saturation; when there was sufficient evidence that most problems had been detected and/or resolved (Patrick et al. 2011a; Boeije and Willis 2013).

Participants were primarily recruited through IADPO's membership network, following the same procedure as described in Chapter 5. Briefly, participants were directed to a secure online platform which included the PIS, electronic consent form and interview booking information. Twelve patient organisations were invited to the interviews; 8 (66.7%) agreed to participate. Reasons for non-participation included lack of staff capacity, scheduling conflicts and non-response.

7.2.3 Materials

A topic guide was developed detailing the interview procedures, instructions and questions (Appendix 15.). The cognitive interview questions were developed following guidance from the International Society for Pharmacoeconomics and Outcomes Research's (ISPOR; Patrick et al. 2011a) and Brod, Tesler and Christensen (2009). They met the COSMIN standards for cognitive interviewing by asking participants about both the comprehensibility *and* comprehensiveness of PRIDD as well as assessing the instructions, items and response options separately (Terwee et al. 2018b). The topic guide was semi-structured to standardise the interviews while allowing the interviewer to probe the reasons or explanations for the participants' responses. An item definition list (Appendix 16.) accompanied the topic guide. The list stated the intended meaning of each item so that the interviewer could assess whether the participant understood the items as intended. Two versions of PRIDD were used during the interview: one with the original item order and one with items in reverse order. This enabled the researchers to test item order effects (i.e. whether the order in which the

items are presented affects people's responses) and establish whether items were understood independently of each other. An online platform was created to enrol potential participants to the study using the PIS and consent form and included a demographics questionnaire.

7.2.4 Procedure

Twelve online synchronous interviews were conducted via Zoom from 2 August to 1 September 2021. Following informed consent, interviews were arranged with one of four researchers (RP, RH, ML and NTG), at a mutually convenient time, taking into account different time zones. All interviewers were trained in cognitive interviewing by CB and had backgrounds in healthcare including health psychology, biochemistry and medicine. Interviews were scheduled for one hour, but participants were reminded that they could choose to end the interview at any point.

Following general introductions, the three steps of the TSTI method were followed, as reflected in the topic guide:

Step 1: The interviewer sent the participant a link to an online platform that included either the original or reversed version of PRIDD using the chat function in Zoom. Participants were asked to share their screen and to not start completing the questionnaire until the audio recorder was turned on so that the observation-based component of the TSTI procedure could be completed. The interviewer observed (both visually and aurally) the respondent while reading, interpreting, and answering PRIDD. During this step, the interviewer did not comment but observed and took notes for use in steps 2 and 3. The interviewer also recorded the time taken to complete PRIDD.

Step 2: The interviewer clarified and supplemented the data gathered in step 1 by interviewing the participant about their response behaviour. The questions asked at the second step depended on the observations of step 1; for example, if the participant was observed to hesitate the interviewer might ask “I saw that you hesitated when answering question 1, can you remember why you hesitated?’’

Step 3: The third and final step was an interview with in-depth probing to elicit experiences, explanations, interpretations and opinions from the participant.

After the first six participants were interviewed, the findings were reviewed by RP, who made a decision as to whether any changes to any aspects of PRIDD were required. The interviews were repeated until there was consensus from participants or data saturation was reached that PRIDD was appropriate and most of the serious problems were detected.

The interviews were audio-recorded using a high-quality audio recorder (OLYMPUS WS-833) and transcribed verbatim by a Cardiff University approved independent transcription provider. Transcripts were checked and anonymised by RP and participants were allocated participant identifiers.

7.2.5 Data analysis

Data collection and analysis were interrelated and concurrent, with analysis beginning after the completion of the first interview. Accordingly, generated themes and edits made to PRIDD were incorporated into subsequent interviews.

Quantitative data were uploaded to SPSS version 26 and sample characteristics were summarised for clinical and demographic variables. Qualitative data were exported to NVivo 12 qualitative data software package. RP independently analysed the data. NTS reviewed the coding and results reporting for accuracy. Analysis followed the thematic analytical model of cognitive interviewing as outlined by Miller and colleagues (2014). Figure 22. illustrates each step and product in the analytical process. The downward pyramid on the left represents the reduction of data from the raw data of individual interviews to the thematic schema generated by the comparisons of interviews. The upwards pyramid on the right represents the progression and growth in understanding of item performance.

Figure 22: The steps in the thematic analytical model of cognitive interviewing and their products in terms of data reduction and knowledge building adapted from Miller and colleagues (2014)

Analytical step	Data reduction product	Tiers of knowledge production
1. Conducting	Cognitive interview text	Individual respondent's explanation of answers
2. Summarising	Fieldnotes	Record of respondent difficulties identification of potential themes
3. Comparing across respondents	Thematic schema	Identification of 'what the question captures'
4. Comparing across groups	Advances schema	Response process differences across groups
5. Concluding	Conclusions	Explanation of question performance

Step one and two apply to the conduct of the interviews. In step three, all participant responses regarding a particular item were reviewed to identify common themes across participants using constant comparison techniques. In step four, subgroups were compared to identify whether any particular theme was more apparent among any specific group of respondents. This served to identify how participants' experiences and social contexts affected item interpretation and responses. In the fifth and final step, the data were synthesised and how the item and subscales performed across participants was summarised. In adhering to the thematic analytical model of cognitive interviewing, a summary of each item's performance was produced that established the comprehensiveness, comprehensibility and relevance of the items, informing evidence-based improvements.

7.3 Results

Eighteen people completed the online consent form and demographics questionnaire. Of these, three people were excluded because they were not sufficiently proficient in English to complete PRIDD independently and three did not respond to invitations to schedule an interview. In total, 12 people (response rate = 67%) across six dermatological conditions (Table 26.) and four countries participated in an interview.

Table 26: Participant characteristics

	***n* (%)**
Total	12
Age	*M* = 53.42 (SD = 15.87, range = 29 – 75)
Gender	
Male	7 (58.3)
Female	5 (41.7)
Dermatological condition	
Common*	7 (58.3)
Rare**	5 (41.7)
Duration (years)	*M* = 31.39 (SD = 20.59, range = 3 – 60)
Country	
UK	7
Ireland	3
Canada	1
USA	1

*Psoriasis (n = 5); Alopecia (n = 2)

**Discoid Lupus, Hidradenitis Suppurativa, Extensive Linear Porokeratosis (n = 1); Pityriasis Rubra Pilaris (n = 2)

Table 27. outlines the changes made to PRIDD between the three rounds of cognitive interviews. Evidence-based adjustments resulted in a 26-item version of PRIDD (Appendix 17.). As only minor edits to the instruction were made following the third round of interviewing, all items were tested in their final form meaning that PRIDD is ready for field-testing in the next (post-thesis) phase of development.

Table 27: Documentation of changes made to PRIDD between cognitive interview rounds

Part of questionnaire	Round 1	Round 2	Round 3
Instructions	We know dermatological conditions impact people over a long period of time, but the aim of this questionnaire is to measure how much your dermatological condition has affected your life OVER THE LAST TWO WEEKS. Please mark one box for each question. **NOTE**: The term 'skin' here includes the skin, hair, nails and mucous membrane.	We know dermatological conditions impact people over a long period of time, but this questionnaire aims to measure how much your dermatological condition has affected your life **OVER THE LAST MONTH**. Please mark one box for each question. **NOTE**: The term 'skin' here includes the skin, hair, nails and the skin-like inner lining of organs and cavities (i.e. the mucous membrane).	We know dermatological conditions impact people over a long period of time, but this questionnaire aims to measure how much your dermatological condition has affected your life **OVER THE LAST MONTH**. Please **consider each question in relation to your dermatological condition**. **Mark one box** for each question. Dermatological conditions can affect the skin, hair, nails and/or mucous membrane. The word 'skin' here includes any of these aspects relevant to your condition.
Recall period	2 weeks	1 month	1 month
Number of response options	6	6	5
Response option wording	Always / Often / Sometimes / Rarely / Never // Not relevant	Always / Often / Sometimes / Rarely / Never // Not relevant	Always / Often / Sometimes / Rarely / Never
No. items refined	8	11	5

Part of questionnaire	Round 1	Round 2	Round 3
Item wording refinements	...the quality, look or feel of my skin has bothered me	…my general physical health has been negatively affected	… my skin has been sensitive to external factors (for example, to touch, light or temperature)
	…my leisure time has been negatively affected	…my treatment has caused practical problems (for example, by taking up time or being messy)	…my life goals and choices have been affected (for example, career choice or having children)
	…I have struggled to concentrate	…I have struggled to perform roles important to me (for example, to be caregiver / parent / partner / employee / student)	…my condition has dominated my thoughts
	…I have had extra financial costs	…my leisure time (for example, hobbies, sports or exercise) has been negatively affected	…I have felt like I've lost some control over my life
	…I have been distracted by my skin	…I have had extra medical or non-medical financial costs	…I have been prevented from or found it difficult to be intimate with another person
	…I have felt low in mood or motivation	…my life goals and choices have been affected (for example, career choice)	
	...my relationships with those close to me have been negatively affected	…I have struggled to think about anything other than my condition	
	…I have felt dismissed by others (including healthcare professionals)	…I have felt depressed or low in mood	
		…I have felt shame or embarrassment	

Part of questionnaire	Round 1	Round 2	Round 3
		…it has (or would have) been difficult to be intimate with another person	
		…I have been excluded, stigmatised or discriminated against by others	
No. items removed	0	1	0
Items removed		…I have felt dismissed by others (including healthcare professionals)	

7.3.1 General feedback

Participants praised the comprehensiveness, comprehensibility and relevance of PRIDD to their lived experiences:

> I've completed a lot of dermatological questionnaires, but I don't think I've ever seen them all integrated like this in such a questionnaire … I'm very, very happy with this. It has stirred my heart … There are things here that I wanted to discuss with my dermatologist … I'm really, really impressed with this. It's very good, it's excellent. (5) Patient with hidradenitis suppurativa, Ireland

> They were short questions, and they were quite easily answered. (15) Patient with alopecia, UK

PRIDD also appeared to be acceptable and feasible to patients. The average time taken to complete the questionnaire was 4.11 minutes (SD = 1.35, range = 2.62 – 7).

> The questions are so concise. You can quickly fill that in, in the waiting room. I think that's important. (12) Patient with extensive linear porokeratosis, Ireland

While no participants found any of the items offensive or objectionable, they felt that others might be "uncomfortable" (9) with item 26 ('it has been difficult to be intimate with a partner') as it referred to intimacy, but stressed it was important to include. Instead, participants felt that completing PRIDD initiated a process of reflection on their experiences with their condition:

> I wasn't offended by any of them … It actually made me aware of how much this is actually controlling my life again. (11) Patient with discoid lupus, Ireland

A minority of participants, most with alopecia, questioned the focus on the negative impacts of dermatological conditions and felt that positive impacts should be included too.

> I think it's sometimes nice to balance the negatives out with positives … in the past week, I've felt a lot of empowerment, I've felt a lot of like confidence, I've felt a lot of people praising me for something I've tried to hide away for so long, so it's not just negatives that you could capture as well, having a separate question saying I've felt confident, or I've felt empowered or something. (15) Patient with alopecia, UK

Some participants wanted to further elaborate on items with qualitative data.

> You could even go deeper than that … you could even have … a box to maybe put is there anything you'd like to add … that [you] feel is relevant … because everybody isn't the same (16) Patient with PRP, UK

7.3.2 Feedback on instructions

Overall, the instructions appeared easy to comprehend as participants were able to summarise them accurately and succinctly.

> It was asking me to answer the below questions based on my condition, how it's affected me in the last week, and answer them with what's relevant to me and my experience. … I felt the instructions were really clear, so I didn't really think there was anything else to add … it's a fairly straightforward questionnaire (15) Patient with alopecia, UK

However, some "didn't read that part [instructions]" (11), which affected the validity of their answers, particularly in relation to the recall period. On this basis, several sections of the instructions were highlighted to draw respondents' attention to the instructions and their most important aspects.

Some suggestions to improve clarity were provided. First, participants felt that the example 'because you do not work' created confusion as it led participants to believe that the items should be answered in relation to their dermatological condition *and* employment. As a result, this example was removed from the instructions.

> I'm not sure why you asked if I worked or not … I was kind of confused with that part ... Going through the questions in my head, I don't know how work would have anything to do with the questions that were asked … I don't even really think you need it all. (14) Patient with psoriasis, Canada

Second, some participants suggested alternatives to the term 'dermatological conditions'. A minority of participants with conditions primarily affecting the skin suggested using 'a simple word like skin' (9) instead. Others with conditions that did not primarily affect the skin such as alopecia felt that dermatology implied a focus on the skin and would prefer another word, but could not provide a suitable alternative:

> It made me feel like it was a skin … obviously skin and dermatology … is there even a terminology to utilise for this sort of research? … is there another word to say skin, which includes hair, nails, whatever, you know? I don't think there is, but that's the only thing that I would maybe look into, but I don't think there is a synonym. (18) Patient with alopecia, UK

Because most participants found it acceptable and it is more inclusive than 'skin', the use of 'dermatological conditions' was retained.

> You need it to be applicable to several different conditions, not just one and … there is the difficulty. So with that in mind, your questions are brilliant. I just wish that there was one specific to alopecia … from a general point of view, they're really good dermatological questions. (18) Patient with alopecia, UK

> I am sure phrases like dermatological, I mean will be familiar to anyone with any sort of conditions (13) Patient with psoriasis, UK

Similarly, while the term mucous membrane was understood by people with associated conditions (e.g. mucous membrane pemphigoid), it created confusion for people with other conditions. However, participants generally understood why this term was included.

> Obviously, I know what skin is, I don't know quite what mucous membrane would be and so I don't quite see the relevance of that note. But maybe for other people, it would be more relevant … people who have got the mucous membrane affected will be very aware of that and consequently, that will hit the point bang on for them and those like me who haven't will just read it as skin. (13) Patient with psoriasis, UK

Some responses suggested that participants replied based on their general health rather than, as intended, in relation to their dermatological condition. On this basis, the sentence 'please consider each question in relation to your dermatological condition' was added to the instructions and the size of the stem ('Because of your dermatological condition…) was increased.

> I'm 75 … I'm tired. (17) Patient with PRP, USA

7.3.3 Feedback on the recall period

Participants were almost unanimous in their criticism of the one-week recall period. Many felt that a longer recall period was required to accurately reflect the impact that their dermatological condition has had on their lives.

> Seven days isn't long enough for someone with … [a] condition that they've no control over, and people can see it. Because that's another thing like, lupus can flare, and it'll go back down, and I can have three good weeks and then one really crap week where it's just blown up on my face. So, I still think that the past week is too short a term to ask someone how it is. (11) Patient with discoid lupus, Ireland

> If the timeframe had been three months, six months, a year, or your lifetime … the feedback would be very different. So, you talk about relationships, intimate with [a] partner, all of these kinds of things, you know, social interactions, if somebody hasn't had a social interaction in the last week

> they're going to say never, whereas if the timeframe is much larger you're going to get a more realistic feedback. (12) Patient with extensive linear porokeratosis, Ireland

A two-week and one-month recall period were tested. These were generally more acceptable to participants than the one-week recall. A one-month recall period was adopted, having been suggested as an alternative to the one-week recall period by multiple participants.

> For a week you might have a very quiet week and nothing happening, nothing going on and you feel comfortable to hide under your hat or behind your masks or whatever … I would go [with] a month. (11) Patient with discoid lupus, Ireland

7.3.4 Feedback on the items

A summary of the evidence of comprehensibility, relevance and detected problems for each item is presented in Table 28. Based on the interview data, nine of the 27 items remained unchanged because they were easily understood, relevant to participants and distinct from other items. Examples are 'I have experienced physical discomfort, soreness or irritation' and 'I have felt unattractive'.

Sixteen items were modified to more closely align them with the intended concept of interest or to reduce conceptual overlap with other items: for example, from 'my skin has been sensitive' to 'my skin has been sensitive to external factors (for example, to touch, light or temperature)'.

One item, 'I have felt dismissed or abandoned by others', was deleted because it was not easily understood by participants and was understood to be highly similar to 'I have been excluded, bullied or discriminated against'.

Overall, participants found both the original and reverse item ordering acceptable:

> They seemed to be grouped together quite well and I think the order of them was fine, it's sort of you got straight into it. (15) Patient with alopecia, UK

The order of seven items was changed to enhance understanding. For example, the item 'my everyday choices have been affected (for example, choice of clothes, hairstyle or products)' was listed before the item 'my life goals and choices have been affected (for example, career choice or having children)' to highlight that the latter does not include everyday choices, which some participants subsumed under life goals and choices.

The conceptual framework domains were evident in the items, as participants correctly recognised categories of items, providing evidence in support of the suitability of the item ordering as well as the conceptual framework.

> You could probably take [items] one, two – those last four questions … And probably maybe roll them up into one … because they're all pretty much a physical ailment really. (14) Patient with psoriasis, Canada

Subgroup differences were found on four items. People with alopecia felt that the item 'my treatment has caused practical problems (for example, by taking up time or being messy)' was not relevant to them as they had no treatments. They also differed from people with other conditions on three items as alopecia appeared to have a positive impact in terms of time-saving, reduced financial costs and feelings of attractiveness.

> It positively impacted it [daily routine], because I don't have to mess about with my hair as much in the morning ... it's a bit of a blessing. (15) Patient with alopecia, UK

Table 28: Summary of the evidence of comprehensibility, relevance and detected problems for each item

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
The quality, look or feel of my skin/hair/nails has bothered me	I'd be looking at it in two … in two respects … my head, which I'm bald, … and then I'd also be thinking about my wigs and how they look (15) Patient with alopecia, UK	Inclusion of 'skin/hair/nails' added complexity to the item.	The quality, look or feel of my skin has bothered me
I have experienced physical discomfort, soreness or irritation	It's a question that does apply to me and my condition. It is discomfort, soreness and irritation … all three would apply to me. (12) Patient with extensive linear porokeratosis, Ireland I would immediately read it as itching, putting it in a different way. (13) Patient with psoriasis, UK	N/A	I have experienced physical discomfort, soreness or irritation
My skin has been sensitive	Sensitive I would understand as it would react easily to certain products if … you're limited to skincare and moisturisers, lotions, that's everything, shampoo, conditioner, body wash, so a reaction to products, easily inflamed, and an easy reaction … That it would really invoke a reaction of some sort if it comes into contact with something. (12) Patient with extensive linear porokeratosis, Ireland	Participants descriptions demonstrated conceptual overlap with the previous item: Has it been itchy? (13) Patient with psoriasis, UK	My skin has been sensitive to external factors (for example, to touch, light or temperature)
My sleep has been disturbed	If your sleep's affected, you don't rest properly, and you're tired and it's like everything's a chore. You know, and that's a good measure, if somebody's not well, they're not sleeping, they're	N/A	My sleep has been disturbed

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
	up, they're itching … good question, I like it. (1) Patient with psoriasis, UK		
I have felt tired, fatigued or lacked energy	You're going to feel tired, fatigue and lack of energy, and that's as a result of your condition. (12) Patient with extensive linear porokeratosis, Ireland	N/A	I have felt tired, fatigued or lacked energy
My general health has been negatively affected	I interpret that as my overall health and how my condition has had an impact on my overall health and if I've suffered any other … ill health due to the condition that I currently have … it does have a knock-on effect on my general health … your condition sometimes will lead you to have to take certain medication, like really strong medication, which has side effects … if you do have a condition your general health is affected because you're at higher risk, so with my condition, I'm at higher risk of developing skin cancer. … it depends what type of feedback you're trying to get, and it could be that it's physical general health versus mental general health, but other way, I combine everything together. (12) Patient with extensive linear porokeratosis, Ireland	Participants were unclear whether this item pertained to physical or mental health or both. I just sort of read that as it affected my health in any way really, sort of general, physical, mental health … general health, I don't think is a great term … is a bit vague. (15) Patient with alopecia, UK	My general physical health has been negatively affected

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
My preferred daily routine has been negatively affected	I read that as, you know, if my condition had made any impact negative, on my daily routine … as it says on the tin. (15) Patient with alopecia, UK	N/A	My preferred daily routine has been negatively affected
My treatment has caused problems (for example, by taking up time or being messy)	I interpret the question as has caused problems, as anything that you, as a patient, would see as a problem. So I wouldn't limit it to just taking up time or being messy – the examples that you provide … I would say it has caused problems … way more than just taking up time or being messy … like being expensive, being frustrating. (12) Patient with extensive linear porokeratosis, Ireland	Participants with alopecia felt this item was less relevant to them. No treatments, not applicable (18) Patient with alopecia, UK	My treatment has caused practical problems (for example, by taking up time or being messy)
My everyday choices have been affected (for example, choice of clothes, hair style or products)	If you had not given the example or choice, clothes, hairstyle, products, if you had just given about my everyday choice, the first thing my brain would connect is choice of clothes, and choice of hairstyle and products … for me, they're prioritised in that way. (12) Patient with extensive linear porokeratosis, Ireland	N/A	My everyday choices have been affected (for example, choice of clothes, hairstyle or products)
I have struggled to perform roles important to me (for example, to be caregiver / parent / partner)	If all of a sudden, my skin and my joints start to really seize up, I couldn't have walked my mum to the car this morning, I couldn't. I'd struggle, between us, my mum can't open a bottle of milk, and if … my hands have gone bad, I can't open a bottle of milk … I think that's actually an important question … even an example of maybe like a parent and a partner … if somebody's married, and … they're going down … it'll affect their partner … Because they're going to have to step [up] and do	With the changes to the item 'I have struggled to work or study', this item was changed to include struggling to perform as an employee or student.	I have struggled to perform roles important to me (for example, to be caregiver / parent / partner / employee / student)

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
	more, they'll have to do the treatment side of it. (1) Patient with psoriasis, UK		
My leisure time/activities have been negatively affected	Avoiding swimming, certain sports … I quite enjoy swimming … Other people's reaction in those days … some people … take offence by the look of you … and that affects you, you know, when you're fairly … self-conscious. Other people's reaction has an effect, so, you know, I avoided swimming. (3) Patient with psoriasis, UK	Participants were unclear as to whether leisure time included social time. I think they could be one question, yeah. It's social life and leisure time, they're pretty much the same thing, I think. My leisure time is my social life basically, so I think they could be one question. (1) Patient with psoriasis, UK	My leisure time (for example, hobbies, sports or exercise) has been negatively affected
it has been hard to work or study	Has the skin irritation made me lack concentration on what I'm doing or trying to do … I've retired and consequently that's why I have to sort of cast my mind back a little bit to answer that question. The sort of things I might be concentrating these days aren't really as important as they would have been in the past, so you know if I'm trying to concentrate on doing the Sudoku, I wouldn't really think twice about my psoriasis but perhaps trying to concentrate on an exam question you suddenly become very aware of how it's irritating you. (13) Patient with psoriasis, UK	Participants understood this as assessing their ability to concentrate. The word 'struggle' was preferred over 'hard'. I don't know whether that'd be better phrased in a similar way to number 10, sort of struggle to perform work and study, duties or things, but obviously it's the same sort of answer. But I mean, it was straightforward and yeah, you're sort of asking whether or not it impacted your work or your study. (15) Patient with alopecia, UK	I have struggled to concentrate

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
I have had extra out-of-pocket expenses	I have had extra medical and non-medical financial costs, yes, exceedingly so … £300 I waste every month [on wigs] … that's 300 times like 12 times 23 years, it's a lot of money when you add it up, so it's like mortgage money we're talking. (18) Patient with alopecia, UK	Participants were unsure of how to interpret the phrase 'out-of-pocket expenses': If I'd asked the question, I would have said I have had extra costs rather than out of pocket expenses … out of pocket expenses to me sort of suggests … immediate cash expenditure rather than you know costs which come from anywhere. (13) Patient with psoriasis, UK Some participants did not consider medical expenses when responding to this item: I suppose I find extra out of pocket expenses outside of my regular doctor bills or regular medical bills … they would be my standard bills. And then everything extra out of pocket would be, you know, when something goes wrong and you need bandages, plasters, scissors, medical kits, creams, ointments. (12) Patient with extensive linear porokeratosis, Ireland	I have had extra medical or non-medical financial costs
My life goals and choices have been affected	I wanted to be a teacher, and just never got there, through one thing and another, and hospitals and illness … shame that question, but it's good it's there. (1) Patient with psoriasis, UK That's pretty self-explanatory. You know, because you do: you have to think of your disease, you know, in the moment and in the long-term. (14) Patient with psoriasis, Canada	Some participants were unsure whether professional choices should be considered when responding to this item.	My life goals and choices have been affected (for example, career choice or having children)

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
I have felt anxious, worried or nervous	"I have felt anxious, worried or nervous." Again, that's very easy to understand and very real. That's a real question. I like that one. (14) Patient with psoriasis, Canada	N/A	I have felt anxious, worried or nervous
I have been preoccupied with my skin, hair or nails	It's something that I think about regularly, but is it better to think about it regularly, or am I distracted by it, am I not able to think about other things … I'm thinking about that instead of other things and can't sort of stop thinking about it. (15) Patient with alopecia, UK	Participants felt the word preoccupied was not right: [Keep] dominated in there, it's better that preoccupied, preoccupied doesn't even touch the sides' (18) Patient with alopecia, UK	My condition has dominated my thoughts
I have felt down, blue or low in motivation	It's a very relevant question. My answer is: often – and I think it's a good choice of words. For me, a synonym for all of them perhaps would be 'depression'. (5) Patient with hidradenitis suppurativa, Ireland	'Low in motivation' was generally associated with items 5 (I have felt tired, fatigued or lacked energy) or 24 (my social life or interactions have been negatively affected), rather than low mood. It was suggested that 'low motivation' was removed from the item: I suppose feeling down and blue is different to low in motivation, to me sometimes, as well. Because you know, you can be low in motivation for a lot of other reasons than feeling low in	I have felt depressed or low in mood

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
		general… you could maybe just remove the low in motivation, if that's captured in energy levels, like fatigue. (15) Patient with alopecia, UK Participants also suggested including the word 'depression' in the item, as it was not clear whether the item was intended to capture this extreme end of the spectrum of low mood, in the way that item 15 does with anxiety. If the question is determined to … quantify the level of depression, I would probably add the word depression in there. Same as anxiety, the word anxiety is in a different question, so that, you know, people that suffer from anxiety, they have panic attacks, they may need like anti-anxiety medication, same as depression … by not putting it in there … it's going to be kind of seen as that it's been overlooked or that you maybe don't want to say the word depression … Question 17) probably needs to be rephrased to link it more to depression, because it's, it's probably, er, a little bit deeper than just being down. (12) Patient with extensive linear porokeratosis, Ireland	
I have felt angry, annoyed or frustrated	I knew what was being asked … if I felt anger, frustration or annoyance, I don't really think	N/A	I have felt angry, annoyed or frustrated

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
	there's any other way to ask that. (15) Patient with alopecia, UK		
I have felt like I've lost some control	Well, it controls every aspect of your life … it dictates what you do, it dictates what you wear, it dictates where you go … it dictates everything … when it's bad. (16) Patient with PRP, UK	It was not clear what control referred to: You've lost some control which would cover a lot of aspects of work. Your personal, your social … angry, frustrated … you covered a lot of that … I suppose it all depends how you read into the question. (11) Patient with discoid lupus, Ireland	I have felt like I've lost some control over my life
I have felt embarrassed	There has been embarrassment with regard to the smell … I have felt embarrassed with clothing – staining has come through on clothing and people have said, 'Have you sat on something, or did you spill something.' (5) Patient with hidradenitis suppurativa, Ireland	Participants felt the word shame was important to include in this item: The only thing I would add there is, shame, I think shame is … an important feeling (12) Patient with extensive linear porokeratosis, Ireland	I have felt shame or embarrassment
I have felt unattractive	I have felt unattractive. Often, is my answer to that. It's a very, very relevant question. (5) Patient with hidradenitis suppurativa, Ireland	N/A	I have felt unattractive

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
I have felt dismissed or abandoned by others	I've frequently been told, 'You should be familiar, or used to it by now.' I feel very dismissed that things that are important to me are just not taken seriously … you hope in a friendship, or in any type of relationship, that people will give proper consideration to things that are important to you, and that doesn't happen. Yeah, you feel somewhat abandoned in a relationship, whether it's an intimate relationship, or friendship, or professional relationship, etc. (5) Patient with hidradenitis suppurativa, Ireland	Participants found that this item was not easy to understand. Most participants could not distinguish between this item and item 27 (I have been excluded, bullied or discriminated) as they considered it to be alluding to social exclusion or workplace discrimination. I read as being kind of excluded from a group or from you know something. (13) Patient with psoriasis, UK	Item removed
I have been focused on hiding, covering or concealing my condition	Great question … people do cover and hide it. Which makes it worse … I like that question … I wouldn't change anything to it. I understand it fully. (14) Patient with psoriasis, Canada	N/A	I have been focused on hiding, covering or concealing my condition
My social life or interactions have been negatively affected	Social life would be interacting with friends, doing things outside of the home, participating in community work or interacting with others. Interactions could be just going about your day-to-day business, interacting with society: going shopping, going to the dentist – your everyday things. Yes, they have been negatively affected. As mentioned, I try and minimise my interaction with others. (5) Patient with hidradenitis suppurativa, Ireland	N/A	My social life or interactions have been negatively affected

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
My relationships with others have been negatively affected	I'd say often my relationships, intimate relationships, family relationships, friends, professional relationships and so on, it's a very relevant question … I like the fact that it's just left at relationships and the patient can interpret that in whatever way they want … Friends will be reluctant to ask me to do things because of this. I'm reluctant to participate and engage fully in relationships, because of my dermatological condition. (5) Patient with hidradenitis suppurativa, Ireland	Participants acknowledged some conceptual overlap with the previous item but generally felt that these items with important and distinct enough to retain both: I think it's important, I think [keep] both because I think affecting your relationships, it's more specific, and I think … it's shown a greater impact than if it's just affecting you socially… if it's actually affecting personal relationships that you have, then I think they are separate things. (15) Patient with alopecia, UK	My relationships with those close to me have been negatively affected
It has been difficult to be intimate with a partner	I think that's also a really relevant question … it's something I've experienced in the past … it should be there. I know it's probably a more personal question, and people might struggle to answer it, but I think it's important because it goes into your relationships, and if that affects you, that's a big impact on your life … there's only so many ways you can reword something … I don't know how you can ask it in a more delicate way than what you already are, so yeah. (15) Patient with alopecia, UK	Participants echoed criticisms of relationship and intimacy items in other dermatology-specific PROMs because, in Round 1, this item was only relevant to people who had a relationship or active sex life: This is the question that I always struggle with, not relevant because I've not got a partner… the reason why I've not got a partner is because it's been difficult … I think it's an important question … [it's] probably the reason why I'm single, in my formative years between when I started getting psoriasis and in hospital, was years when all my mates were getting wives and babies and all	I have been prevented from or found it difficult to be intimate with another person

Original item	Evidence of comprehensibility and/or relevance	Reported problems	Final item after revision
		that. All of a sudden it had just passed me by, it had gone (1) Patient with psoriasis, UK	
I have been excluded, bullied or discriminated against	I have been excluded, bullied, or discriminated against. My answer to that would be: sometimes. Excluded is perhaps most relevant for me here … I've been excluded from things by friends, by family, etc. Because I am restricted in what I can do physically, etc. Bullied … it doesn't apply to me … I think excluded is very, very relevant, very poignant and ... Bullied or discriminated, perhaps when I was younger, when I was a teenage boy, participating in teen sports. Yeah, there would have been comments passed, because of physical marks on my skin, etc., etc. (5) Patient with hidradenitis suppurativa, Ireland	The appropriateness of 'bullied' was questioned as participants felt that it was relevant to childhood rather than adult experiences.	I have been excluded, stigmatised or discriminated against by others

7.3.5 Feedback on the response options

Participants found the Likert-type response options ('never', 'rarely', 'sometimes', 'often' and 'always') to be appropriate, cover the full range of experience and comprehensible.

> I found it quite easy, I think it gives a good range of options. Obviously always and never are complete extreme[s] and then a couple of the intermediates of different intensity, is fine. I think it is a really good way of asking questionnaires and usually makes it quite easy to answer. (13) Patient with psoriasis, UK

The 'not relevant' option created confusion for some. The edits to items 12 ('I have struggled to concentrate) and 26 ('I have been prevented from or found it difficult to be intimate with another person') reduced the need for the not relevant option as these items could now apply to all respondents, regardless of employment or relationship status. This option was no longer necessary and was therefore removed to simplify.

> There were some questions where it was never or … not relevant and I'm thinking … what did not relevant mean? … you might think not relevant is fairly self-explanatory but it's not in my case … what's not relevant? … I've ticked it and it's not relevant because it never occurred … [so] you'd say never, wouldn't you? (9) Patient with psoriasis, UK

7.4 Discussion

This final study in the content validity phase of PRIDD development tested the content validity, acceptability and feasibility of PRIDD. The study findings and resultant adjustments produced a ready for field-testing 26-item version of PRIDD with evidence of comprehensiveness, comprehensibility, relevance, acceptability and feasibility from the target population.

7.4.1 Implications for measuring the impact of dermatological conditions

During PROM development a balance is evidence between maximising the information gained about the construct of interest and reducing respondent burden, meaning that every item in a PROM must earn its place (DeVellis 2017). Where participant interviews demonstrated that items were not easily interpreted or clearly aligned with the underlying concept of interest, they were removed or edited during the interview rounds. In this way, this study provides evidence of the value of each of the 26 final items.

Support for the conceptual framework of the impact of dermatological conditions on the patient's life

The findings of this cognitive interview study support the conceptual framework (Figure 21.) developed during this work. First, participants' lived experiences encompassed the biopsychosocial nature of their conditions. Second, no new items or domains were added to PRIDD and participants could identify which items corresponded to the underlying domains. Third, the data support the decision to remove the 'impact of healthcare' domain from the conceptual framework and the suggestion that this could form the basis of a separate 'quality of dermatological care' measure. One participant, for example, summarised this decision while reflecting on being dismissed by healthcare professionals saying, "that could be a whole … paper all by itself … that's a whole different ball game if you get involved in that" (14). This study, therefore, supports the conceptual framework and comprehensiveness of PRIDD.

The limits of developing a dermatology specific PROM

The data gathered reflect the challenges inherent in developing a dermatology- as opposed to a disease-specific PROM. Participants differed in their relation with the term 'dermatological condition', variously preferring other terms more closely aligned with their specific type of condition (i.e. 'skin' or 'hair'). Nevertheless, participants understood the

rationale behind the use of 'dermatological' and no alternate sufficiently inclusive terms were suggested.

While PRIDD appears to be relevant to people with dermatological conditions overall, some sub-group differences were found. People with alopecia emphasised the positive impacts of their condition, for example, regaining time lost to styling hair, and felt that the treatment-related item was not relevant to them. The physical, psychological and social impacts were generally consistent across conditions but practical impacts such as time and financial resources differed for people with alopecia. This calls into question how appropriate PRIDD is for alopecia. With this in mind, content validity studies and future disease-specific add-ons to PRIDD should be prioritised for people with alopecia. It will also be important to test for Differential Item Functioning (i.e. testing for measurement invariance across different populations) in alopecia during the psychometric testing phase.

Determining the recall period

Choice of recall period is an aspect of internal validity as a suboptimal recall period can introduce measurement error. There is no 'gold standard' recall period for PROMs as "one size does not fit all" (Stull et al. 2009, p. 940). The FDA guidance (2009) on PROM development states a preference for items with short recall periods or those that ask patients to describe their current or recent state. Their rationale is twofold. First, longer recall periods are thought to undermine content validity because they rely on the respondent's memory (i.e. recall bias). Second, longer recall periods may be impractical in research or clinical practice with frequent data collection points or clinic visits due to overlapping periods. Hence, the initial assumption was that a one-week recall period would be most appropriate for PRIDD.

Norquist and colleagues (2012) have criticised the FDA guidance for ignoring the complex interplay of factors that determine the most appropriate recall period. They argue that the choice of recall period is driven by several factors including the PROM's purpose and construct of interest, characteristics of the condition and the patient's ability to easily and correctly recall the information requested.

When developing a PROM for use in research and clinical practice, it is important to balance patients' wishes and cognitive processing with the requirements for psychometrically sound and feasible measures. In their model of question response, Tourangeau and colleagues (2000) propose that recall involves several tasks including generating a retrieval strategy, recalling memories and 'filling in' partial memories through inference, extrapolation, or interpolation. Our cognitive interviews reflect this proposed process as participants tended to recall their experiences over a longer period of time before amending in light of the one- or two-week recall period.

Study participants almost unanimously criticised the one- and two-week recall periods and proposed longer recall periods (e.g. 1 – 6 months, years or lifetime). Their criticisms mirrored Clarke and colleagues' (2008) assertion that while a short recall period may reduce recall bias, there are "potential huge costs in terms of information lost" (p. 1283). Participants' views supported Norquist and colleagues' suggestion that longer recall periods are often most appropriate to assess constructs such as quality of life. As expressed here, participant's views support previous work suggesting that a shorter recall period likely underestimates the burden of long-term conditions (Leidy and Vernon 2008), particularly those with a relapsing-and-remitting course (Patrick et al. 2011b), and that patients can accurately recall over a longer period of time than the FDA guidance suggests (Brod et al. 2009), particularly when their issues are bothersome and memorable (Leidy and Vernon 2008; Norquist et al. 2012). We changed the recall period to one month, which is within the recommended range for PROMs of phenomena such as QoL and is likely to reduce the risk of recall bias and error recall outlined by our participants (Stull et al. 2009).

Feasibility

PRIDD appears to be feasible for use, with participants taking an average of approximately four minutes to complete. The average time to complete PRIDD in research and clinical practice may be lower because, in most cases, participants were thinking and responding aloud while completing PRIDD during the cognitive interviews and edits were consequently made to improve the comprehensibility of the measure.

The positive impact of living with a dermatological condition

In keeping with the concept elicitation study and Tedeschi and Calhoun's (2004) work on post-traumatic growth outlined in Chapter 5 (p. 193 - 194), some participants reported positive impacts of their dermatological conditions and expressed a desire for these to be measured as well as the negative impacts. The positive impacts reported – e.g. empowerment, confidence, gratitude - support the validity of the concept elicitation study analysis as these were captured in the analytical framework (Appendix 9.). Because PRIDD focuses on the burden of dermatological conditions, positive impacts were not incorporated as this would violate the unidimensionality of the measure.

Given the importance of the various positive impacts to patients, the data gathered throughout the development of PRIDD could serve as the basis of a new, separate measure of the positive impact of dermatological conditions. Qualitative research to inform the development of psychological interventions typically focus on the negative aspects of long-term health conditions, but it can be worthwhile to consult with people with positive experiences as they are well placed to provide input that may lead to effective interventions. A measure of the positive impacts of dermatological conditions could identify patients who have adjusted well to their condition and target recruitment efforts for such work.

7.4.2 Strengths and limitations

Study design

The main strength of this study is the use of qualitative methods to examine the content validity of PRIDD. The interviews followed the Three-Step Test-Interview method of cognitive interviewing, eliciting data from a range of sources (i.e. observational, think aloud and probing techniques) enabling the examination of item ordering and interaction effects between items. Our approach of asking participants to elaborate in detail regarding their understanding of each aspect of and item in PRIDD provided manifold definitions and examples of impact as well as identifying how participants understood each item. From these data, we could detect

and resolve problems with item wording, ordering and redundancies. Notably, we followed the COSMIN guidance by testing each aspect of PRIDD separately and in its final form, with the exception of an acceptable "minor adjustment" (p. 28) to the instructions (Terwee et al. 2018b). This study, therefore, met the standards for cognitive interviews outlined by COSMIN (Appendix 18.) and provided high-quality evidence of the comprehensibility, comprehensiveness and relevance of the final version of PRIDD from the target population.

Conducting the interviews remotely using video conferencing software, as opposed to face-to-face or telephone interviews, allowed us to perform the observation component of the TSTI and to interview people from around the world during the COVID-19 pandemic. However, differences in device capabilities meant that we could not perform the observational component for some participants. Nevertheless, pilot-testing of an online version of PRIDD is a strength of this study. Research has demonstrated a clear patient preference for electronic PROMs (Ali et al. 2017b), further strengthening the patient-centredness of PRIDD. The use of PROMs in electronic format is increasing (Leidy and Vernon 2008; Deal et al. 2010; Chatzimichalis et al. 2019) due to their many benefits over their paper-based counterparts (Gwaltney et al. 2008) such as a more streamlined process, increased reliability of data and quality of data analysis, and reduced cost of administration and storage as a result of portability, real-time monitoring and improved data capture (Gwaltney et al. 2008). Data captured electronically can be displayed in graphic reports as visual aids to provide real-time feedback to patients and facilitate clinician-patient communication. This mode of administration overcomes some of the barriers, and assists some of the facilitators, of PROM use in clinical practice identified in Chapter 2, potentially furthering its routine use (Finlay et al. 2017). In response to demands, a web-based application (app) of the DLQI has been developed to encourage its further uptake in modern clinical and research settings in many countries (Ali et al. 2017b). With this in mind, the development and equivalence testing of a PRIDD app would be a useful avenue of research that may improve clinicians' interpretation of the scores and increase the impact of PRIDD.

Sample

Participants were sampled purposively through IADPO's unique global network to achieve a diverse range of people in terms of clinical (e.g. common and uncommon, inflammatory and non-inflammatory dermatological conditions) and demographic variables (e.g. age and gender). However, we were unable to recruit participants with other common conditions such as acne, AD and vitiligo or those who do not speak British, American or Canadian English and did not collect data on participants' reading or educational level, reducing the transferability of PRIDD.

The minimum sample size recommended for cognitive interviews varies from seven to 30 (Willis 2005; Blair and Conrad 2011; Perneger et al. 2014). With a sample size of 12, we were able to demonstrate data saturation as no major problems that could be resolved were identified in the final round of interviews. Still, rarer problems or those pertaining to conditions not represented may have gone undetected. Efforts should be made to recruit people with other dermatological conditions and those speaking other variations of English in future work.

7.4.3 Implications for clinical practice

The data collected here support Greenhalgh and colleagues' (2018) finding that PROM completion is neither a simple nor neutral act of information retrieval but can prompt a process of self-reflection that changes how patients understand, frame or think about their condition and provides them with a framework for raising issues with clinicians (Mallinson 2002; Neale and Strang 2015). Participants in the current study and previous dermatology PROM development work (e.g. Howells 2020) expressed a desire to provide qualitative information alongside their response options to afford clinicians a deeper understanding of their lived experiences. Such insights support my suggestion that, in addition to the data they produce, PROMs can be valuable in facilitating deeper discussions during clinical consultations.

7.4.4 Implications for research

Unlike many of the dermatology PROM development studies evaluated in the Chapter 4 systematic review, PRIDD was pilot tested with patients before psychometric testing or use. Patient input into the item refinement process resulted in many adjustments to PRIDD and provided evidence of its content validity, feasibility and acceptability. This study, therefore, supports COSMIN's position that cognitive interviewing plays an important role in the PROM development and validation process.

While cognitive interviews allow patients to have greater input into the item refinement process than purely statistical methods allow, ideally, they would not be the sole method of item refinement. A number of items were identified as having conceptual overlap in the current study. It will, therefore, be important to test for item redundancies. Statistical techniques will be employed during the post-doctoral psychometric testing phase of PRIDD to test for item redundancies and data structure. Finally, the updated list of item definitions (Appendix 19.) based on the edits to PRIDD will be valuable to test for construct equivalence when translating PRIDD into other languages and cultures.

7.5 Summary

In this final step in the content validity phase of development, PRIDD was pilot-tested through cognitive interviews with the target population. The data triangulated previous findings, recommendations and the conceptual framework of impact. The results provide insight into how patients understood the items in PRIDD. The resultant evidence of construct equivalence along with their confirmation of the comprehensibility, comprehensiveness, relevance, acceptability and feasibility of PRIDD provide evidence of content validity from the target population. The next step in the development of PRIDD is the psychometric testing phase.

Chapter 8: General discussion

This study completed the content validity phase in the development of PRIDD, a new dermatology-specific PROM of the impact of dermatological conditions on the patient's life. The outcome is a pilot-tested version of PRIDD, with evidence of content validity, acceptability and feasibility, ready for psychometric testing in the next and final phase of development. This study was central to and progressed the GRIDD project which aims to collect global quantitative data on the impact of dermatological conditions on patients' lives to challenge the current global burden of disease estimates. To meet the GRIDD project's aim, a measurement of impact is required which PRIDD, as a new measure, provides. PRIDD is the embodiment of a biopsychosocial model of health and illness and PCC and therefore an exemplar of how to assess people more holistically.

The rigorous mixed methods design of the current study allowed for high levels of patient input and provides evidence of content validity by demonstrating the critical link between the target concept and the score produced (Patrick et al. 2011a). The strength of the study design and resultant measure is demonstrated by the overall score of 'very good' according to the COSMIN standards for content validity (Appendices 10 & 18). The design has ensured that PRIDD is in a strong position to begin psychometric testing.

With PRIDD we have been able to develop a conceptual framework of the impact of dermatological conditions (Figure 21.) and identify a list of important impacts shared across dermatological conditions worldwide.

8.1 Interpretation of findings

8.1.1 The biopsychosocial model of dermatological conditions

All of the people with dermatological conditions who participated in this study either explicitly or implicitly reported a biopsychosocial experience of their condition. Consequently, the conceptual framework of impact supports a large body of research and countless calls (e.g. Picardi and Pasquini 2007; APPG on Skin 2020) spanning decades that dermatological conditions are consistent with the biopsychosocial model of illness and should be managed as such.

A biopsychosocial model of dermatological conditions suggests that assessment of disease severity or symptoms alone will fail to capture the extent of their impact on the patient. Previous research has revealed that clinicians assume that skin improvements would inevitably result in the resolution of psychological and social difficulties associated with psoriasis (Chisholm et al. 2016). One participant articulately refuted this assumption stating, "even if EB was cured tomorrow that will always be in your head … so there's an internal scar that doesn't go away". In this way, this study supports a) research showing a lack of a simple, linear relationship between disease severity and wellbeing (Leary et al. 1998; Husted et al. 2001), b) the need for psychological support for patients, and c) NICE's (2012) recommendation that the impact of dermatological conditions on physical, psychological and social wellbeing, and the presence of comorbidities should be assessed as well as disease severity.

Given the above, it is not surprising that study participants expressed frustration with the current predominantly biomedical model of dermatological care and instead championed a 'holistic' approach where psychological, social and lifestyle factors are addressed. In particular, participants were critical of clinicians who exclusively managed dermatological conditions with pharmacological treatments. Instead, they proposed that clinicians should consider and educate patients on lifestyle (e.g. diet) and environmental factors (e.g. choice of fabrics) and provide psychological support – all of which are supported in the literature – alongside pharmacological treatments. Accordingly – and because the dermatology literature and guidance are predominantly focused on the physical aspects of the condition - this section

will focus on findings related to the psychological and social aspects of dermatological conditions and their implications for clinical practice.

Psychological factors

Over the past few decades, the field of dermatology has undergone a gradual shift away from a purely biomedical approach towards a more biopsychosocial one. There has been greater emphasis on QoL and PROMs in clinical trials, and to a lesser extent, clinical practice, though this has mostly been driven by forces outside the field, such as the NHS policy shift towards self-management, FDA regulations requiring QoL outcomes in clinical trials and the advent of core outcome sets. The creation of the British and European Psychodermatology groups over recent years demonstrates that the field is acknowledging the complex relationship between the biological, psychological and social aspects of dermatological conditions. Yet, this group's tendency towards a psychiatric, rather than psychological model of mental health and illness means that the biomedical approach remains dominant. Given the advancements in the understanding of dermatological conditions and their management along with the corresponding expectations of patients expressed here and elsewhere, a biopsychosocial approach to dermatology management is long overdue.

It is clear from the study findings that the psychological aspects of dermatological conditions require more attention. There is a need to establish effective psychological interventions and pathways to psychological support, improve clinicians' skills and confidence to address psychological issues and develop effective collaboration between dermatologists and mental health professionals including psychologists. This study highlights the need for service development to include psychological assessment and appropriate referral for those who need it via an established care pathway with integrated psychological support. To facilitate and evaluate such efforts, measurement instruments that comprehensively assess the broader impact of these conditions are vital. As a biopsychosocial, patient-driven PROM, PRIDD is well-placed to assess psychological distress and identify patients that require psychological support and to capture the full therapeutic benefits and risks of interventions.

Social factors

The social model of health and illness examines the social, cultural, political and environmental factors contributing to health (Bury 1991; Marmot 2005). Based on the social model of disability (Oliver 1996) strongly advocated by the disability community, it proposes that people with long-term conditions are primarily prevented from attaining their preferred functioning by barriers in society, rather than their condition, impairment or difference. Accordingly, societal barriers account for a greater reduction in patients' QoL than the dermatological condition itself. Barriers identified by the model include systematic barriers, derogatory attitudes and social exclusion, all of which were recognised by participants in the current study. The social model provides a framework for recognising and addressing barriers that make life harder for people living with dermatological conditions. Removing such barriers may promote equality and reduce the impact of dermatological conditions on patients' lives.

Participants explained that cultural attitudes contributed to the overall impact of dermatological conditions. As particularly visible health conditions, having a dermatological condition was at odds with the contemporary dominant aesthetic and health parameters that value skin complexion as a key marker of beauty. The associated stigma was sustained by a general lack of awareness of dermatological conditions in society. In the same way that ramps can reduce the level of disability experienced by a wheelchair user, cultural shifts may reduce the social isolation and discrimination experienced by many of the study participants, and therefore, the overall impact of the dermatological condition on their lives. Such as seismic shift would constitute a long-term goal, but other social factors contributing to the burden of dermatological conditions are more readily amenable to intervention.

Participants clearly described how the quality and accessibility of dermatological care directly affected their health status and QoL. Perhaps the most striking and concerning of this study's findings was the high variability in the quality and accessibility of dermatology services at the global, national and regional levels. Inequities and inequalities in dermatology provision were ubiquitous across dermatological conditions, regardless of their prevalence. To illustrate, as psoriasis is one of the world's most common dermatological conditions and both the WHA's (2014) resolution and WHO's (2016) global report on psoriasis require that nation-states improve service provision for psoriasis, it may be expected that patients with this condition

were consistently able to access good-quality healthcare. In reality, it was clear that across the world patients with psoriasis were still routinely struggling to obtain an accurate and timely diagnosis and effective medication, often as a result of being unable to access clinicians with sufficient expertise. Unsurprisingly, such barriers were even more common across other disease groups.

Contextual factors contributed to inequities. Naturally, the healthcare system the patient was navigating played a key role in the accessibility of dermatological care. In particular, patients in countries without free medical care at the point of delivery faced additional barriers to receiving care. Even where free healthcare was available, factors such as long waiting lists, limited resources and lack of sufficient expertise prevented people with dermatological conditions from accessing effective care. Of course, these factors disproportionately affected people with low or no incomes who could not afford to access public nor private dermatologists. This suggests that current dermatology provision contributes to global health inequalities. With this in mind, global health decision-makers need to adequately resource dermatology to address health inequalities and considerable *and established* patient needs.

Many participants were also critical of the organisational and individual approach to routine dermatological care. Further evidencing their underlying biopsychosocial understanding of their conditions, patients expressed frustration with disjointed care where specialists worked in silos. By working in this way, the patient's personhood was challenged, and they were left to manage the coordination of an often complex system of appointments and treatment regimens and synthesise (sometimes conflicting) information. Both the evidence and patient needs point to a holistic, integrated, multidisciplinary approach to dermatological care. Systemic changes are required in the organisation and delivery of dermatological care; this will require backing and funding from high-level decision-makers and patients should be actively involved in identifying, planning, designing and implementing solutions.

We anticipate that PRIDD will facilitate a shift in the model of dermatological care from both the top-down and the bottom-up and raise awareness of the full impact of dermatological conditions on patients' lives. From the top-down, PRIDD can be used as an advocacy tool to support efforts directed towards securing more resources for dermatology from high-level decision-makers. From the bottom-up, it can be used to alert clinicians to potential impacts,

prompt discussion and more holistically monitor the impact of treatments. Nevertheless, it would be unrealistic to expect that one measure would change the field of dermatology and further work is needed to promote a biopsychosocial approach to dermatological care including more relevant training for dermatology staff at all levels (see below).

8.1.2 Patient-centred measures and care

PROMS have become commonplace in healthcare, with increasing recognition that patient input is required to ensure appropriate content (Patrick et al. 2011a; Patrick et al. 2011b). Dalgard and Finlay (2006) stress the importance of person-centred measures in dermatology arguing that "they are essential to assess needs, understand illness behaviour, give and evaluate quality of healthcare and contribute to the challenge of prioritising in healthcare" (p. 283). PRIDD has been developed to include items that are important to people with dermatological conditions. However, standardised questionnaires may never be fully patient-centred as they do not allow individuals to define the dimensions along which to be measured and do not preserve the form of their response (Long and Dixon 1996).

PCC is considered a core concept in healthcare delivery and research internationally (Berwick 2002; Gilbert 2005; Australian Commission on Safety and Quality in Health Care 2011; Mansfield et al. 2011), but the degree of patient-centeredness can be diminished by practical constraints. Because the measurement instruments used in research are standardised to aid assessment of differences in outcomes between groups, yield comparable results across studies and produce valid and reliable data, they are inherently limited in their ability to capture the individual's experience. Patients who participated in the cognitive interviews expressed a desire to provide qualitative information on their experience of living with a dermatological condition alongside the standardised items. Likewise, research conducted by the HOME initiative to develop a measure of long-term eczema control highlighted this tension with one participant summarising: "You are having to fit yourself into somebody else's box. The box isn't the shape of me, it's somebody else's shape and it's got to fit a lot of different people" (Howells 2020, p. 175).

PROMs can enhance the understanding of patients' experiences and responses to therapy and inform clinical practice (Lohr and Zebrack 2009). But a PROM's potential to advance PCC is contingent upon its applicability, comprehensiveness and relevance to patients. Using a measure comprising of items of low priority to patients may defeat the purpose and aggravate feelings by the patient that their needs are not being met (Lohr and Zebrack 2009). Individualised PROMs allow individuals to define the dimensions to be measured but are unlikely to be feasible to develop during routine clinical consultations. By developing PRIDD with dermatology patient input during item generation, reduction and refinement, the dimensions considered most important to the population are included. PRIDD, therefore, provides the validity, reliability and responsiveness of standardised measures, while being highly relevant to dermatology patients. To enhance person-centredness, PRIDD should not *replace* the discussion of the wider impact of the disease during the clinical consultation, but *facilitate* patient-centred discussions (Pattinson and Bundy 2020). As Tourangeau's (1984; 2000) cognitive theory demonstrates, the completion of a PROM requires cognitive processing. Clinicians should be aware that a patient's literacy level, among other factors, may facilitate or create barriers to PROM completion. Consequently, patient-centredness in the administration of PROMs should be paramount to avoid perpetuating health inequalities.

8.1.3 Evidence of life course impairment

While the concept of cumulative life course impairment makes intuitive sense and is supported by cross-sectional data from people with psoriasis (Warren et al. 2011), it has not been established from the patient perspective nor with people with other dermatological conditions. This study has provided qualitative evidence in support of the concepts of CLCI and MLCDPs from people with a range of dermatological conditions. Participants variously reported that their condition had influenced their social development, the decision to have children, and occupation in terms of career choice, opportunities and taking early retirement. Early intervention is key to preventing CLCI, but dermatological services typically focus on medications as services struggle to provide evidence-based interventions. Support should be attuned to the person, their condition management and their wider health, psychological, social, relational, educational and vocational outcomes (Kirk 2008). Longitudinal research will

be vital to establishing the concept of CLCI and identifying opportune targets for interventions.

8.1.4 The value of theory in understanding dermatological conditions

It is apparent from the development of the conceptual framework that the use of the CSM along with aspects of the conceptual model of HRQoL provides an appropriate framework for exploring the impact of dermatological conditions on patients' lives. The application of these theories was consistent with a biopsychological model of dermatological conditions and enabled a multi-level (i.e. individual, organisational and societal) exploration of impact. Use of the CSM ensured that the psychological dimension of impact was adequately addressed by drawing attention to how patients thought, felt and behaved in response to their conditions. While some specific illness representations were less relevant to the item generation process, they were useful for understanding the context and drivers of impact. For example, for PRIDD to remain a unidimensional measure of impact, beliefs about the cause of dermatological conditions are not particularly useful but understanding patients' beliefs helps to understand their emotional reactions and coping strategies. In this way, PRIDD was not developed to reflect the CSM but rather the theoretical framework was useful in facilitating the in-depth exploration of candidate impact concept. This can be seen in the final version of PRIDD where CSM domains of direct relevance to impact can be discerned but domains that do not directly reflect impact are not included. That is, there are items reflecting identity (or symptoms; e.g. pain and itch), consequences (e.g. financial, social and daily routine impairments), emotional representations (e.g. anxiety, depression and anger) and coping behaviours (e.g. hiding) but not cause, timeline or cure/control cognitions. Knowledge of illness representations not of direct relevance to impact is significant as research has shown that psoriasis patients' illness representations predict health outcomes (Fortune et al. 2000; Scharloo et al. 2000; Fortune et al. 2002). More specifically, stronger beliefs about illness identity and an emotional cause of psoriasis, lack of curability/controllability and seriousness of consequences are variously associated with more frequent visits to outpatient clinics, worse physical and mental health, pathological worry, and poorer social functioning (Fortune et al. 2000; Scharloo et al. 2000; Fortune et al. 2002). In light of this, the resultant conceptual framework and theoretical

model are an original contribution to knowledge that can further the understanding of the broader impact of dermatological conditions and be used to target interventions.

8.1.5 PRIDD as a behaviour change intervention

The improvement of dermatological care will require behaviour change across a range of players operating at the global, national, community and individual levels. Theory-based behaviour change interventions appear to be more effective than those which are not (Noar and Zimmerman 2005; Trifiletti et al. 2005; Noar et al. 2007; Glanz and Bishop 2010; Webb et al. 2010; Borrelli 2011), though the association lacks consistency (Greaves et al. 2011; Prestwich et al. 2014; Rhodes et al. 2017; Dalgetty et al. 2019). Sustained behaviour change is most likely to occur when a combination of individual, community and population-level interventions are used (Dahlgren and Whitehead 1991). For this reason, NICE (2007) recommend that behaviour change interventions intervene at many levels, simultaneously and consistently.

The GRIDD project was initiated with the aim of collecting global impact data to be used as an advocacy tool to promote health-decision makers to allocate sufficient resources to dermatology. In this way, GRIDD, and by extension PRIDD, could be described as a behaviour change intervention targeted at global and national decision-makers to make policy changes. At the individual level, PRIDD could also form the basis of behaviour change interventions targeted at patients and clinicians. Firstly, the information gained from the completion of PRIDD could identify behaviour change interventions for individual patients to improve self-management of their condition, though this will not be appropriate in all cases. Psychological interventions to reduce emotional distress appear to be at least as important as behaviour change. Secondly, the content of PRIDD, and the knowledge gained during its development, could form the basis of training to further advance dermatology clinicians' biopsychosocial and patient-centred approach to management, including psychological support (discussed further below).

The BCW (Figure 19.), introduced in Chapter 5, provides a systematic way of identifying relevant interventions and policies to change for a particular target behaviour. This is facilitated by the COM-B model underpinning the BCW and used to complete a behavioural diagnosis that identifies potential behavioural targets and links these to interventions and behaviour change techniques. The use of the BCW ensures that interventions are not limited to only one level (e.g. individual or systems; Michie et al. 2014), thereby likely increasing their effectiveness.

Instead of focusing on a specific intervention, this study explored the impact of dermatological conditions in general. The theoretical model of the impact of dermatological conditions (Figure 14.) developed in Chapter 5 supplements the conceptual framework by providing insight into the wider context of the impact of these conditions and its determinants. The use of this theoretical model alongside the BCW could identify the most promising interventions for modifiable determinants of impact leading to the more efficient design of interventions to enhance dermatological care and reduce the impact of dermatological conditions on patients' lives. Consequently, the study findings could underpin and enhance the development of a wide range of multi-level interventions to improve dermatological care.

8.1.6 The current state of the field of PROM development and validation

It is an exciting time for the development of PROMs. While guidelines on the development of measurement instruments for use in other fields such as education have existed for some time (e.g. the Standards for Education and Psychological Testing; American Psychological Association et al. 1999), comparable guidelines on health-related measurement instruments are relatively new. In 2009, the FDA published guidance on how it reviews and evaluates PROMs used to support claims about medical product labelling. In 2010, the COSMIN group published their methodology for evaluating PROMs (Mokkink et al. 2010b). Before this guidance, there was a lack of clarity about the terminology and definitions of measurement properties, a lack of evidence on the measurement properties of many outcome

measurement instruments, and inconsistency in methods used to determine these measurement properties in the field of health.

At the same time, there has been a slow but steady shift in the choice of measurement theory used to develop and validate measurement instruments more broadly. CTT has dominated the field of psychometrics for nearly a century but Rasch/IRT has received increasing attention in recent years (DeVellis 2017) because it is a modern and superior alternative to CTT (DeVellis 2017; McKenna and Heaney 2021). Through the publication of the COSMIN methodology and the increasing mainstream adoption of IRT, PROM developers have arguably never had better tools to develop, validate and evaluate PROMs transparently, systematically and to the highest psychometric standards. That said, both COSMIN and the FDA guidelines are consensus- rather than evidence-based and, though both stress the importance of patient input during PROM development, this is limited to the item generation and pilot-testing phases. Neither requires patient involvement in the item reduction process. There is room, therefore, for improvement in the current PROM development and validation tools to optimise their patient-centredness and further progression in the field of outcome measurement.

8.1.7 Reflexivity

The interpretation of study findings should be considered in the context of those conducting the research and their attributes and biases. As a health psychologist, the lead researcher (RP) may have been biased towards the psychological and social aspects of dermatological conditions which may have influenced the development and content of PRIDD. Several steps were taken to safeguard against this.

Team science

The unusual nature of this PhD in terms of team science demonstrates the value of interdisciplinary and international teams in healthcare research. The collaborative effort

provided a wider group of people, beyond the PhD supervisors, to support and challenge my ideas and draw upon many skillsets to boost the efficient, quality and impact of this work addressing a global problem. The study was designed, conducted and analysed by me with input from the wider international team of researchers and clinicians with expertise in health psychology, clinical psychology, health sciences, biochemistry, medicine, dermatology and global and public health, which prevented one viewpoint from dominating. A team may be better placed to embrace the variety of different facets of impact than one researcher alone (Bryman 2006). The team science approach facilitated a broader conceptualisation of impact and increased the trustworthiness of the analysis since expertise and perspectives across multiple relevant disciplines were gained (Henwood and Pidgeon 1992; Gale et al. 2013). Douglas (1976), a prominent advocator of team research, argues that a team of investigators benefit from a range of factors including mutual support and the checking and comparison of each other's findings. A team approach to qualitative research may result in a more structured investigation in order to impose a degree of common purpose across team members (Smith and Robbins 1982). In addition to the advantages of generalisability and triangulation (discussed below), the internationality of the team increased the content validity and translatability of PRIDD as non-native English speakers identified problematic items overlooked by native English speakers. This was bolstered by the GRIDD scientific advisory board, an international group of dermatologists, researchers and patients (including the co-author of the DLQI, Professor Andrew Finlay) who provided clinical, scientific and practical input to the study by, for example, providing local knowledge with implications for the conduct of the study.

The role of health psychology

Despite the steps taken to limit biases, the lead researchers' background in health psychology, along with the use of psychological theories, may account for the dominance of the psychological domain in PRIDD. The counterargument that this accurately reflects reality is based on persuasive evidence. The strongest evidence in support of this comes from the results of the plenary respondent validation session (Figure 17.) which demonstrated that the qualitative analysis of the interviews was valid. Not only that, the counting procedures

employed provided clear evidence that many patients felt that the psychological and social aspects of their conditions were the most significant; the psychological domain (135) alone received more than double the votes of the physical domain (56). It could be argued, therefore, that a background in health psychology did not bias the results of the study but rather revealed an under-appreciation of these domains in existing dermatology PROMs.

The development and validation of dermatology PROMs is most often led by dermatologists, sometimes with input from other disciplines. The central role of health psychologists *alongside* dermatologists in PRIDD's development likely enhanced the quality of the research. The primary focus of health psychology is the behaviour, beliefs and experiences of individuals within a health context. The biopsychosocial model is fundamental to the discipline as health psychologists view psychological and social influences to be as important to health as biological factors. In this way, health psychologists are well-placed to develop an in-depth, patient-centred, biopsychosocial understanding of the impact of dermatological conditions on patients' lives. Thus, the collaboration of a multidisciplinary research team enabled the 'bio', 'psycho' and social aspects of dermatological conditions to be more fully explored than they previously had, thereby addressing the limitations of previous dermatology PROMs.

As well as the fundamental assumptions of health psychology, the related skills and training of RP are a further strength of this research. Robust qualitative research is vital to establish the content validity of a PROM. Such rigour requires an interviewer who possesses a range of skills including, but not limited to:

- Experience in conducting qualitative research
- Knowledge of the disease area
- Understanding the importance of accurately reflecting the patient voice
- A person-centred approach to interviewing
- Protecting confidentiality of the participant and information elicited
- Empathetic, sensitive and preparedness to deal with emotions
- Ability to mentally track multiple issues
- Develop a rapport

- Actively listen

As Brod and colleagues (2009) acknowledge, these skills reflect those of a psychologist. Indeed, my additional expertise in MI uses many of the above skills, particularly the role of active listening.

8.2 Strengths and limitations

8.2.1 Patient and public involvement

As the GRIDD project was initiated by IADPO, a global patient organisation, it is clear that PRIDD is an important outcome for patients. PROM development guidance currently suggests involving patients to incorporate their perspective or experience (FDA 2009; Mokkink et al. 2010a), however, this often remains at a consultative level (Staniszewska et al. 2012). Researchers typically involve patients as research participants but ultimately the researchers determine the final shape of the measure (Staniszewska et al. 2012). This study was conceptualised and conducted in active partnership with IADPO. Examples of how IADPO and patient members were involved include:

- As co-applicants on the research project
- Identifying patient priorities
- As members of the scientific advisory board
- Co-developing PISs and other research materials
- Contributing to dissemination. PPI members are co-authors on journal articles, co-presented presentations and collaborated on the development of articles, conference abstracts and lay summaries.

A more collaborative approach may have greater potential to impact research outcomes (Staniszewska et al. 2012) and improve acceptability in the long term. However, measurement instrument development is a challenging area for PPI. Devellis (2017) acknowledges the admirability of giving the target population final approval of a measurement instrument but cautions against it. He argues that there is a need to recognise

the boundaries of patients' expertise: while dermatology patients are uniquely qualified to provide insights into their own understanding of PRIDD's content, they are not experts in the technical details of measurement development such as item construction. Indeed, a lack of understanding of the concepts of the target construct and target population was demonstrated in the Delphi study where participants suggested disease-specific items for inclusion in PRIDD. Devellis recommends that researchers reserve the right of final approval because, ultimately, PROMs need to measure the target construct. If it does not, PRIDD will not only be invalid but its development will have wasted patients' time. This ethical implication is particularly important when conducting research with populations with long-term conditions. Reserving the right to final approval, therefore, capitalises on both the researchers and patients' expertise. Furthering hindering PPI involvement in PRIDD's development was a lack of knowledge about how to go about this and examples within the current literature. There could, however, be a vital role for PPI, particularly regarding the interpretation and dissemination of results. Ultimately, the patients involved in developing PRIDD are prioritising impacts to be evaluated, hence influencing the decision-making and research agenda in this area.

8.2.2 Sample

The systematic review revealed that insufficient patient input during development was a chief reason for the lack of high-quality dermatology-specific PROMs. The current study addressed this methodological weakness through high levels of patient engagement (n = 1235). A strong advantage of patient involvement in the content validity phase indicates PRIDD is relevant to patients. The diversity of the sample in relation to dermatological condition, geographical location, age and gender increases the applicability of PRIDD (Brod et al. 2009), enhances its universality – for example, by avoiding cultural colloquialisms – and resulted in high translatability of the measure.

As a result of the non-probability sampling strategy employed, it is difficult to know how well the study sample represents the target population, reducing the generalisability of the study findings. As noted in Chapter 6, the Delphi study sample was not representative of the global

population of people with dermatological conditions as some groups, most notably PRP, were overrepresented while others, such as acne, were underrepresented. In the quantitative Delphi study, the overrepresentation of such groups was mitigated through statistical means. The qualitative studies, on the other hand, employed purposive sampling and data collection was scheduled strategically to achieve a diverse sample that reflected all the key characteristics of the target population. Moreover, the Delphi and cognitive interview studies validated the conceptual framework derived from the concept elicitation study in a wider group of patients, suggesting that the results are generalisable. According to Yardley (2017), the overriding consideration in generalisability is whether the sample is 'adequate' to supply all of the information needed for a comprehensive analysis. Achieving data saturation demonstrates this. In both the qualitative studies (Chapters 5 and 7), evidence of data saturation was provided, and data collection continued even after saturation was reached and no additional themes emerged. This ensured thoroughness and depth of the data collected. Because of the diversity of participants, between-methods triangulation and data saturation achieved, this study may be less vulnerable to the charge of limited generalisability than that of other qualitative studies.

Recruiting through IADPO's unique membership network allowed relatively quick and easy access to a large and diverse global network of patients and patient organisation leaders who are experts on the impact of dermatological conditions on the patient's life. Without this network, it would have been impossible to achieve the high levels of patient involvement and methodological rigour present in the current study while remaining within the study timeline and budget. However, a consequence of this recruitment strategy is that the majority of study participants were in contact with, if not a member of, a dermatology patient organisation and, therefore, may not be representative of non-members. It has been argued that patient organisations may have an agenda to increase the profile of their condition when participating in research. Indeed, a study investigating the prevalence of interests – both declared and undeclared – among patient organisations contributing to health technology assessment at NICE found that financial interests were highly prevalent (Mandeville et al. 2019). Recruiting participants through IADPO, rather than through the healthcare system, may have reduced the clinical relevance of the data as the current sample were not necessarily in clinical contact. This is exacerbated by the fact that evidence of diagnosis was

not required to participate. However, the easiest way to substantiate whether participants have a condition is to recruit through a clinician but this is often costly, time-consuming and can reduce the response rate (Brod et al. 2009).

A final limitation of the sampling strategy is that other stakeholders such as clinicians, families and caregivers were not recruited to participate. Such stakeholders may have supplemented or provided alternative perspectives on the impact of living with a dermatological condition. Patients were prioritised in this study to overcome the top-down approach to dermatology PROM development identified in the systematic review, whereby clinicians and researchers drive the process. This was balanced out with a strong and multidisciplinary research team and scientific advisory board.

8.2.3 Study design

The mixed methods design of this study allowed for both breadth and depth in the approach to PRIDD's development, achieving greater patient involvement and understanding of the impact of dermatological conditions on the patient's life and how to measure this than either a quantitative or qualitative approach alone (Creswell and Plano Clark 2017). Furthermore, the mixed methods approach underpinned by pragmatism allowed the study design to be driven by the research aims and questions, rather than a specific paradigm, and, therefore, the most robust methods were employed at each stage of the development process (Creswell and Plano Clark 2017). The addition of the Delphi study to the conventional PROM development and validation methods allowed patients to have greater input into PRIDD than is typical of dermatology-specific PROMs, which enhances content validity.

Mixed method research is underpinned by the perceived advantages of comparing, contrasting and attempting to integrate different sorts of data, also known as triangulation. Triangulation, whether for confirmation and/or completeness (Shih 1998), is thought to increase the scientific credibility of the study findings by improving both internal consistency and generalisability (Campbell and Fiske 1959; Hussein 2015). Quantitative researchers assert that triangulation can minimise biases and provides the opportunity for comparing and cross-

checking findings (Hastings 2010). Qualitative researchers, on the other hand, contend that triangulation is beneficial because it allows for multiple perspectives on a topic and prompts the researcher to consider multiple realities. Relevant to this patient-initiated and -led study, triangulation allows patients who typically have less power and influence in health decision-making to have a voice in determining reality and contributing to the evidence base (Hastings 2010). This study was designed and conducted to continually cross-check and validate findings. As a result, 'multiple triangulation' (Polit and Hungler 1995) across four triangulation types (Denzin 1978) – data, methodological, theoretical and investigator - was achieved which increased the credibility of the research findings (Hussein 2015) and enabled a cautious approach to item reduction, ensuring that items were not removed without sufficient patient input. Additionally, the number of conference presentations and journal publications at each step of the process provided an even wider peer-review of the work.

8.3 Implications of this research

8.3.1 Implications for policy

The GRIDD project aims to challenge global estimates of the burden of dermatological conditions, raise awareness of them as serious non-communicable diseases and advocate for WHO and other key influencers to make policy changes. These burden estimates are influential as they provide an important evidence-base for identifying patient need, developing policies, and determining resource-allocation and research priorities globally. PRIDD was developed to provide quantitative, global data that comprehensively captures the impact of dermatological conditions on patients' lives and meets the scientific standards to be accepted by funders, policymakers and health decision-makers. We anticipate PRIDD will raise awareness of the true impact of dermatological disease to inform adequate resource allocation.

Griffiths and Barker (2007) describe psoriasis as "rarely life-threatening [yet] life-ruining for the majority of patients" (p. 269). The WHO resolution (WHA 67.9) and report on psoriasis (WHO 2016) raised awareness of the impact of psoriasis on people's lives and empowered policy-makers with practical solutions to improve patient's healthcare. Qualitative research

conducted to develop PRIDD revealed that both Griffiths and Barker's description of the impact of psoriasis on people's lives apply to dermatology conditions more generally. There is, therefore, a need for global health decision-makers to extend the attention given to policymaking and resource allocation afforded to psoriasis and other non-communicable diseases to dermatology more generally.

PRIDD's role in evidence-based medicine

There is an abundance of PROMs in dermatology and new ones are still being developed. Many of these PROMs aim to measure the same construct and were developed for the same population. Clinicians are left to choose the most suitable instrument for their intended use. However, they lack the time and training to conduct systematic reviews of all the PROMs relevant to a clinical decision. Instead, the main criterion for the choice of PROM tends to be whether it is widely used, irrespective of its quality or suitability, and the most frequently used PROMs are not necessarily the best ones available (Hendrikx et al. 2016; McKenna and Heaney 2021). This explains why the DLQI remains the most widely used PROM in dermatology, despite mounting evidence and frequent calls against its use (e.g. Nijsten 2012). Evidence-based guidance on which measurement to use to capture aspects of living with a dermatological condition important to patients is required.

Eddy (2005) argues that medicine is best served by a unified approach where both individual physicians and those who design guidelines and other policies follow evidence-based methods. It is widely accepted that guidelines should be based on the best available evidence, yet, NICE currently recommend the DLQI to assess QoL. When development and validation are completed, PRIDD may provide a single, evidence-based assessment of QoL. PRIDD scores can also provide individual clinicians with an evidence base for treatment decisions and encourage a dialogue between clinicians and patients to facilitate shared decision-making.

Because of the top-down approach to QoL PROM development in dermatology, the PROMs used often provide data more relevant to clinicians than patients. It is well accepted that patients should be involved in their own treatment. It follows, therefore, that they should

also be involved in assessing whether interventions were successful. McKenna and Heaney (2021) argue that this can be achieved through the selection of a PROM. PRIDD was developed with substantially more patient input, and with a greater focus on determining the most important aspects of impact, than other dermatology-specific PROMs and is, therefore, the most suitable candidate PROM to facilitate shared decision-making.

8.3.2 Implications for education

Clinical use of PROMs is dependent upon clinicians' understanding and acceptance of their value. This is particularly true of dermatologists and other clinicians who manage long-term conditions. Moreover, with the increasing recognition of PCC and the shift to personalised medicine, PROMs will become an ever more present and important part of clinical practice. There are challenges to the implementation of PROMs, though many of these can be addressed through education. First, clinicians need to understand that they are not always able to accurately predict patients' QoL without measuring it (Augustin and Radtke 2008). Second, erroneous beliefs that integrating PROMs may be more time and financially costly or that the 'subjectivity' of PROMs implies a lack of reliability should be challenged. Third, dermatologists have expressed unfamiliarity with PROMs and the interpretation of their scores, recognising that "training would help [to] understand it better" (Taliercio et al. 2021, p. 14). Dermatologists and dermatology-specialist nurses are not currently taught how to use or critically appraise measurement instruments throughout their under- or post-graduate training. The need for proper training and support is essential for increasing clinical use and understanding of PROMs (Conti and Gensini 2008; Santana et al. 2015) and for clinicians to make informed decisions regarding their choice of PROM where guidance does not already exist. It is not necessary that clinicians gain expertise in PROMs, but rather basic and transferable knowledge and skills in this area.

Current medical and specialist dermatology education fails to prepare clinicians to meet the established needs of dermatology patients consistent with evidence-based approaches. Clinicians including dermatologists have expressed a lack of biopsychosocial training (Moser and Stagnaro-Green 2009) and therefore confidence in addressing psychological issues

(Nelson et al. 2013a). The importance of clinicians' psychological competence in the context of this study is twofold. First, the lack of such training has implications for PROM usage. Previous research has found that dermatologists are hesitant to use PROMs for fear that they will steer the consultation to issues they believe they do not have the expertise to address, for example, mood (Nelson et al. 2014). Second, clinician-patient communication can be more influential to patient outcomes than specific treatments (Turner et al. 1994). In their systematic review of the influence of context effects on health outcomes, Di Blasi and colleagues (2001) suggest that clinicians can be instrumental in shaping patients' cognitive and emotional responses to their conditions and treatments through the information provided. Their review concludes: "physicians who adopt a warm, friendly, and reassuring manner are more effective than those who keep consultations formal and do not offer reassurance" (p. 757). The related concept of empathy refers to healthcare that incorporates the patient perspective, shared decision-making and the broader context in which an illness is experienced (Mercer and Reynolds 2002). It is a key healthcare concept emphasised in policy, NICE guidance and medical training and is a high priority for patients (NICE 2009; Derksen et al. 2013). It has been hypothesised that clinician empathy could lead to better patient outcomes and satisfaction (Lelorain et al. 2012; Doyle et al. 2013; Mercer et al. 2016). Evidence suggests that it can elicit a strong placebo response (Olshansky 2007) and affect long-term outcomes including mortality (Dambha-Miller et al. 2019). Consequently, patient-centred, empathetic care appears to be an important contributor for optimising healthcare, emphasising the need to incorporate communication training into medical education. The use of PRIDD may provide clinicians with a window into the lived experience of their patients, thereby increasing their emotional and cognitive care.

Data obtained from PRIDD may point to the patient's need for psychological support. Evidence-based approaches to overcoming some barriers to providing psychological support already exist. Research indicates that MI can bolster self-confidence in clinicians and facilitate effective patient self-management of long-term conditions (Frost et al. 2016; Szczekala et al. 2018) including dermatological conditions (Qureshi et al. 2019) and can be incorporated into 10-minute consultations (Chisholm et al. 2017). This thesis has advocated for the PsoWell™ training and clinical model. As an MI-based training programme and clinical initiative that advocates a holistic, multi-disciplinary approach to managing people with complex psoriasis,

PsoWell™ is well placed to support clinicians to take a biopsychosocial, patient-centred, psychologically informed approach to consultations. It has been shown to improve knowledge and consultation skills in primary and secondary care clinicians (Chisholm et al. 2017) and has been deemed acceptable and feasible by clinicians (Hewitt et al. 2021b). Although this training was developed specifically for the management of psoriasis, clinicians have recognised that the content is highly transferable to other dermatological conditions (Hewitt et al. 2021b) or indeed other long-term conditions. It is, therefore, a promising, evidence-based approach to upskilling clinicians to address the psychological issues highlighted by PROMs. Future work could focus on adapting the PsoWell™ model to apply to dermatological conditions more generally and testing its effectiveness.

8.3.3 Implications for research

Measurement development and validation is a prescriptive process, but developers have some freedom within this process as is evident in the wide variation in the quality of measures. At each stage of the process, researchers can take steps to enhance methodological rigour and the patient voice. Furthermore, it is essential to the task of evaluating content validity that the process is transparent and well documented for both scientific and regulatory purposes (Brod et al. 2009). This study's methodology followed best practise in PROM development and, as a result, is compliant with a range of relevant guidance – most notably COSMIN and the FDA. At each stage of the process, the most rigorous methods were chosen, and the patient voice was amplified but remained within the typical measurement development timeline. This approach ensured that PRIDD was grounded in the lived experience and language of patients and captures issues important to patients with resultant good evidence of content validity. For this reason, this study's methodology provides a model for the development of quality PROMs in other therapeutic or disease areas.

Content validity

The proper development and validation of a PROM is time- and resource-intensive, usually taking between two and five years. Textbooks tend to give validity and reliability equal attention, yet researchers are often more inclined to report that reliability tests have been carried out (Bryman 2006). This gives the illusion that reliability is more important and encourages this to be the main criterion a measure is judged on, whereas arguably the opposite is true. The real reason for this emphasis is likely because validity testing is time-consuming, but it is necessary to establish content validity as a prerequisite for valid data. A result of following the COSMIN methodology is that the importance of content validity and evidence thereof in PROM development has been paramount. Consequently, PRIDD has better quality evidence of content validity than any of the dermatology-specific PROMs identified in the systematic review. A further benefit of conducting rigorous validity testing is that research undertaken to establish content validity has illuminated the construct of impact. For example, the conceptual framework and Delphi rankings were not only relevant to PRIDD's development but are also of clinical relevance and indicate future avenues of research. Further testing of the conceptual framework to explore its utility and application to understand more about the experience of living with a dermatological condition will be important. The conceptual framework defines impact in terms of the five relevant predictor variables (i.e. the domains) and its validity is dependent on the extent to which it can predict variation in item values and person scores (McKenna et al. 2019). Future work should quantitatively hypothesis test the conceptual framework to complete the evaluation of content validity.

Psychometric testing

Researchers, clinicians and regulatory agencies should choose measurement instruments based on their quality. Before PRIDD can be recommended for use in research and clinical practice, validation of the measurement properties (i.e. reliability, responsiveness) and interpretability information (i.e. MCID) is required (Brod et al. 2009). To this end and given the corresponding strengths and limitations of CTT and IRT elucidated above, the

psychometric testing of PRIDD should follow the Rasch model. The value of Rasch is that it confirms the internal construct validity (Kersten et al. 2018) of the PROM and items that misfit the measurement model can be identified and removed. It is, therefore, well-placed to quantitatively test the conceptual framework.

Interpretability of PRIDD

Without meaning (both in terms of shared understanding and context), the scores of PROMs are of little clinical value, but the scores produced by multi-item instruments are often not easily understood. Finlay (2017) points out that for most QoL PROMs there is often no guidance on what the scores mean clinically nor how to interpret a change in score. Once the quality of PRIDD's measurements properties is established, further research will be required to aid its interpretability. Interpretability is defined as the "degree to which one can assign qualitative meaning – that is, clinical or commonly understood connotations – to an instrument's quantitative scores or change in scores" (Mokkink et al. 2010c, p. 743). Two approaches to improve the interpretability of a PROM's score are employed - interpretation of single scores and interpretation of changes in scores – both of which will be important for PRIDD to be used in clinical practice and research. The former assigns clinical connotation to the scores, for example, 'mild', 'moderate' and 'severe', often by using an external reference of well-known groups such as global questions or measures of severity. The latter assigns meaning to a change in scores. A useful concept for interpretability is the minimally important difference which is "the smallest change in score in the construct to be measured which patients perceive as important" (Mokkink et al. 2010c). MCID estimates allow clinicians to interpret a patient's change in the PRIDD score and, therefore, aid treatment decision-making and supports sample size calculations for clinical trials and the interpretation of their results (Wright et al. 2012). Qualitative research has revealed that clinicians often struggle to interpret the presentation of scores (Taliercio et al. 2021). Future research should establish PRIDD's interpretability information, qualitatively explore the optimal way to present this information to clinicians and potentially develop a training package for use.

Core Outcome Sets

In dermatology, and healthcare research more generally, a key focus is on the development and evaluation of interventions to improve disease status, health and wellbeing. The results of systematic reviews and meta-analyses influence intervention implementation which in turn impacts significantly on patient health and healthcare services (Heneghan et al. 2017). Tugwell and colleagues (2007) argue that a clinical trial is only as good as its outcome measure(s) because intervention effects can only be inferred from the outcomes measured and reported (Matvienko-Sikar et al. 2020). The HOME group similarly emphasises that "the use of non-standardised and inadequately validated outcome measures … is a major obstacle to practising evidence-based dermatology" (Schmitt et al. 2012, p. 1111). The choice of outcome measure, therefore, is a crucial consideration in the planning and conduct of trials of health interventions (Heneghan et al. 2017), in synthesising evidence about intervention effects (Clarke 2007) and producing clinical practice guidelines (WHO 2014b). The use of unsuitable or insufficient measurement instruments may introduce bias in the conclusions of studies and may be unethical where patients contribute little to the body of evidence but still suffer from the burdens and risks of the study.

A core outcome set (COS) is an "agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care" (Clarke and Williamson 2016, p. 1). COSs present a promising solution for improving our ability to systematically collate and compare findings from clinical trials and reduce selection bias (Williamson et al. 2005; Clarke 2007). For this reason, there has been widespread development of COSs across many fields of healthcare research (Gargon et al. 2014). It is recognised that COSs should be developed to include the measurement of outcomes that are important to key stakeholders such as patients and so often include PROMs (Layton et al. 2017). COS development presents an opportunity for patients to guide researchers in designing clinical trials to measure outcomes important to them.

Both the COSMIN and the Core Outcome Measures in Effectiveness Trials (COMET) guidance specify that one measurement instrument per outcome domain should be chosen for a COS as this allows for maximum ability to synthesise trial results (Prinsen et al. 2016) and reduces respondent burden. Similarly, the HOME initiative suggests that the one best instrument per

construct is ideal (Schmitt et al. 2015). Measures of these core outcome constructs need to be valid, sensitive to change and feasible (Schmitt et al. 2012). While there is no generic dermatology COS, a number of disease-specific COSs are available or in development, most notably in acne by ACORN (Layton et al. 2017) and AD by HOME (Schmitt et al. 2012; Thomas et al. 2021). ACORN and HOME have determined QoL to be a core outcome domain for acne and AD, respectively. Given the results of this research along with the importance placed on QoL by patients, clinicians and clinical guidance, it is safe to assume that this is an important outcome domain across dermatological conditions. HOME previously recommended the DLQI for measuring QoL in adults with AD (Heinl et al. 2017); however, their more recent COSMIN systematic review found that none of the identified PROMs, including the DLQI, could be recommended for future use (Gabes et al. 2020). As PRIDD is as yet unpublished it was not included in this review. This means there is currently a lack of sound QoL measures in dermatology COSs.

Both HOME and ACORN are prioritising the identification/development of the most appropriate instruments for their core outcome domains (Schmitt et al. 2012; Thiboutot et al. 2019). PRIDD represents a promising candidate for QoL outcomes in dermatology COSs. Dissemination of PRIDD to relevant stakeholders and COS development groups is essential to reduce research waste and promote adoption into COSs. Future research should systematically evaluate whether PRIDD can be recommended for measuring QoL as part of dermatology COSs. Industry stakeholders are much more likely to adopt a measure for use in a trial if it has regulatory endorsement (Thiboutot et al. 2019). For this reason, following the validation of PRIDD, a key step will be to seek regulatory endorsement from the FDA and European Medicines Agency for use in clinical trials.

Adaptations of PRIDD

Following the initial development and validation of PRIDD, a programme of research focused on adaptions should be developed.

Given that the GRIDD project will use PRIDD to collect global data on the impact of dermatological conditions and the intended efforts to include the measures in COSs, future efforts should be directed to ensuring that PRIDD is adapted appropriately for use in different cultures and languages. In addition to the standard battery of measurement properties, cross-cultural validity will be particularly relevant as evidence of construct equivalence will be essential to confidently synthesise and compare data across the language versions. The process of translating, adapting and validating a PROM for different cultural groups requires a methodological strategy such as forward- and back-translation along with time, skill, knowledge and experience (Epstein et al. 2015). Therefore, cross-cultural translation of PRIDD will likely require a coordinated effort by research teams across the globe following a standardised methodology.

As a dermatology-specific measure, PRIDD is adequate for use across dermatological conditions but is likely to lack specificity for specific conditions. The FLQA is a modular QoL instrument consisting of a core set of generic dermatology items as well as additional disease-specific items. Several variants of the FLQA have been developed including allergies and urticaria (Zschoke et al. 1997), chronic venous insufficiency (Augustin et al. 1997), lymphedema (Augustin et al. 2005) and chronic dermatoses (Augustin et al. 2000b). Following the approach of the FLQA, disease-specific variants of PRIDD could at this stage be developed to complement the generic component to gain an impact instrument that can be used at the dermatology- and disease-specific level.

A final useful avenue of research may be to develop and test different modes of administration (e.g. paper-based and electronic methods) that could improve the feasibility and acceptability of responding to PRIDD across settings (e.g. clinical trial and routine clinical practice).

8.4 Concluding remarks

The work presented in this thesis (Table 29.) completed the content validation phase of new measure development for PRIDD. This thesis has resulted in the development and pilot-

testing of PRIDD, an instrument designed to comprehensively measure the impact of dermatological conditions on the patient's life. The rigorous, mixed methods design of this study represents best practise in PROM development, providing strong evidence of content validity. The next major step in PRIDD's development is the completion of psychometric testing. Following validation, a programme of research focused on PRIDD adaptions, add-ons and modes of administration is warranted.

Finlay (2015) helpfully contextualises both the huge number and lack of acceptable dermatology-specific PROMs. Concluding his commentary on PROMs in psoriasis, he writes: "The adoption of various standard measures of weight took about 4000 years to settle down, from the earliest efforts of the Indus Valley Civilization to the universal acceptance (at least in science) of the metric system. Let us hope that we can be a bit speedier agreeing on the most appropriate PROMs for psoriasis" (p. 1179). In IRT and the COSMIN guidance, we now have sophisticated and standardised tools to expedite this process in dermatology.

The patient-centred approach to PRIDD's development will also contribute. Through its focus on the patient voice, this thesis has added evidence to the understanding and measurement of the burden of dermatological conditions. The study demonstrates the multifaceted and considerable burden of dermatological conditions which are demonstrated in the conceptual framework and list of most important impacts of dermatological conditions worldwide produced. This thesis adds to the body of work that provides compelling evidence that dermatological conditions should be managed according to a biopsychosocial model. This shift will require education for clinicians; health psychologists are well-placed to provide evidence-based training and support.

Table 29: Statement of contribution

What is already known on this topic?
• Dermatological conditions are the fourth most common cause of human illness globally and can have a substantial physical, psychological, social burden for patients. • PROMs have the potential to provide a reliable measure of the impact of dermatological conditions from the patient's perspective. • Existing dermatology-specific PROMs are unlikely to capture the true impact of dermatological conditions on the patient's life.
What does this study add?
• This study has developed and pilot-tested PRIDD, a 26-item questionnaire to capture the impact of dermatological conditions on the patient's life. • PRIDD was designed with considerable input from a diverse group of people with dermatological conditions from across the world to ensure good content validity, acceptability and feasibility. • The resultant conceptual framework and list of the most important impacts of dermatological conditions worldwide can be used to judge candidate PROMs and inform policy and clinical practice.

Chapter 9: References

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Chapter 10: Appendix

Appendix 1: Patient-reported Outcome Measures in Dermatology: A Systematic Review

This journal article is largely based on the text in Chapter 4. It was accepted for publication in Acta Dermato-Venereologica in July 2021. The original publication is available at: https://www.medicaljournals.se/acta/content/abstract/10.2340/00015555-3884

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Patient-reported Outcome Measures in Dermatology: A Systematic Review

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By relying on data from existing patient-reported outcome measures of quality of life, the true impact of skin conditions on patients' lives may be underestimated. This study systematically reviewed all dermatology-specific (used across skin conditions) patient-reported outcome measures and makes evidence-based recommendations for their use. The study protocol is registered on PROSPERO (CRD42018108829). PubMed, PsycInfo and CINAHL were searched from inception to 25 June 2018. The Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) criteria were used to assess the measurement properties and methodological quality of studies. A total of 12,925 abstracts were identified. Zero patient-reported outcome measures were assigned to category A (ready for use without further validation), 31 to category B (recommended for use, but only with further validation) and 5 to category C (not recommended for use). There is no gold-standard dermatology-specific patient-reported outcome measure that can be recommended or used without caution. A new measure that can comprehensively capture the impact of dermatological conditions on the patient's life is needed.

Key words: patient-reported outcome measures; measurement properties; dermatology-specific; burden; quality of life.

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SIGNIFICANCE

This is the first study to systematically evaluate all published dermatology-specific (for use across skin conditions), patient-reported outcome measures against the gold-standard Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) criteria and make evidence-based recommendations for their use. The study found that no dermatology-specific patient-reported outcome measure can be unequivocally recommended for use. These results question the validity of the data collected using these patient-reported outcome measures, which has implications for clinical decision-making and research.

Dermatological conditions are reported to cause substantial pain, disfigurement, disability, and stigma and have a psychological, social and financial burden (1, 2). Our qualitative research with people with dermatological conditions resulted in the first conceptual framework of the impact of these conditions on patients' lives (unpublished data). Impact was defined as a multifaceted construct shown across physical, psychological, social, financial and daily functioning.

The measurement of impact is particularly pertinent to dermatology, where the goal of treatment is often to improve the patient's quality of life (QoL) rather than prolong it. The true impact of dermatological conditions on patients' lives is probably underestimated, because most of the evidence derives from data collected using QoL patient-reported outcome measures (PROMs), which have some limitations. First, these PROMs are typically used to assess the impact of an intervention on the patient's life, not the impact of the skin condition on the patient's life. Secondly, individual dermatology QoL PROMs do not adequately address all of the relevant domains or aspects thereof. For example, the psychological functioning domain has focussed largely on emotions and, to a lesser extent, coping behaviour, and typically ignores the cognitive impact. Cognitions are known to predict outcomes for a range of long-term conditions (1). In dermatology, beliefs about psoriasis are better predictors of outcomes than clinician-assessed disease severity (2–4) and are closely linked with medication adherence (5). Thirdly, work on cumulative life course impairment (CLCI) and major life decisions has established that skin conditions have a cumulative impact over time (4, 5). Recall bias increases with a long recall period, so it is generally recommended that PROMs are repeatedly administered to capture impacts over time. However, dermatology QoL PROMs typically do not contain items that can be used to track CLCI over time. Finally, the measurement properties of most PROMs used in dermatology have not been evaluated according to the "gold-standard" criteria, the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) criteria (9). This is important because PROMs must meet pre-defined cri-

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Table I. Levels of measurement

	Definition	Example
Generic	Instrument can be used across therapeutic areas, e.g. dermatology, diabetes or cancer.	Short Form-36, EuroQOL 5D, Nottingham Health Profile
Dermatology-specific	Instrument is specific to dermatology and can be used across skin conditions.	Dermatology Life Quality Index, Skindex, Patient Benefit Index
Disease-specific	Instrument is to be used only with a certain skin condition.	Patient Oriented Eczema Measure, Rosacea Quality of Life Index, Comprehensive Appraisal of Life Impact of Psoriasis

teria across a range of measurement properties (including validity, reliability and responsiveness) for the data they produce to be meaningful (6–8). Without knowledge of their measurement properties, we cannot judge the quality of a measure nor have confidence in the data it produces.

To fully understand the impact of skin conditions on patients' lives there is a need to develop a measure specifically designed to capture this. This systematic review is the first step in the development of the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure: a dermatology-specific PROM of the impact of dermatological conditions on the patient's life for use with adults worldwide. PRIDD will have discriminative and evaluative applications for use in research and clinical practice. This review aims to: (*i*) identify all dermatology-specific PROMs (see **Table I** for information on levels of measurement) and assess their suitability for use as a measure of impact, (*ii*) evaluate their measurement properties according to the COSMIN criteria, and (*iii*) make evidence-based recommendations for their use.

MATERIALS AND METHODS

The review protocol was registered on PROSPERO (CRD42018108829), an international database of prospectively registered systematic reviews with a health outcome. Ethics approval was not required. A comprehensive search strategy (Table SI[1]) identified published evidence of the development and validation of dermatology PROMs. It comprised 3 blocks of search terms: (*i*) dermatological conditions; (*ii*) life impact; and (*iii*) a validated, highly sensitive search filter for measurement properties (10). Searches of PubMed, PsycInfo and CINAHL from inception to 25 June 2018 were limited to journal articles and human subjects. No limit was applied for language, and non-English papers were translated. Due to the volume of articles retrieved, the current study focused on dermatology-specific PROMs. Disease-specific PROMs will be reported in a separate manuscript.

The systematic review was conducted according to the COSMIN methodology which is the gold-standard critical appraisal tool for systematic reviews of PROMs (9). According to COSMIN, all PROMs in a review should be assessed according to both the construct of interest and target population of the review (9). The aim of this review was to identify measures of impact and to establish the quality of dermatology-specific PROMs currently in use. As such, the target population was patients with dermatological conditions (as opposed to disease-specific samples, e.g. atopic dermatitis) and the construct of interest was that of the PROM assessed. This allowed us to both identify measures of impact and establish the quality of PROMs currently used in dermatology.

Three reviewers independently screened titles and abstracts. To satisfy the inclusion criteria, the title and/or abstract had to include at least one term from each of the 3 search strategy blocks. Three reviewers independently assessed and ranked the selected articles according to adapted criteria by Kitchen et al. (11) (**Table II**). Only articles ranked 1a were included. Reviewers screened and rank-ordered 10% of the others' samples to determine inter-rater reliability. The results were compared and any discrepancies were resolved through discussion.

An electronic data extraction form complied with the COSMIN guidance (12). The key data extracted were: summary data of included studies; the characteristics of included studies; the measurement properties of the studied PROM(s); and information on the interpretability and feasibility of included PROMs.

Methodological quality of included studies

The COSMIN risk of bias checklist (9, 12) was used by 6 independent reviewers to evaluate the methodological quality of included studies.

Quality of measurement properties

Measurement properties from the COSMIN checklist were evaluated against predefined criteria by 6 independent reviewers (9). Criterion validity was not assessed, as no gold-standard exists for the constructs evaluated (e.g. QoL) (13). Interpretability and feasibility data were collected where available.

Best-evidence synthesis

For each PROM, evidence for the methodological quality of the studies and quality of measurement properties per measurement property were pooled and summarized. The summary was rated against the criteria for good measurement properties and then graded using a modified Grades of Recommendation, Assessment, Development and Evaluation (GRADE) to form a best-evidence synthesis (9, 12). The quality of the evidence was graded as high, moderate, low or very low evidence, according to the COSMIN procedures (9). All versions of a PROM were considered separately (9, 12).

Table II. Ranking criteria for articles adapted from Kitchen et al. (11)

Rank	Criteria
1a	• Published journal article (excludes conferences, dissertations, books or chapters) • Relevant terms included in the title and/or abstract • Main focus is on the development, validation, feasibility or acceptability of a skin condition PRO or patient impact measure with complete reporting of the measurement property(ies) • Measure must be patient-reported
1b	• As above but with partial reporting of the measurement property(ies)
2	• Relevant terms included in the title and/or abstract • PRO term is in the abstract but *not the main aim of article (i.e. secondary or exploratory)* • Relevant results in the abstract
3	• Relevant terms in the background or as an implication in the discussion of the article • No relevant data
X	• Exclude if no relevant terms • Papers related to carer-rated measures and proxy-rated measures

PRO: patient-reported outcome.

[1]https://www.medicaljournals.se/acta/content/abstract/10.2340/00015555-3884

The GRADE approach specifies 5 factors to determine the quality of evidence: risk of bias (quality of the studies), inconsistency (of the results of the studies), indirectness (evidence comes from different populations, interventions or outcomes than the ones of interest in the review), imprecision (wide confidence intervals), and publication bias (9). The fifth factor, publication bias, is not included in the COSMIN methodology, since there are no registries for studies on measurement properties. Thus, a modified GRADE approach specifying 4 factors was used to downgrade the evidence.

Generating recommendations for use of dermatology-specific patient-reported outcome measures

The primary outcome assessed was recommendation for use. Each PROM was assigned to 1 of 3 standardized "recommendation for use" categories according to COSMIN criteria (9) similar to a traffic-light system of green indicating good to go, amber meaning proceed with caution and red do not proceed:

A: PROM **can be recommended** for use (has evidence for sufficient content validity [any level] and at least low-quality evidence for sufficient internal consistency).

B: PROM **has potential to be recommended** for use, but requires further validation (cannot be categorized into A or C).

C: PROM **should not be recommended** for use (has high-quality evidence demonstrating insufficient measurement criteria).

The secondary outcome was establishing the existence of dermatology-specific PROM capable of measuring impact, achieved by evaluating the domains measured in each PROM.

RESULTS

The search identified 12,925 abstracts. An additional 3 articles (14–16) were identified through reference lists and expert input. **Fig. 1** details the full article selection process. Of the 53 dermatology-specific PROM articles identified, data were extracted from 52 articles. One article (17) was excluded, since the psychometric testing for 2 separate PROMs was combined. Two studies examined more than one PROM (18, 19). Six articles that met inclusion criteria were not included in the COSMIN analysis, but data were extracted (17, 20–25); 2 because only interpretability information was reported (22, 24); and 4 review articles did not provide sufficient information on the methodological quality of included studies, but included information on interpretability and feasibility (20, 21, 23, 25). In all, 36 PROMs (Tables SII and SIII[1]), reported in 46 articles (Table SIV[1]), were included in the COSMIN analysis.

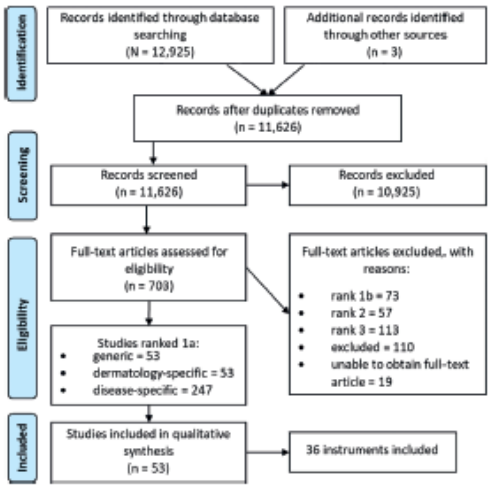

Fig. 1. Flow diagram of the screening and selection process.

Identification of an impact measure

A comparison of each PROM at the domain level is shown in **Table III**. Domains were derived based on the subscales reported by the developers or through structural validity analyses (i.e. factor analysis). Many of the instruments (83%) measured QoL. The most common domains observed were symptoms, emotional/psychological functioning, physical functioning, social functioning and daily activities. None of the PROMs included other life domains, such as financial impact and life course impairment; therefore, they should not be considered a comprehensive measure of the impact of living with a skin disease.

Methodological quality of included studies and quality of measurement properties

Table IV shows the methodological quality of studies and the quality of the results for the PROM content validity studies. Evidence for content validity was based only on development and pilot-testing studies (n=22) for most instruments, as a content validity study was conducted only for the Spanish version of Skindex-29 (S29-S). The majority (86%) of the development studies were of very low methodological quality. Only the Patient Benefit Index (PBI; low quality), Turkish Quality of Life Instrument (TQL; low quality) and Skindex 29-Spanish (high quality) were rated as having adequate methodological quality. The most common reason for the downgrading of the overall quality of evidence to very low was that a cognitive interview was not conducted or was of poor methodological quality.

The methodological quality of studies on measurement properties (**Table V**) and quality of the measurement properties (**Table VI**) per study are also presented. No PROM was tested for all measurement properties. The amount of measurement properties tested per PROM ranged between 1 and 6. Internal consistency was the most popular psychometric test (n=37), measurement invariance the least (n=2) and measurement error was not tested at all.

Quality of PROMs: best-evidence synthesis and recommendations

The results of the best-evidence synthesis per PROM (**Table VII**) are shown below according to the category of recommendation (A–C). The results presented are an

Table III. Comparison of patient-reported outcome measures (PROMs) at domain level

PROM	Symptoms	Emotional/ psychological functioning	Physical functioning	Social functioning	Daily activities	Treatment beliefs/ impact	Work/ school	Quality of care	Coping behaviours	Stigmatization	Education/ support needs	Intimacy
ACSD	×	×	×	×	×	×	×		×	×	×	×
CDLQI	×	×	×	×	×	×	×			×		
CQI-CSD								×				
DIS												×
DLQI	×	×	×	×	×	×	×					×
DQOLs	×	×	×	×								
DSQL	×	×		×	×		×					
FLQA-d	×	×	×	×	×	×						
PBI						×						
PeDeSI											×	
PRISM												
SF-QES		×							×	×		×
Skindex	×	×	×	×	×					×		×
S29	×	×	×									
S16	×	×	×									
TQL	×	×		×	×							×
VQ-Dermato	×	×		×	×	×						

×: domain present; ACSD: Adjustment to Chronic Skin Diseases Questionnaire; CDLQI: Children's Dermatology Life Quality Index; CQI-CSD: Consumer Quality Index Chronic Skin Disease; DIS: Dermatology Intimacy Scale; DLQI: Dermatology Life Quality Index; DQOLs: Dermatology Quality of Life scales; DSQL: Dermatology-specific Quality of Life; FLQA-d: Freiburg Life Quality Assessment; PBI: Patient Benefit Index; PeDeSI: Person-Centred Dermatology Self-Care Index; PRISM: Pictorial Representation of Illness & Self-Measure; SF-QES: Short-form of the Questionnaire on Experience with Skin Complaints; S29: Skindex-29; TQL: Turkish Quality of Life Instrument for skin disease.

overview; a more detailed account is shown in Table SV[1]. The best-evidence synthesis shows the overall evidence for each measurement property per PROM expressed as 1 result, combining both the level of evidence (high, moderate, low, very low) and the quality of the measurement property (sufficient, insufficient, indeterminate, inconsistent).

Category A (green traffic light). No PROMs met the requirements for use as an ideal dermatology-specific PROM.

Category C (red traffic light). Five PROMs (18, 26–31) had high-quality evidence for insufficient measurement properties and are not recommended for use: the Sinhala version of the Dermatology Life Quality Index (DLQI-S), the Short-form of the Questionnaire on Experience with Skin Complaints (SF-QES), the Serbian and Spanish versions of Skindex-29 and the Chinese version of Skindex-16.

Category B (amber traffic light). A total of 31 PROMs can be recommended for use pending further validation.

Table VI. Methodological quality and quality assessment of results per development and content validity study per patient-reported outcome measure (PROM)

	Methodological quality						Quality assessment of results					
PROM	Design	Comprehensibility	Comprehensiveness	Cognitive interview study	Total development	Content validity study	Overall relevance	Overall comprehensiveness	Overall comprehensibility	Content validity study	Overall content validity	Quality of evidence
ACSD (32)	D	×	×	I	I	×	+	+	+		+	Very low
CDLQI (33)	I	×	I	I	I	×	+	+	+		+	Very low
CDLQI-C (34)	I	D	I	I	I	×	+	+	+		+	Very low
CQI-CSD (74)	A	I	I	I	I	×	±	+	+		±	Very low
DIS (35)	I	D	D	D	I	×	+	+	+		+	Very low
DLQI (36)	I	D	D	D	I	×	+	+	+		+	Very low
DQOLs (48)	I	×	×	I	I	×	?	?	?		?	Very low
DSQL (49)	D	I	D	I	I	×	+	+	+		+	Very low
FLQA-d (14)	D	D	I	I	I	×	+	+	+		+	Very low
PBI (51)	D	D	D	D	D		±	+	±		±	Low
PeDeSI (52)	D	×	×	I	I	×	+	+	+		+	Very low
SF-QES (15)	I	I	I	I	I	×	±	+	+		+	Very low
Skindex (54)	D	I	I	I	I	×	+	+	+		+	Very low
S29 (55)	D	I	D	I	I	×	+	+	+		+	Very low
S29-S (31)	D	I	I	I	I	×	−	?	?		?	Very low
S29-Sp (26)	D	I	I	I	I	A	−	−	−	−	−	High
S29-C (18)	D	D	I	I	I	×	−	?	−		−	Very low
S16 (57)	D	I	D	I	I	×	+	+	+		+	Very low
S16-C (18)	D	D	I	I	I	×	−	?	−		−	Very low
S16-M (61)	D	I	I	I	I	×	−	?	?		?	Very low
TQL (62)	D	D	D	D	D	×	±	?	−		±	Low
VQ-D (63)	D	D	D	D	I	×	+	+	+		+	Very low

ACSD: Adjustment to Chronic Skin Diseases Questionnaire; CDLQI: Children's Dermatology Life Quality Index; CDLQI-C: CDLQI Cantonese; CQI-CSD: Consumer Quality Index Chronic Skin Disease; DIS: Dermatology Intimacy Scale; DLQI: Dermatology Life Quality Index; DQOLs: Dermatology Quality of Life scales; DSQL: Dermatology-specific Quality of Life; FLQA-d: Freiburg Life Quality Assessment; PBI: Patient Benefit Index; PeDeSI: Person-Centred Dermatology Self-Care Index; SF-QES: Short-form of the Questionnaire on Experience with Skin Complaints; S29: Skindex-29; S16: Skindex-16; TQL: Turkish Quality of Life Instrument for skin disease; A: adequate; D: doubtful; I: inadequate; ×: study not performed; +: sufficient; −: insufficient; ±: inconsistent; ?: indeterminate.

Table V. Methodological quality of each study per measurement property

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/ measurement invariance	Responsiveness
ACSD	(32)	V						
CDLQI	(33)			I		D		
CDLQI-C	(34)		D	D		D		
CQI-CSD	(74)	I	I			I		
DIS	(35)					D		
DQLI	(38)	I	I					
	(24)		V			V		V
	(39)	V	V					A
	(16)	A	D	D				
	(76)			I		I		I
	(75)					D		
	(36)		D	D		V		
DLQI-B	(40)			I		A		
DLQI-C	(42)	V	D			V	I	
	(41)	A	I				I	
	(44)	V	V			V		
	(43)	A	A					
DLQI-D	(27)		I	D				
DLQI-I	(45)	V	V			V		
DLQI-N	(46)	A	A			A		
DLQI-S	(30)		V	D		D		
DLQI-T	(47)	A	D					
DLQI-U	(19)		I					
DQOLs	(48)	A	I	D		D		
DSQL	(50)		V	D		V		V
	(49)	V	V	I		A		
FLQA-d	(14)	V				V	I	V
PBI	(51)		D	D				A
PeDeSI	(52)	A	A					
PRISM	(53)					V		D
SF-QES	(29)	V	V					D
Skindex	(54)	V	I	I		D		I
S29	(77)					V		
	(55)	V	V	I		D		I
S29-C	(18)	A	I			V		
S29-G	(56)	V	V			V		I
S29-S	(31)		V	D		V		
S29-Sp	(28)		V	I		A		D
	(26)		V			V		
S16	(57)	A	A	I		D		D
S16-BP	(59)		V	A		V		
S16-A	(58)		V			A		
S16-C	(18)	V	I			V		
S16-J	(60)		V			V		
S16-M	(61)		V	D		V		
S16-U	(19)		V					
TQL	(62)	A	A	D		A		
VQ-Dermato	(63)	A	A	D		V		A

PROM: patient-reported outcome measures; ACSD: Adjustment to Chronic Skin Diseases Questionnaire; CDLQI: Children's Dermatology Life Quality Index; CDLQI-C: CDLQI Cantonese; CQI-CSD: Consumer Quality Index Chronic Skin Disease; DIS: Dermatology Intimacy Scale; DLQI: Dermatology Life Quality Index; DLQI-B: DLQI-Portuguese; DLQI-C: DLQI Chinese; DLQI-D: DLQI Danish; DLQI-I: DLQI Italian; DLQI-N: DLQI Norwegian; DLQI-S: DLQI Sinhala; DLQI-T: DLQI Turkish; DLQI-U: DLQI Ukrainian; DQOLs: Dermatology Quality of Life scales; DSQL: Dermatology-specific Quality of Life; FLQA-d: Freiburg Life Quality Assessment; PBI: Patient Benefit Index; PeDeSI: Person-Centred Dermatology Self-Care Index; PRISM: Pictorial Representation of Illness & Self-Measure; SF-QES: Short-form of the Questionnaire on Experience with Skin Complaints; S29: Skindex-29; S29-C: S29-Chinese; S29-G: S29-German; S29-S: S29-Serbian; S29-Sp: S29-Spanish; S16: Skindex16; S16-BP: S16-Brazilian-Portuguese; S16-A: S16-Arabic; S16-C: 16-Chinese; S16-J: S16-Japanese; S16-M: S16-Moroccan-Arabic; S16-U: S16-Ukrainian; TQL: Turkish Quality of Life Instrument for skin disease; V: very good; A: adequate; D: doubtful; I: inadequate.

Where no PROMs categorized as A are found (as here), COSMIN recommends that the PROM with the best evidence for content validity in category B could be provisionally recommended for use until further evidence is provided (9). Based on the evidence for content validity across instruments in the best-evidence synthesis, the Patient Benefit Index (PBI) and Turkish Quality of Life (TQL) instrument are provisionally recommended for use as measures of patient needs and treatment benefits, and QoL, respectively. However, it is worth noting that, although both of these have content validity studies of acceptable methodological quality, their results were inconsistent. Here, we report only on the PROMs that require further context or to provide additional information that is not shown in Tables IV–VII.

Dermatology Life Quality Index and translations

Dermatology Life Quality Index (DLQI) (36) is a QoL PROM for patients with skin disease. Minimally important difference (MID) thresholds range between 2.34 and 5.7 (24, 37). One study found a ceiling effect with 11% of patients (22).

A number of studies assessed the structural validity of the DLQI, although most were of low methodological quality (38) or did not report statistics corresponding to the COSMIN criteria (16). One good methodological study (defined as a very good or adequate rating on the COSMIN Risk of Bias checklist) suggests that the DLQI is unidimensional (39), although relevant statistics were not reported. Sufficient internal consistency, construct validity and responsiveness were supported by high-quality evidence. There was some evidence of indeterminate reliability in the DLQI.

The measurement properties of the DLQI-Chinese have been evaluated using Rasch analysis (41, 42) and classical test theory (CTT) (43, 44). The results of the Rasch analyses do not directly correspond to the criteria for good structural validity, internal consistency and measurement invariance and, therefore, were not included in the best-evidence synthesis. There is high-quality evidence of a unidimensional structure and internal consistency. One study of adequate methodological quality found 2 factors (43), though these violated criteria for good measurement properties (Comparative Fit Index [CFI] 0.935). Another study of very good methodological quality found evidence of unidimensionality that met the criteria for good measurement properties (44). There was sufficient construct validity.

Dermatology-specific Quality of Life

Dermatology-specific Quality of Life (DSQL) (49) is a QoL PROM for patients with skin disease. Two studies

Table VI. Quality assessment of measurement properties per study according to predefined criteria proposed by Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) (12)

PROM	Study	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Cross-cultural validity/ measurement invariance	Responsiveness
ACSD	(32)	?						
CDLQI	(33)			?		+		
CDLQI-C	(34)		+	?		?		
CQI-CSD	(74)	?	+			?		
DIS	(35)					?		
DLQI	(38)	?	?					
	(37)		+			?		+
	(39)	?	+					?
	(16)	–	?	–				
	(76)			?		?		±
	(75)					+		
	(36)		?	?		?		
DLQI-B	(40)			+		?		
DLQI-C	(42)	–	?				?	
	(41)	?	?				?	
	(44)	+	+			?		
	(43)	+	+					
DLQI-D	(27)		+	?		?		
DLQI-I	(45)	+	+			+		
DLQI-N	(46)	?	+			?		
DLQI-S	(30)		–	+		+		
DLQI-T	(47)	?	+					
DLQI-U	(19)		+					
DQOLs	(48)	?	+	+		±		
DSQL	(50)		+	+		–		
	(49)	?	+	?		±		
FLQA-d	(14)		–	?		?		?
PBI	(51)		+	?				
PeDeSI	(52)	?	+					
PRISM	(53)					+		+
SF-QES	(29)	+	+					+
Skindex	(54)	?	?	?		+		?
S29	(77)					+		
	(55)	?	+	?		+		+
S29-C	(18)	–	?			+		
S29-G	(56)	?	+			?		?
S29-S	(31)		+	–		±		
S29-Sp	(28)		+	+		+		+
	(26)		+			+		
S16	(57)	+	+			+		?
S16-A	(58)		+			+		
S16-BP	(59)		+	+		+		
S16-C	(18)	+	?			+		
S16-J	(60)		+			+		
S16-M	(61)		+	+		+		
S16-U	(19)		+					
TQL	(62)	?	+	–		?		
VQ-Dermato	(63)	?	–	?		+		+

PROM: patient-reported outcome measures; ACSD: Adjustment to Chronic Skin Diseases Questionnaire; CDLQI: Children's Dermatology Life Quality Index; CDLQI-C: Children's Dermatology Life Quality Index Cantonese; CQI-CSD: Consumer Quality Index Chronic Skin Disease; DIS: Dermatology Intimacy Scale; DLQI: Dermatology Life Quality Index; DLQI-B: DLQI Brazilian-Portuguese; DLQI-C: DLQI Chinese; DLQI-D: DLQI Danish; DLQI-I: DLQI Italian; DLQI-N: DLQI Norwegian; DLQI-S: DLQI Sinhala; DLQI-T: DLQI Turkish; DLQI-U: DLQI Ukrainian; DQOLs: Dermatology Quality of Life scales; DSQL: Dermatology-specific Quality of Life; FLQA-d: Freiburg Life Quality Assessment; PBI: Patient Benefit Index; PeDeSI: Person-Centred Dermatology Self-Care Index; PRISM: Pictorial Representation of Illness & Self-Measure; SF-QES: Short-form of the Questionnaire on Experience with Skin Complaints; S29: Skindex 29; S29-C: S29-Chinese; S29-G: S29-German; S29-S: S29-Serbian; S29-Sp: S29-Spanish; S16: Skindex-16; S16-A: S16-Arabic; S16-BP: S16-Brazilian-Portuguese; S16-C: S16-Chinese; S16-J: S16-Japanese; S16-M: S16-Moroccan-Arabic; S16-U: S16-Ukrainian; TQL: Turkish Quality of Life Instrument for skin disease; +: sufficient; -: insufficient; ±: inconsistent; ?: indeterminate.

found floor effects for the daily activities (25.2%), social functioning (27.6%), and work/school (41.2% and 53.8%) subscales (49, 50). High-quality evidence for sufficient internal consistency, construct validity and indeterminate structural validity was found, but low-quality evidence of sufficient reliability.

Freiburg Life Quality Assessment

The Freiburg Life Quality Assessment (FLQA) is a set of core, generic items and additional disease-specific items used to assess QoL in dermatology patients. The FLQA-d (14) is a variant of the FLQA for use with patients with long-term skin conditions. High-quality evidence for insufficient internal consistency, sufficient construct validity and responsiveness was found, but so was low-quality evidence of indeterminate reliability.

Patient Benefit Index

The Patient Benefit Index (PBI) (51) is a measure of patient needs and treatment benefits for dermatology patients. The developers found a "major floor effect". Although the PBI showed low-quality evidence of inconsistent content validity; the overall development study was methodologically adequate and the criteria for good content validity and reviewers' rating were sufficient overall. There was moderate evidence of sufficient responsiveness, and low-quality evidence of indeterminate internal consistency and reliability.

Skindex

Skindex (54) is a QoL PROM for patients with skin disease. High-quality evidence for indeterminate structural validity was found. Internal consistency was indeterminate because it was tested using hypothesized subscales, rather than those identified by the factor analysis. Low-quality evidence for insufficient construct validity was found.

Skindex-29 and translations

Skindex-29 (55) is a revised version of Skindex. There was high-quality evidence for sufficient internal consistency and construct validity, but also indeterminate structural validity.

Skindex-29-Chinese (18) had high-quality evidence for sufficient construct validity. Moderate evidence suggested insufficient structural validity. No floor or ceiling effects were observed.

Skindex-16 and translations

Skindex-16 (57) is a revised version of Skindex-29. There was moderate evidence for sufficient structural validity

Table VII. Best-evidence synthesis and recommendations

PROM	Content validity	Structural validity	Internal consistency	Reliability	Measurement error	Construct validity	Measurement invariance	Responsiveness	Recommendation
ACSDQ	W	???							B
CDLQI	W			W		+			B
CDLQI-C	W		?	W		W			B
CQI-CSD	W	W	W			W			B
DIS	W					?			B
DLQI	W	???	+++	?		+++		+++	B
DLQI-B				W		++			B
DLQI-C		+++	+++			+++	W		B
DLQI-D			W	W		???			B
DLQI-I		+++	+++			+++			B
DLQI-N		??	++			++			B
DLQI-S			---	W		+			C
DLQI-T		?	W						B
DLQI-U			W						B
DQOLs	W	??	W	+		–			B
DSQL	W	???	+++	+		+++		+++	B
FLQA-d	W		+++	?		+++		+++	B
PBI	±		?	?				++	B
PeDeSI	W	??	++						B
PRISM						+++		+	B
SF-QES	W	---	++						C
Skindex	W	???	W	W		–		W	B
S29	W	???	+++	W		+++		W	B
S29-C	W	--	W			+++			B
S29-G		???	+++			+++		W	B
S29-S	W		+++	–		---			C
S29-Sp	---		+++	W		+++		W	C
S16	W	++	++			+		W	B
S16-A			+++			++			B
S16-BP			+++	W		+++			B
S16-C	W	---	W			+++			C
S16-J			+++			+++			B
S16-M	W		+++	+		+++			B
S16-U			++						B
TQL	±	??	++	W		++			B
VQ-Dermato	W	??	--	?		+++		++	B

PROM: patient-reported outcome measures; ACSD: Adjustment to Chronic Skin Diseases Questionnaire; CDLQI: Children's Dermatology Life Quality Index; CDLQI-C: CDLQI Cantonese; CQI-CSD: Consumer Quality Index Chronic Skin Disease; DIS: Dermatology Intimacy Scale; DLQI: Dermatology Life Quality Index; DLQI-B: DLQI Brazilian-Portuguese; DLQI-C: DLQI Chinese; DLQI-D: DLQI Danish; DLQI-I: DLQI Italian; DLQI-N: DLQI Norwegian; DLQI-S: DLQI Sinhala; DLQI-T: DLQI Turkish; DLQI-U: DLQI Ukrainian; DQOLs: Dermatology Quality of Life scales; DSQL: Dermatology-specific Quality of Life; FLQA-d: Freiburg Life Quality Assessment; PBI: Patient Benefit Index; PeDeSI: Person-Centred Dermatology Self-Care Index; PRISM: Pictorial Representation of Illness & Self-Measure; SF-QES: Short-form of the Questionnaire on Experience with Skin Complaints; S29: Skindex 29; S29-C: S29-Chinese; S29-G: S29-German; S29-S: S29-Serbian; S29-Sp: S29-Spanish; S16: Skindex-16; S16-A: S16-Arabic; S16-BP: S16-Brazilian-Portuguese; S16-C: S16-Chinese; S16-J: S16-Japanese; S16-M: S16-Moroccan-Arabic; S16-U: S16-Ukrainian; TQL: Turkish Quality of Life Instrument for skin disease; +++: High-quality evidence for a sufficient measurement property. ---: High-quality evidence for an insufficient measurement property. ???: High-quality evidence for an indeterminate measurement property. ++: Moderate evidence for a sufficient measurement property. --: Moderate evidence for an insufficient measurement property. ??: Moderate evidence for an indeterminate measurement property. +: Low-quality evidence for a sufficient measurement property. –: Low-quality evidence for an insufficient measurement property. ?: Low-quality evidence for an indeterminate measurement property. W: Very low evidence for a measurement property. ±: Conflicting evidence for a measurement property.

and internal consistency and low-quality evidence for sufficient construct validity.

Turkish Quality of Life instrument for skin disease

Turkish Quality of Life (TQL) instrument (62) is a Turkish language QoL PROM for patients with skin disease. TQL has low-quality evidence for inconsistent content validity. The cognitive interview (n=40) was methodologically adequate, although the results were inconsistent. Moderate evidence was found for sufficient internal consistency and construct validity, and indeterminate structural validity.

DISCUSSION

To our knowledge, this is the first study to systematically evaluate published dermatology-specific PROMs in accordance with the COSMIN guidelines. A total of 36 dermatology-specific PROMs were identified and the majority measured QoL. Examination of the instruments at the domain level revealed that no single PROM could comprehensively assess the impact of living with a skin condition according to our conceptual framework, indicating that the development of a new PRIDD measure is warranted.

Based on their reported measurement properties, no PROM met the COSMIN requirements to be recommended for unqualified use, 30 showed potential to be recommended for use, but require further validation, and 6 are not recommended for use. Of those with the potential to be recommended for use, in accordance with the COSMIN guidance, only the PBI and TQL can be provisionally recommended for use, as they have the best evidence for content validity (9).

The use of PROMs of poor or unknown quality is wasteful and unethical, in part, because measures that are not valid or reliable can produce misleading results (64). Although, in some situations, an imperfect PROM (bey-

ond accepted levels of measurement error) may be better than no PROM; it is useful to recognize the limitations of the measure so that conclusions drawn can be tempered accordingly (7). This is pertinent in dermatology, where PROMs are used in research, including clinical trials, and in clinical practice to make individual treatment decisions. This review highlighted the paucity of high-quality evidence for dermatology-specific PROMs these findings concur with another recent COSMIN systematic review of dermatology-specific QoL instruments used in the context of eczema (65). Of the 135 measurement properties evaluated, only 26 had evidence of both adequate methodological quality and sufficient psychometric properties. No PROM performed well across all measurement properties; evidence for measurement invariance and interpretability was lacking and measurement error was absent. Content validity is considered to be the most important measurement property (12). Because PROMs aim to capture information directly from patients, adequate patient input is necessary to establish content validity. However, all original PROM development studies identified were of low or very low methodological quality and only 1 PROM, the Spanish version of Skindex-29, underwent an additional content validity study. Together, this indicates a lack of adequate patient input to the initial development of these PROMs. Future PROM validation and development work should focus on improving the methodological quality of studies, establishing content validity and addressing gaps in known measurement properties.

Four of the 5 PROMs not recommended for use were translated versions of other PROMs, potentially indicating an issue with current practise in cross-cultural translation. Our findings cannot generalize to all translated PROMs in dermatology, as we did not find published development and validation studies for some known translations. It does seem, however, that there are issues in the translation of PROMs in this area. There was a lack of measurement invariance (or cross-cultural validity) testing for translated PROMs in any recommendation category. Measurement invariance is core to the process of validation as it provides evidence of "construct equivalence", the assumption that items in the translated version measure the same construct in the same way as in the original version (65–68). Evidence of construct equivalence, therefore, is required to synthesize and compare data across the language versions with obvious implications for research. We believe there is a need to standardize cross-cultural translation studies of PROMs in terms of methods (e.g. back- and forward-translation procedures) and measurement properties tested.

Strengths and weakness

Given that no PROMs could be unreservedly recommended for use, it could be argued the COSMIN criteria are too strict. The COSMIN criteria were developed with a range of experts including PROM developers, psychometricians, statisticians, qualitative researchers and clinicians (69, 70). In their systematic review of dermatology-specific QoL instruments, Gabes et al. concluded that the COSMIN guidance was "less strict and slightly more sympathetic to candidate PROMs" (p. 72) (64) than the previously recommended OMERACT approach (71, 72). Use of COSMIN is a strength of this review as it: (*i*) reduces bias in the evaluation of measurement properties; (*ii*) allows comparisons between PROMs; (*iii*) enables standardized recommendations; and (*iv*) highlights issues in the field, including poor methodological quality and reporting. However, COSMIN conflates inadequate reporting of studies with poor inherent methodological quality, which reduces the validity of the best-evidence synthesis. In addition, COSMIN tools do not adequately evaluate the methodological quality of studies conducted with Rasch analysis, which is considered superior to the CTT framework, since they make limited reference to Rasch relevant statistics. Inadequate evaluation of item response theory/Rasch studies also reduces the validity of the best-evidence synthesis.

A further strength of this review is that the search strategy was developed by a multidisciplinary team with expertise in dermatology, psychology and measurement instrument development and included a COSMIN-validated search filter. Three databases recommended by a subject librarian were searched. However, reference lists of included studies were not searched, which may explain why some translated PROMs were not found. Finally, at least 3 independent reviewers were involved in screening, data extraction and analysis; 2 of whom were involved at every step to ensure consistency.

Conclusion

This study found that no dermatology-specific PROMs could be unreservedly recommended for use according to the COSMIN standards. The single most common reason for poor quality assessment was the lack of patient input to the initial development of the measure. No measure of impact across skin conditions exists in dermatology and, therefore, we argue that the new measure PRIDD, developed with substantial patient input, is warranted.

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Appendix 2: Systematic review search strategy

Database(s): **PsycINFO** 1806 to

Present search strategy: 25-07-2018

#	Searches	Results
1	health related quality of life.tw.	9638
2	hrqol.tw.	4000
3	qol.tw.	8839
4	patient experience.tw.	1000
5	subjective experience.tw.	5463
6	emotion*.tw.	294431
7	coping.tw.	76169
8	satisfaction.tw.	100379
9	burden.tw.	31071
10	patient centred.tw.	1281
11	patient centered.tw.	4135
12	"quality of life"/	37013
13	quality of life.tw.	61763
14	patient imapct.tw.	0
15	life impact.tw.	184
16	"patient reported outcome*".tw.	1784
17	"self report".tw.	57425
18	PRO.tw.	14947
19	psychosocial*.tw.	79790
20	psychological*.tw.	335203
21	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20	877535
22	(viral infection and (skin or cutaneous)).tw.	5
23	pityriasis rosea.tw.	4
24	(bacterial infection and (skin or cutaneous)).tw.	9
25	(fungal infection and (skin or cutaneous)).tw.	6
26	Pityriasis versicolor.tw.	3
27	dermatitis.tw.	636
28	eczema.tw.	376
29	atopic eczema.tw.	67
30	seborrhoeic dermatitis.tw.	4
31	nummular dermatitis.tw.	1
32	lichen simplex.tw.	5
33	asteatotic eczema.tw.	0
34	psoriasis.tw.	547
35	lichen planus.tw.	24

#	Searches	Results
36	Pityriasis lichenoides.tw.	0
37	Pityriasis rubra pilaris.tw.	0
38	parapsoriasis.tw.	0
39	urticaria.tw.	199
40	angioedema.tw.	54
41	annular erythema.tw.	0
42	erythema multiforme.tw.	24
43	Pyoderma gangrenosum.tw.	3
44	Eosinophilic cellulitis.tw.	1
45	Erythema nodosum.tw.	7
46	Pemphigus.tw.	27
47	Pemphigoid.tw.	10
48	Linear IgA bullous dermatosis.tw.	0
49	Epidermolysis bullosa acquisita.tw.	1
50	dermatitis herpetiformis.tw.	7
51	Cutaneous lupus erythematosus.tw.	3
52	chronic discoid lupus.tw.	1
53	Lichen sclerosus.tw.	15
54	morphoea.tw.	0
55	mucinosis.tw.	2
56	myxedema.tw.	79

#	Searches	Results
57	cutaneous xanthoma.tw.	0
58	porphyria.tw.	142
59	(calcification and (skin or cutaneous)).tw.	13
60	ichthyosis.tw.	43
61	Darier disease.tw.	3
62	Hailey-Hailey disease.tw.	1
63	palmoplantar keratodermas.tw.	0
64	Pachyonychia congenital.tw.	0
65	albinism.tw.	180
66	epidermolysis bullosa.tw.	17
67	pseudoxanthoma.tw.	5
68	naevus.tw.	14
69	port wine stain.tw.	21
70	pruritus.tw.	359
71	prurigo.tw.	14
72	(self infected and (skin or cutaneous)).tw.	0
73	Ichthyoses.tw.	0
74	(Diffuse epidermal hyperkeratosis and acanthosis).tw.	0

#	Searches	Results
75	Porokeratoses.tw.	0
76	Skin peeling.tw.	4
77	Xerosis cutis.tw.	4
78	asteatosis.tw.	0
79	Keratosis pilaris.tw.	1
80	Acquired hypermelanosis.tw.	0
81	Melasma.tw.	0
82	freckles.tw.	9
83	Endogenous non-melanin pigmentation.tw.	0
84	Vitiligo.tw.	93
85	Alopecia.tw.	326
86	hair loss.tw.	326
87	Hypertrichosis.tw.	19
88	Hirsutism.tw.	110
89	acne.tw.	340
90	rosacea.tw.	45
91	periorificial dermatitis.tw.	0
92	hidradenitis suppurativa.tw.	5
93	Hyperhidrosis.tw.	171
94	Hypohidrosis.tw.	11
95	Miliaria.tw.	1
96	Onycholysis.tw.	3
97	skin atrophy.tw.	1
98	Cutis laxa.tw.	12
99	Anetoderma.tw.	0

#	Searches	Results
100	Poikiloderma.tw.	0
101	Keloid.tw.	7
102	Hypertrophic scar.tw.	4
103	fibromatosis.tw.	13
104	Perforating dermatoses.tw.	0
105	Granuloma annulare.tw.	0
106	Necrobiosis lipoidica.tw.	0
107	Lymphocytoma cutis.tw.	0
108	(Panniculitis and (skin or cutaneous)).tw.	1
109	Lipoatrophy.tw.	30
110	lipodystrophy.tw.	115
111	Subcutaneous lipomatosis.tw.	0
112	Cellulite.tw.	6
113	Angiokeratoma.tw.	4
114	Purpura.tw.	163
115	bruising.tw.	165
116	lipoedema.tw.	1
117	(Vasculitis and (skin or cutaneous)).tw.	53
118	(ulcer and (skin or cutaneous)).tw.	111
119	pilonidal sinus disease.tw.	0
120	drug eruption.tw.	9

#	Searches	Results
121	pressure ulcer.tw.	297
122	callosity.tw.	1
123	Polymorphic light eruption.tw.	0
124	Chronic actinic dermatitis.tw.	0
125	sunburn.tw.	91
126	allergic contact dermatitis.tw.	14
127	cutaneous cyst.tw.	0
128	skin tags.tw.	5
129	actinic keratosis.tw.	4
130	Histiocytoses.tw.	2
131	(paraneoplastic syndrome and (skin or cutaneous)).tw.	1
132	radiodermatitis.tw.	3
133	nevus.tw.	52
134	nevi.tw.	43
135	lentigo maligna.tw.	0
136	(adnexal carcinoma and (skin or cutaneous)).tw.	0
137	(basal cell carcinoma and (skin or cutaneous)).tw.	28

#	Searches	Results
138	(neuroendocrine carcinoma and (skin or cutaneous)).tw.	0
139	(sarcoma and (skin or cutaneous)).tw.	16
140	(melanoma and (skin or cutaneous)).tw.	295
141	(squamous cell carcinoma and (skin or cutaneous)).tw.	34
142	bowen disease.tw.	0
143	(lupus erythematosus and (skin or cutaneous)).tw.	36
144	dermatomyositis.tw.	117
145	systemic sclerosis.tw.	96
146	(Sjogren syndrome and (skin or cutaneous)).tw.	2
147	(mixed connective tissue disease and (skin or cutaneous)).tw.	0
148	(Vasculitis and (skin or cutaneous)).tw.	53

#	Searches	Results
149	SAPHO syndrome.tw.	5
150	behcet disease.tw.	36
151	(graft versus host disease and (skin or cutaneous)).tw.	0
152	(sarcoidosis and (skin or cutaneous)).tw.	16
153	bacterial cellulitis.tw.	0
154	erysipelas.tw.	12
155	lymphangitis.tw.	4
156	necrotising fasciitis.tw.	0
157	Impetigo.tw.	14
158	ecthyma.tw.	0
159	bacterial folliculitis.tw.	0
160	(pyogenic abscess and (skin or cutaneous)).tw.	0
161	Molluscum contagiosum.tw.	5
162	varicella zoster.tw.	308
163	roseola infantum.tw.	1
164	rubella.tw.	415
165	measles.tw.	569
166	erythema infectiosum.tw.	6

#	Searches	Results
167	(picornavirus infection and (skin or mucous membrane)).tw.	0
168	(leishmaniasis and (skin or cutaneous or mucous membrane)).tw.	15
169	(larva migrans and (skin or cutaneous)).tw.	1
170	(onchocerciasis and (skin or cutaneous)).tw.	4
171	pediculosis.tw.	18
172	scabies.tw.	33
173	(mites and (skin or cutaneous)).tw.	6
174	(parasitic mites and (skin or cutaneous)).tw.	0
175	(lymphoma and (skin or cutaneous)).tw.	41
176	(burns and (skin or cutaneous)).tw.	98
177	frostbite.tw.	20
178	(Adenoma and (skin or cutaneous)).tw.	7

#	Searches	Results
179	(adnexal and (skin or cutaneous)).tw.	4
180	trichilemmoma.tw.	0
181	trichoepithelioma.tw.	0
182	trichofolliculoma.tw.	0
183	(syphilis and (skin or cutaneous)).tw.	19
184	(tuberculosis and (skin or cutaneous)).tw.	83
185	extragenital condylomata acuminate.tw.	0
186	keratoacanthoma.tw.	0
187	seborrhoeic keratosis.tw.	1
188	(mast cell tumo?r and (skin or cutaneous)).tw.	0
189	ectodermal dysplasia.tw.	21
190	ehlers danlos syndrome.tw.	66
191	juvenile xanthogranuloma.tw.	4
192	(disorder and "sebaceous gland*").tw.	2
193	(deform* and "nail plate*").tw.	0

#	Searches	Results
194	scleroderma.tw.	117
195	histiocytosis.tw.	44
196	("skin condition*" or "skin disorder*" or "skin disease*").tw.	843
197	("cutaneous condition*" or "cutaneous disorder*" or "cutaneous disease*").tw.	48
198	("dermatolog* condition*" or "dermatolog* disorder*" or "dermatolog* or disease*").tw.	204
199	skin tags.tw.	5
200	(human papillomavirus infection and (skin or mucous membrane)).tw.	2
201	(herpes simplex and (skin or cutaneous or mucosa)).tw.	41

#	Searches	Results
202	(candidosis and (skin or cutaneous or lip or mucous membrane)).tw.	0
203	22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71 or 72 or 73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106 or 107 or 108 or 109 or 110 or 111 or 112 or 113 or 114 or 115 or 116 or 117 or 118 or 119 or 120 or 121 or 122 or 123 or 124 or 125 or 126 or 127 or 128 or 129 or 130 or 131 or 132 or 133 or 134 or 135 or 136 or 137 or 138 or 139 or 140 or 141 or 142 or 143 or 144 or 145 or 146 or 147 or 148 or 149 or 150 or 151 or 152 or 153 or 154 or 155 or 156 or 157 or 158 or 159 or 160 or 161 or 162 or 163 or 164 or 165 or 166 or 167 or 168 or 169 or 170 or 171 or 172 or 173 or 174 or 175 or 176 or 177 or 178 or 179 or 180 or 181 or 182 or 183 or 184 or 185 or 186 or 187 or 188 or 189 or 190 or 191 or 192 or 193 or 194 or 195 or 196 or 197 or 198 or 199 or 200 or 201 or 202	7374
204	validation studies.pt.	0
205	comparative study.pt.	0
206	psychometr*.tw.	70525
207	clinimetr*.tw.	238
208	clinometr*.tw.	11

#	Searches	Results
209	outcome assessment.tw.	1213
210	outcome measure*.tw.	34570
211	observer variation.tw.	21
212	reproducib*.tw.	5199
213	reliab*.tw.	142366
214	unreliab*.tw.	4110
215	valid*.tw.	232261
216	coefficient.tw.	18608
217	homogeneity.tw.	5561
218	homogeneous.tw.	10930
219	internal consistency.tw.	23874
220	agreement.tw.	39145
221	precision.tw.	12120
222	imprecision.tw.	579
223	precise values.tw.	13
224	test-retest.tw.	16441
225	(test and retest).tw.	17744
226	(reliab* and test).tw.	55034
227	(reliab* and retest).tw.	15902
228	stability.tw.	42500
229	interrater.tw.	5383
230	inter-rater.tw.	3633
231	intrarater.tw.	337
232	intra-rater.tw.	353
233	intertester.tw.	16

#	Searches	Results
234	inter-tester.tw.	21
235	intratester.tw.	4
236	intra-tester.tw.	13
237	interobserver.tw.	712
238	inter-observer.tw.	355
239	intraobserver.tw.	98
240	intra-observer.tw.	89
241	intertechnician.tw.	0
242	inter-technician.tw.	0
243	intratechnician.tw.	0
244	intra-technician.tw.	0
245	interexaminer.tw.	36
246	inter-examiner.tw.	40
247	intraexaminer.tw.	3
248	intra-examiner.tw.	14
249	interassay.tw.	11
250	inter-assay.tw.	19
251	intraassay.tw.	0
252	intra-assay.tw.	25
253	interindividual.tw.	3399
254	inter-individual.tw.	2119
255	intraindividual.tw.	2270

#	Searches	Results
256	intra-individual.tw.	1619
257	interparticipant.tw.	17
258	inter-participant.tw.	27
259	intraparticipant.tw.	7
260	intra-participant.tw.	26
261	kappa.tw.	6752
262	kappa's.tw.	289
263	kappas.tw.	289
264	repeatab*.tw.	2188
265	((replicab* or repeat*) and (measure* or finding* or result* or test or tests)).tw.	67260
266	generaliza*.tw.	36123
267	generalisa*.tw.	2028
268	concordance.tw.	6046
269	(intraclass and correlation*).tw.	3840
270	discriminative.tw.	9295
271	known group.tw.	365
272	factor analysis.tw.	47527
273	factor analyses.tw.	11214
274	dimension*.tw.	157682
275	subscale*.tw.	38814

#	Searches	Results
276	(multitrait and scaling and (analysis or analyses)).tw.	63
277	item discriminant.tw.	47
278	interscale correlation*.tw.	138
279	error.tw.	65133
280	errors.tw.	52704
281	individual variability.tw.	2363
282	(variability and (analysis or values)).tw.	12613
283	(uncertainty and (measurement or measuring)).tw.	1000
284	standard error of measurement.tw.	528
285	sensitiv*.tw.	150259
286	responsiv*.tw.	42081
287	((minimal or minimally or clinical or clinically) and (important or significant or detectable) and (change or difference)).tw.	24550

#	Searches	Results
288	(small* and (real or detectable) and (change or difference)).tw.	866
289	meaningful change.tw.	546
290	ceiling effect.tw.	789
291	floor effect.tw.	244
292	item response model.tw.	322
293	IRT.tw.	3207
294	Rasch.tw.	3735
295	differential item functioning.tw.	2142
296	dif.tw.	1646
297	computer adaptive testing.tw.	176
298	item bank.tw.	401
299	cross-cultural equivalence.tw.	162
300	(cronbach* and (alpha or alphas)).tw.	10837
301	measurement propert*.tw.	1051
302	instrumentation.tw.	2075
303	psychometrics/	55935
304	health status indicator.tw.	6
305	reproducibility of results.tw.	135
306	test validity/	70957
307	discriminant analysis.tw.	4481
308	Item response theory.tw.	5194
309	questionnaire*.tw.	253001
310	instrument.tw.	62954
311	("item correlation*" or "item selection*" or "item reduction*").tw.	1858

#	Searches	Results
312	204 or 205 or 206 or 207 or 208 or 209 or 210 or 211 or 212 or 213 or 214 or 215 or 216 or 217 or 218 or 219 or 220 or 221 or 222 or 223 or 224 or 225 or 226 or 227 or 228 or 229 or 230 or 231 or 232 or 233 or 234 or 235 or 236 or 237 or 238 or 239 or 240 or 241 or 242 or 243 or 244 or 245 or 246 or 247 or 248 or 249 or 250 or 251 or 252 or 253 or 254 or 255 or 256 or 257 or 258 or 259 or 260 or 261 or 262 or 263 or 264 or 265 or 266 or 267 or 268 or 269 or 270 or 271 or 272 or 273 or 274 or 275 or 276 or 277 or 278 or 279 or 280 or 281 or 282 or 283 or 284 or 285 or 286 or 287 or 288 or 289 or 290 or 291 or 292 or 293 or 294 or 295 or 296 or 297 or 298 or 299 or 300 or 301 or 302 or 303 or 304 or 305 or 306 or 307 or 308 or 309 or 310 or 311	1155114
313	21 and 203 and 312	690
314	limit 313 to (human and journal article)	545
315	from 314 keep 1-545	

Appendix 3: Characteristics of PROMs included in the systematic review

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
ACSD (Stangier et al. 2003)	Patients with chronic skin disease	Adjustment	6	Social anxiety/avoidance, itch-scratch cycle, helplessness, anxious-depressive mood, impact of QoL, deficit in active coping(Stangier et al. 2003)	5-point Likert scale	51	51 - 357	Higher score indicates greater impairment in adjustment	1 week	English	nr
CDLQI (Lewis-Jones and Finlay 1995)	Children with skin disease	QoL			4-point Likert scale	10	0 - 30	0-1 = no effect on child's life 2-6 = small effect 7-12 = moderate effect 13-18 = very large effect	1 week	English (Lewis-Jones and Finlay 1995), Cantonese (Chuh 2003)	nr

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
								19-30 = extremely large effect(Waters et al. 2010)			
CQI-CSD (van Cranenburgh et al. 2015)	Patients receiving dermatological care	Quality of patient care	2	Experience, importance	Likert scales, multiple choices	65	Quality improvement: 0 – 4 Experience: 1 - 4	Quality improvement: higher scores indicate more urgency for improvement Experience: Higher scores indicate more positive experience	nr*	Dutch	nr

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
DIS (Malakouti et al. 2017)	Patients with skin disease	Intimacy			5-point Likert scale	18	0 - 72	A higher score corresponds to greater impairment in intimacy	Two weeks	English	nr
DLQI (Finlay and Khan 1994b)	Patients with skin disease	QoL			4-point Likert scale	10	0 - 30	0-1 = no effect at all on patient's life 2-5 = small effect on patient's life 6-10 = moderate effect on patient's life 11-20 = very large effect on patient's life 21-30 = extremely large effect on patient's life(Cardiff University)	1 week	English (Finlay and Khan 1994b), Brazilian-Portuguese (Ferraz et al. 2006), Chinese (He et al. 2013), Danish (Zachariae et al. 2000), Italian (Mazzotti et al. 2005), Norwegian (Mork et al. 2002), Sinhala (Madarasingha et al. 2011), Turkish	1 – 5

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
										(Balci and Inandi 2008), Ukrainian(Chernyshov 2016)	
DQOLs (Morgan et al. 1997)	Patients with skin disease	QoL	3	Psychosocial, physical activity, symptoms	5-point Likert scale	41	0 - 100	Higher score indicates higher impairment of QoL	nr	English	5
DSQL (Anderson and Rajagopalan 1997)	Patients with skin disease	QoL	5	Physical symptoms, daily activities, social functioning, work/school, self-perception	nr	52	0 - 20	nr	1 month	English	<15
FLQA-d (Augustin et al. 2000a)	Patients with chronic skin disease	QoL	6	Physical complaints, everyday life, social life, emotional status, treatment, satisfaction	5-point Likert scale and 3 Visual	53	nr	nr	1 week	German	nr

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
					Analogue scales						
PBI (Augustin et al. 2009)	Dermatology patients	Needs & treatment benefits	2	Treatment goals, treatment benefits	5-point Likert scale	50	Global score ranging from 0 to 4 calculated by averaging the preference-weighted results of all items.	Higher score indicated greater treatment benefit.	nr	German	nr

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
PeDeSI (Cowdell et al. 2012)	Patients with chronic skin disease	Education and support needs			4-point Likert scale	10	0 - 30	0-10: needs intensive education and support to develop knowledge, ability and confidence 11-20: needs some education and support to develop knowledge, ability and confidence 21-29: needs limited education and support to develop knowledge, ability and confidence 30: has sufficient knowledge, ability and confidence to manage on their own	nr	English	nr

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
PRISM (Muhleisen et al. 2009)	Dermatology inpatients	QoL			Visual; the patients mark the tool	1	0 to 270 mm	Higher SIS distances corresponded to lesser perceived impairment.	nr	German	5
SF-QES (Muller et al. 2007)	Patients with skin disease	Feelings of stigmatisation	5	Self-esteem, retreat, experienced refusal, concealment, composure	nr	23	nr	Higher scores indicate higher experience of stigmatization	nr	German	nr
Skindex (Chren et al. 1996)	Patients with skin disease	QoL	7	Negative affect, self-esteem, anxiety, physical discomfort, physical limitations, self-consciousness, intimacy	5-point Likert scale	61	0 - 100	Higher score indicates higher impairment of QoL	4 weeks	English	15(de Tiedra et al. 1998)
S29 (Chren et al. 1997a)	Patients with skin disease	QoL	3	Emotions, symptoms, functioning	5-point Likert scale	29	0 - 100	Higher score indicates higher impairment of QoL	4 weeks	English (Chren et al. 1997a), Chinese (He et al. 2014), German (Augustin	5 - 15(Chren et al. 1997a;

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
										et al. 2004), Serbian (Milutinovic et al. 2017), Spanish(Jones-Caballero et al. 2000)	de Tiedra et al. 1998; De Korte et al. 2002a; Jones-Caballero et al. 2002; Bronsard et al. 2010)
S16 (Chren et al. 2001)	Patients with skin disease	QoL	3	Emotions, symptoms, functioning	5-point Likert scale	16	0 - 100	Higher score indicates higher impairment of QoL	4 weeks	English (Chren et al. 2001), Arabic (AlGhamdi and AlShammari 2007),	3(AlGhamdi and AlSham

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
										Brazilian-Portuguese (Carcano et al. 2018), Chinese (He et al. 2014), Japanese,(Higaki et al. 2002), Moroccan-Arabic (El Fakir et al. 2014), Ukrainian(Chernyshov 2016)	mari 2007; El Fakir et al. 2014)
TQL (Gurel et al. 2005)	Patients with skin disease	QoL	6	Social life, emotional, daily activities, cognitive, symptom, sexual life	5-point Likert scale	11	0 - 44	nr	1 month	Turkish	nr

PROM	Target population	Construct	Sub-scales	Domains	Method of rating	Number of items	Scoring	Interpretation	Recall period	Available languages	Completion time (minutes)
VQ-Dermato (Grob et al. 1999)	Patients with chronic skin disease (excluding melanoma)	QoL	7	Self-perception, daily living activity, mood state, social functioning, leisure activity, treatment-induced restriction, physical discomfort	5-point Likert scale	28	nr	nr	4 weeks	French	<13

Appendix 4: Characteristics of studies included in the systematic review

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
ACSD	1 (Stangier et al. 2003)	Dermatology clinic in and outpatients	Germany	German	442			Atopic dermatitis, Contact eczema, Psoriasis, Acne, Vitiligo, Epidermolysis bullosa
CDLQI	1 (Lewis-Jones and Finlay 1995)	Paediatric dermatology clinic	UK	English	233	11.1 (SD = 3.5)	62	Eczema, viral warts, molluscum contagiosum, psoriasis, acne, infection, other discrete lesions e.g. moles, naevi, other inflammatory disease, others
CDLQI-C	1 (Chuh 2003)	nr	China	Cantonese	60	Children with skin problems = 9.47.	25	Scabies (n=2), Atopic dermatitis (n=8), Acne (n=5), Miscellaneous (n=4), Psoriasis (n=2), Molluscum contagiosum (n=3), Viral warts (n=3),

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
						Children with problems unrelated to skin = 8.87		Moles and nevi (n=3), Problems unrelated to skin (n= 30)
CQI-CSD	1 (van Cranenburgh et al. 2015)	Recruited through insurance providers	Netherlands	Dutch	116	Means not reported 18-34: 10.5% 35-54: 19.7% 55-64: 20.7% 65-74: 24.9%	58.5	Acneiform dermatoses, Allergological problem, Eczema, Hair and nail disorders, Inflammatory dermatoses, Pigment disorders, Premalignant dermatoses, Psoriasis form dermatoses, Leg ulcers

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
						>=75: 24.2%		
DIS	1 (Malakouti et al. 2017)	Online survey	USA	English	1109	49.1 (SD = 13.6)	70	Psoriasis
DLQI	8 (Finlay and Khan 1994b; Herd et al. 1997; Hahn et al. 2001;	Dermatology outpatient clinic (Finlay and	UK	English	352	Dermatology patients = 43.7 (median = 42 years, range = 15-75).	59	Acne, psoriasis, other eczema, mole, atopic eczema, viral wart, BCC, seborrheic wart, solar keratosis, Bowen's disease, facial rash/flushing, alopecia areata, cyst, discoid lupus erythematosus, dermatofibroma,

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
	Reilly et al. 2003; Lennox and Leahy 2004; Shikiar et al. 2005; Shikiar et al. 2006; Twiss et al. 2012)	Khan 1994b)				Controls = 36.9 (median = 34.5, range = 15-75). Test-retest reliability group: median = 36, range = 15-66.		granuloma annulare, onychomycosis, pityriasis rosea, rosacea/rhinophyma, chondrodermatitis, dermatitis herpetiformis, drug reaction, hair loss, haemangioma, lentigo simplex, localised blistering, leg callosity, pilar cyst, pityriasis versicolor, scabies, Sweet's syndrome, other
		Randomised-	USA	English	826	nr	nr*	Chronic idiopathic urticaria

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
		controlled trial (Lennox and Leahy 2004)						
		Randomised-controlled trial (Shikiar et al. 2006)	USA	English	147	44.2 (SD = 12.7)	33	Psoriasis (moderate to severe)
		Dermatology outpatient clinic (Reilly et al. 2003)	USA	English	257	44.9 (SD = 13.3)	57	Chronic hand dermatitis

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
		Dermatology outpatient clinic (Hahn et al. 2001)	USA	English	179	43 years (Range = 17-82)	67	Psoriasis, eczema
		Dermatology outpatient clinic (Ofenloch et al. 2014)	Germany	English	527	44.7 (SD = 11.6; range = 18 – 67)	37	Hand eczema
		Clinical trial (Shikiar et al. 2005)	USA, Canada	English	826	nr	nr	Chronic idiopathic urticaria

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
		Postal survey (Twiss et al. 2012)	UK	English	292	Psoriasis: 44.4 (SD = 14.7, range = 17 – 83) Atopic dermatitis: 45.5 (SD = 16.6, range = 20 – 82)	50	Psoriasis, atopic dermatitis
		Community (Herd et al. 1997)	UK	English	56	Range = 16 - 53	nr	Atopic dermatitis

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
DLQI-B	1 (Ferraz et al. 2006)	Dermatology outpatient clinic	Brazil	Brazilian-Portuguese	115	Derm patients = 42 (SD = 15); LE patients = 38 (SD = 12)	Derm patients: 75 LE patients: 83	Derm patients: onychomycosis and psoriasis (6 patients each), Contact dermatitis (4 patients), and solar keratosis, viral warts and vitiligo. Lupus erythematosus with cutaneous lesions.
DLQI-C	4 (Liu et al. 2012; He et al. 2013; Liu et al. 2016;	Hospital (He et al. 2013)	China	Chinese	851	38.5 (SD = 13.8)	39	Psoriasis

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
	He et al. 2018)							
		Hospital (Liu et al. 2012)	China	Chinese	131	32.94 (±0.70)	63	Chronic urticaria
		Dermatology clinic (Liu et al. 2016)	China	Chinese	150	nr	44.4	Neurodermatitis (lichen simplex chronicus)
		Hospital (He et al. 2018)	China	Chinese	9845	33 (SD = 13.5; range = 16-91)	63	Acne, eczema, dermatitis, psoriasis, urticaria, other

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
DLQI-D	1 (Zachariae et al. 2000)	Hospital (in and outpatient)	Denmark	Danish	400	Outpatients - 43 (Range = 18 - 81) Hospitalised - 48 (range = 17 - 89)	Outpatients: 63 Hospitalised: 64	Psoriasis, atopic eczema, other eczema, urticarial, bullous disease, erythroderma, hyperhidrosis, collagenosis, pruritus, acne, viral warts, 'miscellaneous'
DLQI-I	1 (Mazzotti et al. 2005)	Dermatology clinic inpatient ward	Italy	Italian	900	44 (SD = 16.2, range = 18 - 88)	40	Psoriasis
DLQI-N	1 (Mork et al. 2002)	Health Centre	Norway	Norwegian	230	48 (SD = 13.4)	41	Psoriasis

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
DLQI-S	1 (Madarasingha et al. 2011)	Dermatology clinic	Sri Lanka	Sinhala	200	40.3	nr	Eczema, psoriasis, acne, vitiligo, infections, other
DLQI-T	1 (Balci and Inandi 2008)	Dermatology outpatient clinic	Turkey	Turkish	90	Lichen Planus = 41.33 (SD = 16.57) Psoriasis = 40.03 (SD = 16.10) Control = 39.20 (SD = 16.25)	58	Lichen Planus (duration: 1.92 (SD = 2.68); Psoriasis (duration: 11.5 (SD = 8.75)

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
DLQI-U	1 (Chernyshov 2016)	Dermatology clinic	Ukraine	Ukrainian	63	28.55 (SD=10.72)	57	Atopic dermatitis
DQOLs	1 (Morgan et al. 1997)	Hospital outpatient clinic	UK	English	118	38 (range = 13 - 84)	46	Psoriasis, eczema, acne, other
DSQL	2 (Anderson and Rajagopalan 1997; Anderson and Rajagopalan 1998)	Dermatology outpatient clinic (Anderson and Rajagopalan 1998)	USA	English	292	20.7 (± 3.8)	60	Acne

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
		Dermatology clinics (Anderson and Rajagopalan 1997)	USA	English	567	45.4 (range = 13 - 87)	29	Contact dermatitis
FLQA-d	1 (Augustin et al. 2000a)	Dermatology clinic	Germany	German	747	38.9 (SD = 14.4; range = 16-89)	58	Psoriasis, atopic dermatitis, urticaria, other dermatoses
PBI	1 (Augustin et al. 2009)	nr	Germany	German	1406	nr	nr	Acne, atopic dermatitis, autoimmune, hand/foot eczema, alopecia, herpes zoster, hyperhidrosis, psoriasis, leg ulcer, urticaria

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
PeDeSi	1 (Cowdell et al. 2012)	Dermatology clinic	UK	English	145	nr	nr	nr
PRISM	1 (Muhleisen et al. 2009)	Dermatology inpatients	Switzerland	German	101	Median = 64.6; IQR = 45.3-76.2; Range = 16.5 - 92.1	49	Dermatitis, tumor, leg ulcer, psoriasis, cutaneous eruptions from drug use, hypodermitis, prurigo, urticaria, vasculitis, acne inverse, dyskeratosis follicularis, dermatomyositis, and lichen sclerosus et atrophicans.
SF-QES	2 (Muller et al. 2007)	Multicentre, randomised clinical	nr	nr	827	nr	nr	nr

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
		psoriasis trial for outpatients.						
	(Schmid-Ott et al. 2003)	Dermatology clinic	Germany	German	463	R = 16 - 85	35	Psoriasis, neurodermatitis
Skindex	1 (Chren et al. 1996)	Private and general dermatology clinics	USA	English	308	51 (SD =17)	60	Skin cancer, benign growth, eczematous dermatitis, acne vulgaris, acne rosacea, psoriasis, nail disease, warts, alopecia, skin ulcer, other

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
S29	2 (Chren et al. 1997a; Nijsten et al. 2009)	Dermatology clinic (Chren et al. 1997a)	USA	English	682	56 (SD = 18)	nr	Eczematous dermatitis, acne vulgaris, tinea (not of the nails), intertrigo , candidiasis, other inflammatory dermatoses, non-melanoma skin cancer, benign growth, warts, other isolated lesions, nail disease, other dermatoses
		Dermatology outpatient clinic (Nijsten et al. 2009)	USA	English	454	45	60	Acne, psoriasis, seborrheic dermatitis, alopecia areata, vitiligo, nevi

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
S29-C	1 (He et al. 2014)	Dermatology clinic	China	Chinese	221	32.5±12.2		Isolated skin lesions (nevi, warts) and inflammatory dermatosis (psoriasis, acne)
S29-G	1 (Augustin et al. 2004)	Dermatology inpatient clinics	Germany	German	Study 1: 121 Study 2: 174	Study 1: 47.8; SD: 4.6 Study 2: 41.4; SD: 15.7	Study 1: 44 Study 2:59	Psoriasis, atopic dermatitis
S29-S	1 (Milutinovic et al. 2017)	Dermatology outpatient clinic	Serbia	Serbian	285	42, 46±20	70	Acne vulgaris, verrucae vulgaris, psoriasis, mild dermatitis, venous ulcers, eczema, ulcers, other skin diseases (acne rosacea, urticaria,

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
								keratosis, tinea corporis or pedis, scabies, etc.).
S29-Sp	2 (Jones-Caballero et al. 2000; Jones-Caballero et al. 2002)	Dermatology outpatient clinic (Jones-Caballero et al. 2002)	Spain	Spanish	318	36 (SD = 15)	65	Melanocytic Nevus, Warts, Seborrheic and actinic keratosis, Fibroma, Basal cell carcinoma, Acne, Eczema, Psoriasis, Alopecia areata, Urticaria, Other
		Outpatient clinic (Jones-	Spain	Spanish	103	40±16	69	Melanocytic nevi , acne, warts, psoriasis, seborrheic keratosis, eczema, seborrheic dermatitis, lichen planus, basal

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
		Caballero et al. 2000)						cell carcinoma, lymphoma, melanoma, nonmelanocytic nevi, alopecia areata, atopy, oral Aphthae, urticaria, vitiligo, actinic keratosis, epidermal cyst, broma, keloid, multiple angioleiomyomas, actinic porokeratosis, balanitis, hidradenitis, leg ulcer.
S16	1 (Chren et al. 2001)	Dermatology clinics	USA	English	541	58 (SD = 18)	35	Eczematous dermatitis, basal cell carcinoma, actinic keratosis, benign growths, acne vulgaris, warts, psoriasis, squamous cell carcinoma, other

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
S16-A	1 (AlGhamdi and AlShammari 2007)	Dermatology clinic	Saudi Arabia	Arabic	678	28.2 (SD=12.87)	49	Vitiligo, acne, eczema, post-inflammatory, hyperpigmentation, warts, psoriasis, benign nevi, fungal infections, urticarial, alopecia areata, others
S16-BP	1 (Carcano et al. 2018)	Dermatology outpatient clinic and healthcare institution exclusively for the treatment	Brazil	Brazilian-Portuguese	110	47.39 (SD = 15.27, range = 18.95 - 87.48)	71	Dermatitis, non-melanoma skin cancer, leprosy, melasma, acne, senile freckle, other

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
		of cancer patients						
S16-C	1 (He et al. 2014)	Dermatology clinic	China	Chinese	216	32.5±12.2	53	Isolated skin lesions (nevi, warts) and inflammatory dermatosis (psoriasis, acne)
S16-J	1 (Higaki et al. 2002)	Dermatology outpatient clinic	Japan	Japanese	130	Patients = 43 (SD = 16); controls = 41 (SD = 12)	Patients = 66; controls = 67	Atopic dermatitis, psoriasis, atheroma, seborrheic Keratosis, eczema, melanocytic nevi, fibroma, dermatofibroma, warts, alopecia areata, senile freckle, contact dermatitis, acne, erythema multiforme, panniculitis, calcifying epithelioma, epidermal nevus,

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
								glomus tumor, neurofibroma, subcutaneous tumor, thrombosed vein, venous lake, basal cell epithelioma, urticaria, Hailey-Hailey disease, herpes simplex, keratoacanthoma, lichen planus, phlegmone, allergic vasculitis, rosacea, rosacea like dermatitis, tylosis.
hS16-M	1 (El Fakir et al. 2014)	Dermatology	Morocco	Moroccan Arabic	120	39 (SD = 16, range = 15 - 90)	nr	Acne; bullous dermatoses; neutrophilic dermatosis; infectious dermatitis; toxiderma; system

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
		outpatient clinic						disease; psoriasis; eczema; urticaria; skin tumours; other (not specified)
S16-U	1 (Chernyshov 2016)	Dermatology clinic	Ukraine	Ukrainian	63	40.64 (SD=13.71)	38	Psoriasis
TQL	1 (Gurel et al. 2005)	Dermatology outpatient clinic	Turkey	Turkish	327	With skin disease: Mean: 26.84; range: 14-57 Healthy: Mean: 29.06; range: 15-51	With skin disease: 51.8%. Healthy: 53.1%	Acne vulgaris, contact dermatitis, tinea, psoriasis, verruca, benign skin tumour, vitiligo, norodermatitis, hyperpigmentations, bacterial infections, alopecia, acute urticarial, hirsutismus, photo. Dermatitis, skin cancer, scabies, drug eruptions, lichen ruber planus, morbus behcet, other

		Study characteristics			Study population			
PROM	**No. of studies**	**Study setting**	**Country of study**	**Language(s)**	**Sample size**	**Age (SD, range)**	**Female (%)**	**Dermatologic condition(s)**
VQ-Dermato	1 (Grob et al. 1999)	University hospital, non-university hospital and private practice	France	French	256	49.3 (SD = 18.8)	nr	Severe trophic disorders of the legs (including leg ulcers), psoriasis, chronic eczema, chronic urticarial, dyschromic disorders, dermatitis of the face, hand and foot dermatitis, alopecia, bullous dermatoses, lichen planus, recurrent herpes, parapsoriasis, mycosis fungoides, multiple carcinomas, cutaneous manifestations of systemic disorders.

Abbreviations are found in **Error! Reference source not found.**

Appendix 5: Evidence of data saturation

Saturation was evaluated across the sample to determine data sufficiency for breadth and depth of analysis to meet the aim of the study. This evaluation was facilitated by a saturation matrix, which summarised the new codes discerned during the workshop and subsequent individual interviews. The saturation matrix indicated that the workshop captured all codes. These codes were validated by the first two individual interviews conducted (PID 4 and 5). No new codes were added after the third interview (PID 7). The remaining individual interviews tested whether these codes were endorsed across clinical and demographic groups (e.g. dermatological conditions geographic location, type of healthcare system).

Data saturation matrix table

Code	Workshop	Individual interviews		
		PID 4	PID 5	PID 7
Cause	x	x		
Consequences	x	x		
Physical	x	x		
Cognitions	x	x		
Emotions	x	x		
Coping	x	x		
Social	x	x		
Financial	x		x	
Daily life and responsibilities	x	x		
Control/cure	x	x		
Identity	x		x	
Timeline	x	x		
Other	x	x		

Appendix 6: Group discussion topic guide

Question type	Question wording	Prompts
Opening	Can you tell us who you are, which patient organisation you represent, and, if you feel comfortable, whether you have a skin condition yourself?	
Introductory	What do you understand by impact?	
Transition	How do skin conditions impact the people living with them?	
Vignettes	What do you think the main impact of skin conditions are on this person?	Physical Social Psychological Economical Cultural Religious Access to medical care Age Gender Ethnicity Socioeconomic status
Ending questions	What are the key issues we've identified today?	
	Is there anything we have missed that you would like to add?	

Appendix 7: Individual interview topic guide

Stage 1: Set-up (5 - 10 mins)

1. Briefly introduce self

Hi. Thank you for agreeing to take part in this interview. We really appreciate you giving your time. I'm Rachael and I will be interviewing you today. I'm one of the researchers on the GRIDD project and I'm based at Cardiff University.

2. Brief GRIDD overview

You will know a little bit about the GRIDD project already from the emails and documents you received from GlobalSkin. If you would like, I can give a brief overview of the project or answer any questions you might have.

If they would like an overview:

The GRIDD project aims to collect global data on the impact of skin conditions on people's lives. We need to create a new questionnaire that can be used to collect this data. So that the questionnaire captures the full impact of living with a skin condition from the patient perspective, we need to speak to people with skin conditions to find out how their skin condition has affected them. We will use the data to create the questions for the questionnaire.

We have already conducted several group discussions where we discussed this topic. Participants at those group discussions really highlighted the social and psychological impact of their skin condition. We would like to build on what we've learned so far by investigating some of the topics in more depth and also by asking about other topics which may be important but haven't come up yet.

3. Ground rules

I just need to run through a few things before we start the interview.

- We will have 50 minutes for the interview, but you can choose the end the interview any time you'd like; for example, if you feel you don't have anything more to say.
- There are no right or wrong answers to any of the questions - we are interested in **your** views and experiences so be as open and honest as you can. But please refrain from offering your medical history as I can't address that in this interview. We have a limited time to cover a broad topic, so it's important that we stay on topic.
- Please don't hesitate to ask for questions to be repeated or explained.
- Taking part in the interview is voluntary and you have the right to decide not to discuss any topic or stop the interview at any time.
- The interview will be audio recorded. The interview will remain confidential unless you reveal something that would be harmful to your or others. Any information that can identify you such as names of people or places will be anonymised and if we use quotes from you, they will not have your name on them.

Before we begin, are there any questions you'd like to ask me?

Let participant know that we are beginning the interview and I will start recording.

Stage 2: Interview (50 mins)

Introductory question: 1. What does the term 'impact' mean to you? (5 mins)

Key questions: (30 – 40 mins)

2. What skin condition do you have?
3. What are the symptoms of your skin condition?
4. What do you think caused your skin condition?
5. In what ways has your skin condition impacted upon your life?

a. Social life
b. Relationships

Possible prompts:

We know from other measures, such as the DLQI, that some people are reluctant to talk about how their skin condition effects their ability to be intimate with others. Why do you think this is? Further prompt: Is this because it's not an issue or because they feel uncomfortable talking about intimacy? If it is an issue, how do you think we can approach this subject?

c. Life at home
d. Work

6. How does your skin condition make you feel?
7. Tell me about some of the ways you cope with your skin condition?

Possible prompts:

People cope with their skin condition in lots of different ways. Some participants have said that they've used drugs or alcohol to help them cope with living with their skin condition. Is this something you can relate to? Or do you know how people with skin conditions who cope in this way?

8. To what extent do you think you can control your condition?
9. How do you see your skin condition in:
    a. 3 months' time? Better or worse or staying the same?
    b. 1 years' time? Better or worse or staying the same?

Ending questions: 10. Of all the issues we discussed today, which ones are the most important to you (5 – 10 mins)

Possible prompts:

- If someone was to measure/assess the impact of skin conditions on a person's life, what questions do you think they should ask?
- If you were speaking to a friend with a different skin condition to you and were interested to know how their skin condition impacts on their life, what questions would you ask them/what would you ask them about?

Stage 3: Ending (5 – 10mins)

We have now come to the end of our discussion.

Before we finish, is there anything we've missed that you would like to add or any discussions where you felt you didn't fully manage to state your opinion?

Thank you all so much for taking the time to participate in this discussion. Your opinions are very important in guiding the development of this new measure and further research. You can track the progress of this research on GlobalSkin's website where the research team will be posting updates.

Appendix 8: Vignettes for group discussions

Acne

Alice

'Alice is an 18-year-old woman from the UK who has widespread acne. She currently lives in the family home. Her family regularly tell her to stop eating unhealthy food and not to wear makeup as they believe this clogs her pores and causes her acne. Alice will be starting university soon and will be moving out of the family home to live in halls.

While at school, Alice was bullied and woke up extra early every morning to apply makeup in order to cover up her acne, which made it worse. Alice is looking forward to moving away to university because she wants to meet new people and start to meet boys, but the thought of this also fills her with dread. She is worried that people will react negatively to her acne. Alice won't be able to hide her acne from other students in university as she did in high school as she will be living in accommodation with a communal bathroom and kitchen.'

Lok

'Lok is a 49-year-old man who developed acne in his late 30s. He lives in a rural town in China where he works as a veterinary assistant. Lok's acne is typical of that which appears in Chinese skin: he has hardened bumps and reddening, which can lead to permanent scarring if they are not treated quickly and effectively. Lok isn't aware of this and thinks he'll 'outgrow' his acne.

Lok has visited the local hospital which doesn't have specialist dermatology services for treatment. They have prescribed him a number of antibiotic courses which are costly and don't seem to work to clear the acne. Clinicians in the local hospital advised Lok to travel to a city hospital to receive specialist dermatology care. Lok travelled for three hours for his appointment. He was prescribed Roaccutane, a medication that needs careful monitoring.

Lok has now been on this medication for some months but has not been able to get back to the city hospital since his first visit.'

Alopecia

Logan

'Logan is a 25-year-old man from Canada with alopecia. He was training to be a music teacher when his hair started to fall out. After completing his degree, Logan secured a job as a high school music teacher. He was worried about how the children would react to his bald patches so decided to shave his hair off. Previously, Logan had long hair. He plays in a heavy metal band and is now the only member of the band with a shaved head. He tried to grow a beard instead, but the school will not allow this. Hardly any of the children notice his appearance but Logan is very self-conscious, and this is beginning to affect his self-esteem.'

Marie

'Marie is a 38-year-old woman who lives in France. She is a single parent to an 8-year-old boy Marc and works part-time in a patisserie to support them. Marie's hair started to fall out when she was pregnant with her Marc. Her friends told her not to worry because it's "just hair, it will grow back" but it hasn't. The first dermatologist Marie saw told her to "stop stressing" and prescribed her local steroids in the form of a sticky mousse. Marie had been considering quitting smoking but feels that it helps her when she's stressed. Marie hasn't seen so much of her friends recently and now is upset that Marc has asked her not to come to his school Christmas party.'

Atopic dermatitis

Jana

'Jana is a 24-year-old woman from Oman who has atopic eczema. She is not looking forward to the upcoming summer months as her eczema gets worse and she tends to scratch more when it's hot. Her sleep isn't as good as it once was, and she wakes up every morning feeling unrefreshed from the sleep. Her husband is a surgeon. He works irregular hours and is often called out at night. He recently suggested that they start to sleep in separate beds so that he will not disturb her and vice versa. This has caused Jana some distress because they would like to have children. Jana is also worried that her child will inherit the eczema.'

Ray

'Ray is a 62-year-old man from the UK who has atopic dermatitis. He is a widower and lives alone. Ray worked as a skilled carpenter but lost his job a couple of years ago. He used to play football but doesn't anymore. He is now very overweight and has osteoarthritis in both knees, which has reduced his mobility. He struggles to get to his GP or pharmacy independently. Ray is prescribed two ointments, an emollient and topical steroid, for his eczema, but doesn't know what they are for or what they're called. He often gets them confused and applies the wrong medicines to the wrong areas. His back, in particular, is untreated since he can't reach it alone. The ointments create a mess on his clothes and bed sheets.'

Psoriasis

Diane

'Diane an African-American lawyer in her 50s based in Chicago. She has had chronic plaque psoriasis since she was a teenager but was only recently diagnosed. Diane has found that there is a general lack of knowledge in the medical community about psoriasis in people of colour. As a teenager, she was repeatedly told by general doctors that people of colour don't

get psoriasis. She felt very alone because the only photographs of psoriasis she could find were on Caucasian people. Their psoriasis looked very different to hers which was very dark and thick. Because of this, Diane became a patient advocate. Her psoriasis has become more severe since she hit the menopause.

Diane had managed her psoriasis using expensive creams but now needs medical treatment. She was initially prescribed creams that made her feel wet and greasy and made it difficult to dress and feel confident in her corporate job. More recently, she has been prescribed biologics, which are effective, but cost her $1,200 per month and she has to self-inject. Diane is finding this a big challenge.'

Paulo

'Paulo is a 43-year-old man from Brazil who has psoriasis and psoriatic arthritis. He is the breadwinner in a family with four children. They do not have enough money to make ends meet each month. Until recently, Paulo worked in a popular restaurant, but his manager didn't understand psoriasis and thought it was contagious. He forced Paulo to wear gloves before finally firing him. Paulo has started to drink every day. He has noticed that his psoriasis and psoriatic arthritis are getting worse. He believes that his conditions are stopping him from finding another job. He wants to see improvements and is currently managing his psoriasis with topical treatment. Biologics are not available through the public health system in Brazil and he can't afford to pay for them privately.'

Rare skin disease

June

'June is a 20-year-old with mild Epidermolysis Bullosa, which is often mistaken for other skin conditions. She dropped out of school aged 14 as it took a great deal of time every day to manage her condition. Until recently, June had a job working in a retail store, however, her

skin deteriorated, and she had to leave. Each morning, June goes through a routine of removing dressings, bathing, showering, draining blisters, applying creams, antiseptic gels, bandages and plasters, and removing dead skin which can take up to two hours. Despite this, June is an EB blogger and uses her platform to raise awareness of the condition.'

Yaron

'Yaron is a 35-year-old man from Israel who lives with neurofibromatosis. He works for a cancer charity as a fundraiser. His employers understand that he needs to take regular breaks and time off to attend his many hospital appointments. Yaron is very knowledgeable about cancer and is hypervigilant about checking his tumours. After his most recent check-up in the skin department, Yaron received a letter to come back to discuss his recent results, so is very concerned.'

Vitiligo

Raka

'Raka is a 27-year-old laboratory-based scientist from India who lives with vitiligo. Vitiligo is not openly talked about and stigmatised in her community and Raka was told that she will find it very difficult to get married. This has affected her family's reputation and, since her white patches began to appear, they have been ostracised in their community. When she was a teenager, Raka's parents took her to a few doctors who sold pills, herbs and lotions that didn't work to improve the condition at all. They next turned to Hindu astrology, which led them to believe that her vitiligo was karmic justice for actions in a previous life. Raka was banned from talking about her vitiligo by her family because they didn't want her to draw attention to her condition. It wasn't until Raka moved away to Delhi to go to college that she could see a conventional doctor about her condition and found she'd been living with several undiagnosed and mistreated conditions.'

Jordan

‘Jordan is a 52-year-old African-American man with vitiligo. He received a sports scholarship for college and was a promising basketball player. He followed this with a successful career as a sports reporter where he travelled around the world commentating on games and interviewing players. Being in the spotlight is the meaning of his life. Jordan has had white spots on his arms and scalp since he was a child, but he has been able to cover them well. They have started to expand and now he has developed white patches on his face. Since these becoming visible, Jordan’s employer has insisted that he take a more backstage role. He has begun to gain weight making it increasingly difficult to get back in front of the camera. Jordan hates being behind the scenes and is becoming less interested in his appearance. He now has to sit for long periods in work which he knows isn't good for his health. However, he feels that he can’t quit his job because he needs the health insurance benefit to pay for his medication. Jordan is taking stock of his life because he is now the same age as his father was when he died.’

Appendix 9: Analytical framework

Category	Theme	Subtheme	Code	Description
Physical	Sleep disruption			Comments that the skin condition directly or indirectly impacts sleep such as poor-quality sleep, disrupted sleep (e.g. waking to itch).
	Symptoms		Altered sensation	Changes in how the individual experiences touch and/or temperature; for example, being extremely sensitive and responsive to hot and cold.
			Hot or burning	Descriptions of a burning sensation in the skin or body.
			Comorbidities	Comorbidities associated (or perceived to be associated) with the skin condition (e.g. arthritis listed as a symptom of psoriasis).
			Discomfort	Experiencing physical discomfort.
			Disfigurement	Descriptions of altered appearance, particularly of the skin, nails or hair.
			Fatigue or loss of energy	Describing tiredness, exhaustion, lack of energy or weakness, particularly if this isn't alleviated by sleep.
			Itch	The sensation and physical act of itching.
			Pain	Painful sensation in affected areas or other areas.

Category	Theme	Subtheme	Code	Description
			Rashes	Descriptions of rashes may include scaly, bumpy, itchy, or otherwise irritated. Rashes are distinct from plaques or lesions which are generally demarcated.
			Plaques or lesions	Dry or inflamed plaques or lesions.
			Weeping	Fluid leaking from affected areas e.g. wounds, burns, blisters.
			Rough or scratchy skin	Descriptions of skin being rough or scratchy (not in terms of itch but rather in the texture of the skin).
			Pompholyx	Descriptions of pompholyx - tiny itchy blisters that may weep fluid – in people with eczema.
			Pigmentation	Descriptions of loss or changes in pigmentation including the development of white patches.
			Peeling	Descriptions of skin peeling.
			Sensitivity to the sun	The skin condition causes sensitivity to the sun.
			Colour	Comments about the skin changing colour or redness.
			Hair loss	Comments about loss of hair or balding.
			Spots	Comments about spots.
			Oily skin	Comments about oily skin.

Category	Theme	Subtheme	Code	Description
			Dry skin	Comments about skin being dry or 'ashy'.
	Secondary physical consequences		Wounds	Comments about wounds, usually as a result of itching
			Bleeding	Comments about bleeding, usually as a result of scratching.
			Scarring	Comments about having scars because of the skin condition – but not as a symptom. Scaring from scaring alopecia would as a symptom, whereas acne scars or scars from itching would be coded here.
			Scratching	Descriptions of scratching the skin.
			Hospitalisation	Examples of being admitted to hospital as a result of the skin condition, but not for routine appointment.
			Mobility	Comments about affected mobility due to skin condition e.g. trouble walking.
			Flakes	Descriptions of skin flaking, falling off or shedding.
	Treatment consequences			Physical consequences of treatments e.g. pain, liver dysfunction.
Psychological - Emotions	Jealousy			References to feeling jealous because of the skin condition.
	Anger	Skin condition		Anger towards the skin condition.
		Other's comments		Anger regarding other people's comments.

Category	Theme	Subtheme	Code	Description
		Treatment time		Anger at the time spent on treatments.
		Explaining		Anger at having to explain skin condition.
	Betrayal	Own body		Feeling that their body has betrayed them.
	Frustration	Skin condition		Frustration arising from the skin condition.
		Treatment regime		Frustration arising from the treatment regime.
		Treatment failure/effectiveness		Frustration arising from treatment failure or effectiveness.
		Treatment options		Frustration arising from (lack of) available treatment options.
	Anxiety	Anticipatory worry	Assumptions	Comments about being worried that people will make assumptions about them based on their skin condition.
			Comments	Comments about being worried that people will make comments to or about them because of their skin condition.
			Progression	Worrying that the condition will deteriorate.
			Comorbidities	Worry about developing comorbidities.
			Skin before person	Worrying that other people see the skin condition before they see the person.

Category	Theme	Subtheme	Code	Description
			Treatment consequences	Worrying about treatment consequences.
			Genetics on to children	Worrying that they will pass their condition on to their future children.
		Fear	Rejection	Fear of being rejected by others.
			Treatment stopped	Fear that their treatment will be stopped.
			Flares	Fear of flares.
			Skin condition itself	Fear of the condition itself.
		Hypervigilance	Symptom monitoring	Descriptions of monitoring symptoms.
			Checking for triggers	Descriptions of being alert to triggers.
			Alert	Descriptions of a heightened sense of alertness with regard to the skin condition. Frequent thinking, planning and engaging in behaviours to manage the skin condition.
		Guilt	General	General feelings of guilt that do not fit in with the other guilt codes.
			Scratching	Guilt about scratching.

Category	Theme	Subtheme	Code	Description
			Making condition worse	Guilt that they may be making the condition worse e.g. by scratching
			Parental	Feeling guilty that they have passed the skin condition on to their children.
			Brought on family	Feelings of guilt regarding the skin condition. This could be feeling guilty for bringing the skin condition into the family and perceived or real consequences of that (e.g. family ostracised by community).
		Preoccupation/rumination/obsession		The person expresses that they spend a great deal of time thinking about the skin condition or ruminating which has a negative impact.
	Low mood	Self-esteem		An unfavourable attitude towards one's self. The individual may express feelings of low self-worth or value or negative appraisals of their own appearance, beliefs, emotions and behaviours.
		Low mood		Expressions of low mood, feeling low in spirits or a general loss of interest in things.
		Self-harm		Intentionally damaging or injuring one's self.
		Suicide	Thoughts	Suicidal ideation - serious thoughts about taking one's own life.

Category	Theme	Subtheme	Code	Description
			Actions/actual	Attempts at suicide.
		Low motivation		Reference to or examples of lack of motivation.
		Hopeless/helpless		Comments about feeling hopeless or helpless with regards to their condition.
		Sad		Feelings of sadness, being upset.
		Depressed		Explicit referral to depression.
	Shame	Shame		Comments about feeling shame.
		Embarrassment		Comments about feeling embarrassed.
	Emotional pain	General		References to feeling emotional pain or hurt.
		Hurtful comments		Feeling emotional pain or hurt as a result of other people's comments.
	Shock/surprise			Comments about feeling shocked or surprised about the skin condition.
	Desperation	Cure		Being desperate for a cure.
		Relief		Being desperate for relief.
		Awareness		Being desperate for more awareness of skin conditions.

Category	Theme	Subtheme	Code	Description
	Empowered			Comments that the skin condition or how they have coped with the skin condition makes them feel empowered.
	Grateful			Comments that they feel gratitude or appreciation because of the skin condition.
	Stress			Reference to stress or feeling unable to cope with or respond to threats or demands.
	Disappointment			Comments about feeling disappointed as a result of the skin condition and/or its secondary impacts
Psychological - Cognitions	Uncertain/confused			Comments about the skin condition causing confusion or uncertainty.
	Confidence			Comments about how the skin condition has affected their confidence.
	Normalising			Comments about the degree to which the skin condition has become a normal part of their life.
	Identity	I am skin condition		Feeling that their skin condition is their identity.
		Part of me		Feeling that their skin condition is just one part of their identity.
		Masculinity/femininity		The individual expresses that themselves or others feel that the skin condition makes them feel less feminine or masculine or less able to engage in associated behaviours.

Category	Theme	Subtheme	Code	Description
		Change in identity		Comments about changes in identity (changed them as a person, how they express themselves) or absorbing the skin condition into their identity.
		Attractiveness		Perception that the skin condition has altered how attractive the individual is.
		Change appearance		The individual has changed their appearance as a result of the skin condition.
	Acceptance			The skin condition has affected whether the individual can accept themselves as they are.
	Exposed	Exposed		Perception that the skin condition draws unwanted attention
		Privacy		Feeling that the skin condition invites others to invade their privacy or causes them to expose things they would rather be kept private. An example is allowing student doctors to see affected areas, such as genitals.
		Paranoid		Comments about feeling like people are looking at them or talking about them. This code is different from other people's reactions because it is not necessarily true but is how the person feels.
		Self-conscious		Comments about feeling self-conscious.
	Cynicism	Abandoned		Feeling abandoned by individuals, organisations or society.

Category	Theme	Subtheme	Code	Description
		Loss of faith on others		Loss of faith in individuals, organisations or society.
	Pressure	Pressure to perform		Feeling pressure to perform to the same standards as people who do not have a skin condition.
		Proving self		Feeling pressure to prove that people with skin conditions are as good as others.
		Pressure to participate		Feeling pressure to participate in activities that will harm their condition.
	Perspective			Comments about the skin condition giving the person a new perspective or outlook.
	Autonomy	Choice		Comments that the skin condition restricts choice.
		Control		Comments that the skin condition influences how much control they have.
	Concentration			Expressions of finding it hard to concentrate, maintain focus or pay attention to detail.
	Discomfort/unease			Comments about or alluding to psychological discomfort.
	Blaming condition			The belief or tendency to blame the skin condition for all of their problems.

Category	Theme	Subtheme	Code	Description
Psychological - Coping	Avoidance	Behavioural disengagement	Hiding/Concealing/ Disclosing	Comments about hiding the skin condition whether physically or by not disclosing it.
			Limiting self (choices and challenges)	Allowing the skin condition to determine or limit choices such as where to socialise in an attempt to reduce emotional impact. Not engaging in anything deemed a challenge, remaining in comfort zone at all times, in an attempt to reduce emotional impact.
		Denial		e.g. 'I've been saying to myself, "this isn't real"
		Distancing		e.g. 'I didn't let it get to me. I refused to think about it too much'
		Escape/avoidance		e.g. 'I wished that the situation would go away'
		Self-control		e.g. 'I've tried to keep my feelings to myself'
		Self-distraction		e.g. I've been turning to work or other activities to take my mind of things'
		Substance use		'I've been using alcohol or other drugs to get me through it'
		Unhealthy lifestyle choices		Engaging in unhealthy behaviours, such as poor diet, smoking or a lack of exercise, with the view to mitigate the impact of the skin condition e.g. not exercising to avoid itching.

Category	Theme	Subtheme	Code	Description
	Approach	Active coping	Advocacy	Participating in advocacy work either formally (e.g. through patient organisation) or informally (e.g. answering questions, educating others).
			Enhancing wellbeing	Engaging in activities to enhance wellbeing, feel calm and reduce stress.
			Healthy lifestyle behaviours	Engaging in healthy behaviours such as eating healthily, being physically active, and ceasing smoking, not drinking alcohol or taking drugs.
			Seeking information	Researching to better understand the condition and/or how to manage it.
		Positive reframing		Reframing the skin condition and living with the skin condition in positive terms.
		Humour		Making light of or making jokes about the skin condition.
		Religion		Turning to their faith or spirituality.
		Emotional support		Getting emotional support from others.
		Planning		e.g. I've been trying to come up with a strategy about what to do
Social	Social	General		Comments about general social impact not covered below.

Category	Theme	Subtheme	Code	Description
	Impact on others			Perception that the skin condition has had an impact on the individual's friends, family, colleagues etc.
	Isolation	By choice		Choosing to isolate oneself.
		By others		Being excluded by others.
		Medium		Comments that the skin condition has led to a change in the medium used to socialize, for example, now using internet or telephone to socialise rather than in person.
	Romantic	Dating		Skin condition affects the desire or ability to date.
		Initiating		Skin condition affects the desire or ability to approach people of romantic interest.
		Maintaining		Skin condition affects the desire or ability to maintain romantic relationships.
		Breakdown		Skin condition has caused the breakdown of a relationship.
	Responsibility			Feeling responsible for educating others about skin conditions.
	Social conditioning			Comments that the skin condition directly affected how the individual was brought up and how that led to differences in expectations or life goals.
	Intimacy	Pain/physical barrier		Skin condition physical prevents or deters from sex.

Category	Theme	Subtheme	Code	Description
		Psychological		Skin condition psychologically prevents or deters from sex.
	Socialise	Meeting new people		Skin condition makes it difficult to meet new people.
		Friends		Skin condition has affected relationship with friends.
		Family		Skin condition has affected relationship with family.
	Other people	Bullying		Experience or perception that the individual has been bullied as a result of the skin condition.
		Discrimination		Discrimination follows stigma and is the unfair or unjust *treatment* of an individual.
		Stigma		Comments about individuals, groups or society stigmatising the person with the skin condition. Stigma is a social process whereby people or groups are *viewed* negatively or devalued based on a real or perceived difference.
		Assumptions		Reference to others making assumptions about them based on their skin condition.
		Comments		Comments are made about the skin condition.
		Questions		Other people ask questions about the skin condition.
		Stares		Comments that other's stare at the person with the skin condition.

Category	Theme	Subtheme	Code	Description
		Effect on mood		How other people react to the condition affects their mood.
	Social support			Increase or decrease in perceived social support as a result of the skin condition.
	Social conformity			The skin condition makes it hard for the individual to conform to social norms or fit in. For example, not being able to wear what is fashionable or being unable to take part in cultural traditions or norms.
	Social comparisons			Engaging in upward or downwards social comparisons.
Healthcare services	Clash of beliefs			The meeting of opposing beliefs regarding the skin condition. Example: clinicians express a medical belief that is at odds with the cultural beliefs about the skin condition.
	Diagnosis	Accuracy		Discussing how accurately clinicians have been able to diagnose the skin condition. For some, they might have had multiple, incorrect diagnoses.
		Timely		Discussing the timing of the diagnosis of the skin condition. Particularly in reference to how quickly a diagnosis is made following symptom onset and the consequences of the time difference between onset and diagnosis. For example, in terms of severity, progression and variability of symptoms.

Category	Theme	Subtheme	Code	Description
	Equity of access	System		Discussing to what extent equity of access to affordable, high quality, culturally and linguistically appropriate care in a timely manner exists and whether/how social, economic, demographical, or geographical factors interact with this.
		Individual		Whether the person is personally able to access treatment. For example, whether they are physically capable of attending medical appointments due to disability. This may be perceived to have consequences for the progression of the condition.
	Shared decision-making	General		Discussing the extent to which clinicians involve or share decision making with people with skin conditions. For example, whether the patient is able to be involved in choosing which treatment is administered or treatment goals.
		Discrepancies in goals, outcomes and expectations		Expressions of differences between clinician and patient expectations, goals and appraisal of outcomes.
	System	Availability of treatment		Discussing whether services (e.g. access to dermatologist, psychologist etc.) are available to people with skin conditions.
		Organisation of care		Discussing how care is co-ordinated with other services. For example, how well the dermatology and rheumatology services co-ordinated for people with psoriatic arthritis.
	Information provided by			Comments about the quality of the information given by clinicians. For example, references made clinicians focusing

Category	Theme	Subtheme	Code	Description
	health professionals			information only on medical treatments and not discussing triggers.
	Scepticism			A lack of trust or scepticism of services or clinicians. For example, a belief that clinicians purposely behave and manage the condition in a way that brings continued income.

Appendix 10: Evaluation of the concept elicitation study according to the COSMIN standards for evaluating the quality of the PROM design

COSMIN standard		Requirement	Rating	Details
1	Is a clear description provided of the construct to be measured?	Construct clearly described	**Very good**	A description of the construct to be measured is provided in the introduction. PRIDD measures the impact of dermatological conditions patients' lives.
2	Is the origin of the construct clear: was a theory, conceptual framework or disease model used or clear rationale provided to define the construct to be measured?	Origin of the construct clear	**Very good**	A conceptual framework of the impact of dermatological conditions does not exist. The study findings were used to develop the first conceptual framework of impact, which will form the basis of PRIDD development.
3	Is a clear description provided of the target population for which the PROM was developed?	Target population clearly described	**Very good**	'Adults (≥ 18-years) living with a dermatological condition' (Table 15).
4	Is a clear description provided of the context of use?	Context of use clearly described	**Very good**	'Discriminative application to distinguish people according to the amount of impact their dermatological condition has had on their lives'.

COSMIN standard		Requirement	Rating	Details
5	Was the PROM development study performed in a sample representing the target population for which the PROM was developed?	Study performed in a sample representing the target population	**Very good**	To identify how dermatological conditions impact the patients' lives and to select the most relevant issues for PRIDD participants were sampled purposively sampled in order to achieve maximum variation according to dermatological condition and demographic factors: country of residence, gender and age. Tables 15. and 16. demonstrate that the sample represented the target population.
6	Was an appropriate qualitative data collection method used to identify relevant items for a new PROM?	Widely recognized or well justified qualitative method used, suitable for the construct and study population	**Very good**	Relevant items were identified during qualitative interview study featuring group and individual interviews.
7	Were skilled group moderators/ interviewers used?	Skilled group moderators/ interviewers used	**Very good**	All group discussions and interviews were conducted by a skilled interviewer (RP, RH, NTS or

COSMIN standard		Requirement	Rating	Details
				EC). All interviewers had experience in conducting dermatological and qualitative research.
8	Were the group meetings or interviews based on an appropriate topic or interview guide?	Appropriate topic or interview guide	**Very good**	A topic guide, including the semi-structured interview guide, was developed to structure interviews (Appendices 6 & 7). The guide was continually adapted to reflect new topics or themes that needed further probing.
9	Were the group meetings or interviews recorded and transcribed verbatim?	All group meetings or interviews were recorded and transcribed verbatim	**Very good**	Each group discussion and interview were recorded using a Dictaphone. Audio data were subsequently transcribed verbatim by a Cardiff University approved independent transcription provider.
10	Was an appropriate approach used to analyse the data?	A widely recognized or well justified approach was used	**Very good**	A framework analysis was conducted from an essentialist/realist standpoint.
11	Was at least part of the data coded independently?	At least 50% of the data was coded by at least two researchers independently	**Very good**	Each transcript was coded independently by at least two of the research team.

COSMIN standard		Requirement	Rating	Details
12	Was data collection continued until saturation was reached?	Evidence provided that saturation was reached	**Very good**	Data collection continued until saturation was reached. Evidence of data saturation is provided in Appendix 6.
13	For quantitative studies: was the sample size appropriate?	Not applicable	-	-
		Overall score	**Very good**	

Appendix 11: Excerpt of item generation process based on the conceptual and analytical frameworks using Microsoft Excel

Subtheme	Code	Concept description	Item (1st draft)	Items (2nd draft)	Items (3rd draft)	Final item
Symptoms	Altered sensation	Changes in how the individual experiences touch and/or temperature; for example, being extremely sensitive and responsive to hot and cold.	How things feel to the touch is affected by my skin condition My skin is very sensitive and/or responsive to hot or cold objects Objects feel too hot/cold to touch because of my condition My skin makes me sensitive to change in temperature I am extremely sensitive to hotter/colder temperatures because of my condition	… your skin is over sensitive … your skin is overly sensitive to changes in temperature	… your skin is over sensitive … your skin is overly sensitive to changes in temperature	your skin is very sensitive your skin is very sensitive to changes in temperature
	Hot or burning	Descriptions of a burning sensation in the skin or body.	My skin feels like it is hot or burning I have a burning sensation on my skin My skin is very hot to touch	… you have a burning sensation in/on my skin	… you have a burning sensation on or under your skin	… you have a burning sensation on or under your skin
	Comorbidities	Comorbidities associated (or perceived to be associated) with the skin condition e.g. arthritis listed as a symptom of psoriasis, skin cancer.	I have another condition related to my skin condition I have developed another condition due to/as a result of my skin condition	… you developed another condition	… You have developed a related condition	… You have developed a related condition
	Discomfort	Experiencing physical discomfort.	I experience physical discomfort because of my skin condition My skin condition is physically uncomfortable/intolerable/unbearable	… you feel physically uncomfortable/ you feel physical discomfort	you feel physical discomfort	you feel physical discomfort
	Disfigurement	Descriptions of altered appearance, particularly of the skin, nails or hair.	My skin condition makes me visibly different I am disfigured because of my condition My hair/skin/nails have defects because of my condition My skin/hair/nails looks different because of my condition	… your skin/hair/nails look visibly very different	your skin, hair or nails look visibly different	your skin, hair or nails look visibly different
	Fatigue or loss of energy	Describing tiredness, exhaustion, lack of energy or weakness, particularly if this isn't alleviated by sleep. (Loss of energy)	I feel tired/fatigued/exhausted/weak/lack energy because of my condition	… you feel tired/exhausted … you feel lack of energy/energyless (?)		

Item list | Conceptual framework & items | Existing measures info | +

Appendix 12: Item generation principles and how they informed the Delphi items

Simple	**Clear**
• Items were worded as simple and straightforward as possible to increase readability which in turn makes the survey quick and easy to complete and increased the likelihood of obtaining good data. • Items were designed so that they could be answered even by respondents who had not read the introductory paragraph as a certain percentage of participants will not read this. • Each item asked one question. Double-barrelled items that combine two different questions were avoided.	• Each item was worded to be specific enough to address the underlying construct and reduce the likelihood that respondents interpreted it differently while not being too specific. • Items were worded to be understood by the target population. This is a lay group who are likely to have more knowledge on dermatological conditions than the general population. Items were worded as simply as possible and technical terms and jargon were avoided to increase readability though some complex (dermatological instead of skin) or medical words (e.g. plaques) that this population were likely to understand were included.
Avoids biased language	**Uses a common structure**
• In the introduction to the survey, participants were reminded that not all items would be relevant to them and asked to "answer each statement based on what is **relevant to you**." This was intended both to pre-empt confusion arising from unexpected or irrelevant items and reduce the tendency for demand bias responses. • Emotional words and phrases are known to bias respondents' answers. Items were worded as neutrally as possible to get the most accurate results; however, this was challenging since many of the impacts identified were emotive.	• The same stem and response options were used for every item.

Appendix 13: First draft of PRIDD

Patient-Reported Impact of Dermatological Diseases

We know dermatological conditions impact people over a long period of time, but the aim of this questionnaire is to measure how much your dermatological condition has affected your life OVER THE LAST WEEK. Please mark one box for each question. If a statement does not apply to you, for example because you do not work, please mark "not relevant". NOTE: The term ‘skin’ here includes the mucous membrane.

Because of my dermatological condition…

		Never	Rarely	Sometimes	Often	Always	Not relevant
1	...the quality, look or feel of my skin/hair/nails has bothered me	◯	◯	◯	◯	◯	◯
2	…I have experienced physical discomfort, soreness or irritation	◯	◯	◯	◯	◯	◯
3	…my skin has been sensitive	◯	◯	◯	◯	◯	◯
4	…my sleep has been disturbed	◯	◯	◯	◯	◯	◯
5	…I have felt tired, fatigued or lacked energy	◯	◯	◯	◯	◯	◯
6	…my general health has been negatively affected	◯	◯	◯	◯	◯	◯
7	...my preferred daily routine has been negatively affected	◯	◯	◯	◯	◯	◯

8	…my treatment has caused problems (for example, by taking up time or being messy)	◯	◯	◯	◯	◯	◯
9	…my everyday choices have been affected (for example, choice of clothes, hair style or products)	◯	◯	◯	◯	◯	◯
10	…I have struggled to perform roles important to me (for example, to be caregiver / parent/ partner)	◯	◯	◯	◯	◯	◯
11	…my leisure time/activities have been negatively affected	◯	◯	◯	◯	◯	◯
12	…it has been hard to work or study	◯	◯	◯	◯	◯	◯
13	…I have had extra out-of-pocket expenses	◯	◯	◯	◯	◯	◯
14	…my life goals and choices have been affected	◯	◯	◯	◯	◯	◯
15	…I have felt anxious, worried or nervous	◯	◯	◯	◯	◯	◯
16	…I have been preoccupied with my skin, hair or nails	◯	◯	◯	◯	◯	◯
17	…I have felt down, blue or low in motivation	◯	◯	◯	◯	◯	◯
18	…I have felt angry, annoyed or frustrated	◯	◯	◯	◯	◯	◯
19	…I have felt like I've lost some control	◯	◯	◯	◯	◯	◯
20	…I have felt embarrassed	◯	◯	◯	◯	◯	◯
21	…I have felt unattractive	◯	◯	◯	◯	◯	◯
22	…I have felt dismissed or abandoned by others	◯	◯	◯	◯	◯	◯
23	…I have been focused on hiding, covering or concealing my condition	◯	◯	◯	◯	◯	◯

24	…my social life or interactions have been negatively affected	◯	◯	◯	◯	◯	◯
25	...my relationships with others have been negatively affected	◯	◯	◯	◯	◯	◯
26	…it has been difficult to be intimate with a partner	◯	◯	◯	◯	◯	◯
27	…I have been excluded, bullied or discriminated against	◯	◯	◯	◯	◯	◯

Please make sure you have answered every question clearly. Thank you for helping us understand and measure the impacts of your dermatological condition.

Appendix 14: Excerpt of the item mapping of first draft of PRIDD to existing measures identified in the systematic review using Microsoft Excel

PRIDD		Systematic review measures								
Domain	Item	DLQI	ACSD	DIS	DSQL	FLQA-d	PBI	SF-QES	Skindex-29	
Physical	...the quality, look and feel of my nails, skin, hair has bothered me				Feel more oily (3) 1. How often did the affected area(s) of your skin... Feel dryer than nonaffected areas How satisfied have you been with your skin	6 discharge from the skin 5 dry skin	4. ...be healed of all skin defects		27. My skin condition bleeds	
	...I have experienced physical discomfort, soreness or irritation	1. Over the last week, how itchy, sore, painful or stinging has your skin been?	38. Itching is a sign that I feel uncomfortable.		Cause burning sensation (6) How often did you experience intervals of discomfort? (8) Feel itchy (5) 2. Feel sore/tender Feel painful (4)	1 burning sensation of the skin 9 feeling of tightness in the skin 8 itching	3. ..no longer have burning sensations on your skin 1. be free of pain 2. be free of itching		1. My skin hurts 7. My skin condition burns or stings 19. My skin is irritated 10. My skin itches	(28) bu other ty (27) itc
	...my skin has been sensitive					13 tingling sensation on the skin			16. Water bothers my skin condition (bathing, washing hands)	
	...my sleep has been disturbed		prevents me from getting a good night's		cause you to lose sleep or sleep badly? (9)	4 sleeping problems	5. ..sleep better		2. My skin condition affects how well I sleep	(8) slee
	...I have felt tired, fatigued or lacked energy		32. I lack energy. 44. The itching makes me exhausted.			5 exhaustion 7 tiredness				(13) tir
	...my general health has been affected						effect			
						1 The treatment is a strain				

Appendix 15: Cognitive interview topic guide

Stage 1: Set-up (5 - 10 mins)

1. Briefly introduce self

Hi. Thank you for agreeing to take part in this interview. We really appreciate you giving your time. I'm [name]. I'm one of the researchers on the GRIDD project and I'm based at [affiliation] and I will be interviewing you today.

2. Overview of purpose and process of the cognitive interview

Ask participant whether they have done a cognitive interview before.

It's helpful to understand the context of the study and the purpose and process we'll be going through during the interview, before we start.

As you know, we developed a new questionnaire called PRIDD which will be used to collect global data on the impact of dermatological conditions. The measure will be used by adults with any dermatological condition, so we have designed the questionnaire and the questions so that they broad enough to be relevant across many dermatological conditions. During the interview, I'll send you a link and ask you to complete GRIDD in real-time. I'll then be asking your questions about different aspects of the questionnaire

It's important to know that we haven't just sat down and written these questions out. This is the end product of many, many discussions with people face-to-face individually and in small groups and an online survey with over one thousand people with over 90 dermatological conditions. So it's a distillation of a lot of information. Some of which we will have gotten right but some we won't have gotten right yet and that's why we're doing this next stage, interviewing you, because we think you can give us more information, more insight to help us understand further to make sure that we absolutely get it right.

We want to find out what's the best way we can answer each of the questions in PRIDD. So you and your responses to PRIDD won't be judged, the questions and the value of the questionnaire will be.

You might find some of the questions I ask a bit uncomfortable. The reason I'm asking is because I really want to get into what it's like for you living with this condition so we can represent that adequately on this questionnaire. You may even find that some make you feel a bit sad when you're recalling things that've happened. If that happens and you really don't want to talk about it, that's absolutely fine. It helps me to understand what you've taken away from the question, but if you really don't want to talk about it, that's fine. We'll just move on to the next question.

We won't go on for over an hour. There're 27 questions in PRIDD which is a lot to get through in an hour. I do really want to understand your response to these questions, but you may find that I ask you about the next question. This is because I don't want you to go beyond an hour because I'm aware that it's very tiring for me to keep asking you these questions.

Before we begin, are there any questions you'd like to ask me?

I am sending you the link to PRIDD in the chat section:

- [Link to PRIDD (original)]
- [Link to PRIDD (reversed)]

Once the screen has loaded please could you share your screen with me. But please don't start completing the questionnaire until I turn the recorder on.

Let participant know that we are beginning the interview and I will start recording.

Stage 2: Observation (5 - 10 mins)

Please start completing the questionnaire and let me know when you've finished.

Use timer to time how long it takes the participant to complete PRIDD.

Observe the respondent completing the questionnaire. Note facial expressions or indications of reading difficult. Listen for comments about difficulty reading or questions that indicate lack of clarity or ease of use.

Stage 3: Interview (30 - 50 mins)

A. General questions

- What did you think of the measure overall?
- Were any of the questions in any way offensive or objectionable to you?
- What did you think about the amount of time it took you to complete the questionnaire?
- What suggestions do you have for changing the questionnaire, so it is easier to complete?

B. Instructions questions (refers to intro paragraph starting 'We know dermatological conditions impact people over a long period of time')

- Can you tell me in your own words, what this instruction is asking you to do?
- Can you describe any confusion or difficulty you had in understanding these instructions?
- Are there any words or phrases that you would change to improve the instructions?

C. Recall period questions

- What period of time did you think about when you were completing the questionnaire?
- Does the time frame you were asked to think about when answering the questions allow you to easily answer the questions?
- When you completed the questionnaire, do you think you were able to accurately remember your experiences over the last two weeks?

D. Items questions

Ask the participant to go through the questionnaire and explain what each item means in their own words. Ask them to talk about what they thought about when they were answering the item and give a relevant example.

The participant may have already answered the item specific questions while completing the above exercise. If not, ask the following item specific questions.

Item specific questions

- Which of these questions do you think refers to the symptoms of your condition? (The answer we want is Item 1)
- Do you experience itch? If so, which of these questions do you think refers to itch? (The answer we want is Item 2)
- Item 4 When you say your sleep is being disturbed, are you finding it hard to go to sleep in the first place or do you find you wake up periodically during the night?
- Item 14 - (…my life goals and choices have been affected) – How well does this question work with the two-week recall period?
- Item 25 - (…it has been difficult to be intimate with a partner) - Is there a more acceptable way that we could word this item?

Composite items questions (items 1, 2, 5, 15, 17, 18)

- We've grouped them together, because we think they belong together. Otherwise, we'd have three separate questions. Which of those applies to you most?
- Do they fit together?

General prompts [No need to ask all of these]

- Using your own words, how would you explain what this question means?
- Is the question worded in a way that made sense to you?
- Was the question about something which is important or relevant to you?
- If you can, give me an example of when that question has applied to you.
- What do you think that question means? Can you put it in your own words?
- What was the key word in that question that meant something to you? Is that the correct word or do you think another word is more appropriate. What substitute word might you use for [key word]?
- This question seemed to be less straightforward than some of the others. Can you take me through that?
- You seemed to understand this question very easily. What was it about this question that you found easy to answer?

E. Response options questions

- I’m keen that we use the best scoring system. There isn’t one single way of scoring a response, but this is how we’ve decided to do it. I want you to tell me whether you found that easy or difficult and whether you have any advice for us about the scoring system.
- Do you understand the time differences between each option?
- What caused you to choose this response?

Stage 4: Ending (5 – 10mins)

We have now come to the end of our discussion.

Before we finish,

- Is there anything I forgot to ask?
- Is there anything else you would like to comment on regarding the survey?

Thank you all so much for taking the time to participate in this interview. Your opinions are very important in guiding the development of PRIDD and further research. You can track the progress of this research on GlobalSkin’s website where the research team will be posting updates.

Appendix 16: Item definition list (version 1)

Item no.	Item	Domain	Description
1	...the quality, look or feel of my skin/hair/nails has bothered me	Physical	This item is intended to capture how bothersome the physical symptoms of the patient's dermatological condition have been. It is worded broadly so that it applies across dermatological conditions, but patients should understand that this item relates also to their disease-specific symptoms. For example, we would expect that patients with psoriasis would think about their plaques when answering this item.
2	…I have experienced physical discomfort, soreness or irritation	Physical	This item is intended to assess the patient's degree of physical discomfort which includes pain and itch.
3	…my skin has been sensitive	Physical	This item assesses how sensitive the patient's skin has been. This may include sensitivity to touch, temperature or the sun.
4	…my sleep has been disturbed	Physical	This item assesses the extent to which their patient's dermatological condition has affected their sleep. This includes their sleep quality, duration, disturbances and onset.
5	…I have felt tired, fatigued or lacked energy	Physical	This item is intended to assess the degree to which the patient's dermatological condition negatively affects their energy levels.
6	…my general health has been negatively affected	Physical	This item is intended to assess the extent to which the patient's dermatological condition has affected their general health whether directly (e.g. treatment consequences and comorbidities) or indirectly (e.g. unhealthy coping strategies).
7	...my preferred daily routine has been negatively affected	Daily life and responsibilities	This item is intended to capture the extent to which the patient has had to change or adapt their daily routine to accommodate their dermatological condition. For example, the sun may dictate when a patient can leave their home.
8	…my treatment has caused problems, (for example, by taking up time or being messy)	Daily life and responsibilities	This item assesses the extent to which the patient's treatments affect their daily life. For example, by being time consuming, ruining possessions or resulting in extra cleaning chores.

Item no.	Item	Domain	Description
9	…my everyday choices have been affected (for example, choice of clothes, hair style or products)	Daily life and responsibilities	This item assesses the extent to which the patient's dermatological condition restricts their everyday choices. This may include how they chose to style themselves (e.g. choice of clothes, makeup and hair styles), the products they use and food or drink they consume.
10	…I have struggled to perform roles important to me, (for example, to be caregiver / parent/ partner)	Daily life and responsibilities	This item assesses the extent to which the patient's dermatological condition negatively affects their ability to perform their social or caring roles or responsibilities.
11	…my leisure time/activities have been negatively affected	Daily life and responsibilities	This item assesses the extent to which the patient's dermatological condition negatively affects their ability to engage in or enjoy their preferred leisure activities.
12	…it has been hard to work or study	Daily life and responsibilities	This item is intended to capture the extent to which the patient's dermatological condition has negatively affected their work or school life.
13	…I have had extra out-of-pocket expenses	Financial	This item assesses the financial impact of the patient's dermatological condition. This may include medical (e.g. consultations and prescriptions) or related non-medical expenses (e.g. products that cover or do not trigger their condition)
14	…my life goals and choices have been affected	Psychological	This item is intended to capture the cumulative life course impairment of the patient's dermatological condition or its impact of major life decisions such as choice of career or decision to have children.
15	…I have felt anxious, worried or nervous	Psychological	This item assesses the extent to which the patient's dermatological condition causes anxiety or related emotions
16	…I have been preoccupied with my skin, hair or nails	Psychological	This item is intended to capture the extent to which the patient is preoccupied by or obsesses or ruminates over their dermatological condition.
17	…I have felt down, blue or low in motivation	Psychological	This item assesses the extent to which the patient expresses depression or low mood as a result of their dermatological condition.
18	…I have felt angry, annoyed or frustrated	Psychological	This item assesses the extent to which the patient experiences anger, frustration or hostility as a result of their dermatological condition.

Item no.	Item	Domain	Description
19	…I have felt like I've lost some control	Psychological	This item assesses the extent to which the patient feels that they have lost control as a result of their condition. This may include feeling at the mercy of their condition or reliant on others.
20	…I have felt embarrassed	Psychological	This item assesses the extent to which the patient has felt embarrassed, ashamed, humiliated or self-conscious as a result of their dermatological condition.
21	…I have felt unattractive	Psychological	This item assesses the extent to which the patient has felt unattractive, low in confidence or 'disgusting' as a result of their dermatological condition.
22	…I have felt dismissed or abandoned by others	Psychological	This item assesses the extent to which the patient has felt dismissed or abandoned by others including healthcare professionals or the healthcare system more generally as a result of their dermatological condition.
23	…I have been focused on hiding, covering or concealing my condition	Psychological	This item assesses the extent to which the patient copes by hiding their dermatological condition.
24	…my social life or interactions have been negatively affected	Social	This item assesses the extent to which the patient's dermatological condition has negatively affected their social life.
25	...my relationships with others have been negatively affected	Social	This item assesses the extent to which the patient's dermatological condition has negatively affected their relationships with their close ones such as partners, friends or family.
26	…it has been difficult to be intimate with a partner	Social	This item assesses the extent to which the patient's dermatological condition negatively affects their sex life.
27	…I have been excluded, bullied or discriminated against	Social	This item assesses the extent to which the patient has been stigmatised or discriminated against as a result of their dermatological condition.

Appendix 17: PRIDD (version 2)

Patient-Reported Impact of Dermatological Disease

We know dermatological conditions impact people over a long period of time, but this questionnaire aims to measure how much your dermatological condition has affected your life **OVER THE LAST MONTH**. Please **consider each question in relation to your dermatological condition**. **Mark one box** for each question. We have provided examples to give you an idea of the things you might consider, but these should not limit your answers. Dermatological conditions can affect the skin, hair, nails and/or mucous membrane. The word 'skin' here includes any of these aspects relevant to your condition.

Because of my dermatological condition…

		Always	Often	Sometimes	Rarely	Never
1	…the quality, look or feel of my skin has bothered me	◯	◯	◯	◯	◯
2	…I have experienced physical discomfort, soreness or irritation	◯	◯	◯	◯	◯
3	…my skin has been sensitive to external factors (for example, to touch, light or temperature)	◯	◯	◯	◯	◯
4	…my sleep has been disturbed	◯	◯	◯	◯	◯
5	… I have felt tired, fatigued or lacked energy	◯	◯	◯	◯	◯
6	…my general physical health has been negatively affected	◯	◯	◯	◯	◯

7	…my treatment has caused practical problems (for example, by taking up time or being messy)	◯	◯	◯	◯	◯
8	…my preferred daily routine has been negatively affected	◯	◯	◯	◯	◯
9	…my leisure time (for example, hobbies, sports or exercise) has been negatively affected	◯	◯	◯	◯	◯
10	…my everyday choices have been affected (for example, choice of clothes, hairstyle or products)	◯	◯	◯	◯	◯
11	…my life goals and choices have been affected (for example, career choice or having children)	◯	◯	◯	◯	◯
12	…I have struggled to perform roles important to me (for example, to be caregiver / parent / partner / employee / student)	◯	◯	◯	◯	◯
13	…I have had extra medical and/or non-medical financial costs	◯	◯	◯	◯	◯
14	…I have felt anxious, worried or nervous	◯	◯	◯	◯	◯
15	…my condition has dominated my thoughts	◯	◯	◯	◯	◯
16	…I have felt depressed or low in mood	◯	◯	◯	◯	◯
17	…I have felt angry, annoyed or frustrated	◯	◯	◯	◯	◯
18	…I have felt shame or embarrassment	◯	◯	◯	◯	◯
19	…I have felt unattractive	◯	◯	◯	◯	◯
20	…I have been hiding, covering or concealing my condition	◯	◯	◯	◯	◯
21	…I have struggled to concentrate	◯	◯	◯	◯	◯

22	…I have felt like I've lost some control over my life	◯	◯	◯	◯	◯
23	…my social life or interactions have been negatively affected	◯	◯	◯	◯	◯
24	…my relationships with those close to me have been negatively affected	◯	◯	◯	◯	◯
25	…I have been prevented from or found it difficult to be intimate with another person	◯	◯	◯	◯	◯
26	…I have been excluded, stigmatised or discriminated against by others	◯	◯	◯	◯	◯

Please make sure you have answered every question. Thank you for helping us understand and measure the impacts of your dermatological condition.

Appendix 18: Evaluation of the quality of the cognitive interview study according to the COSMIN standards

COSMIN standard		Requirement	Rating	Details
14	Was a cognitive interview study or other pilot test conducted?	A cognitive interview study or other pilot test performed to test the PROM for comprehensibility and comprehensiveness	**Very good**	A cognitive interview study was conducted.
15	Was the cognitive interview study or other pilot test performed in a sample representing the target population?	Study performed in a sample representing the target population	**Very good**	Participants were drawn from PRIDD's target population. Purposive sampling was employed to achieve a sample with maximum variation according to participants' dermatological condition and demographic factors (e.g. age, gender, and country of residence). Table 26 demonstrates that the sample represented the target population.
16	Were patients asked about the comprehensibility of the PROM?	Patients asked about the PROM instructions, items, response options, and recall period	**Very good**	Participants were asked about the comprehensibility of PRIDD's instructions, items, response options, and recall period.

COSMIN standard		Requirement	Rating	Details
17	Were all items tested in their final form?	All items were tested in their final form	**Very good**	All items were tested in their final form. No edits were made to PRIDD during the fourth and final round of interviews Table 27.
18	Was an appropriate qualitative method used to assess the comprehensibility of the PROM instructions, items, response options, and recall period?	Widely recognised or well justified qualitative method used	**Very good**	The Three-Step Test-Interview method was employed to test the comprehensibility of PRIDD's instructions, items, response options, and recall period separately (see Appendix 15).
19	Was each item tested in an appropriate number of patients?	≥7 patients	**Very good**	Each item was tested by 12 participants.
20	Were skilled interviewers used?	Skilled group moderators/interviewers used	**Very good**	All interviews were conducted by a skilled interviewer (RP, RH or ML). All interviewers had experience in conducting dermatological and qualitative research and were trained in cognitive interviewing techniques.

COSMIN standard		Requirement	Rating	Details
21	Were the interviews based on an appropriate interview guide?	Appropriate topic or interview guide	**Very good**	A topic guide, including the semi-structured interview guide, was developed to structure interviews (Appendix 15). The interview questions were developed based on ISPOR and other guidance. The guide was continually adapted to reflect refinements made to PRIDD or new topics or themes that needed further probing.
22	Were the interviews recorded and transcribed verbatim?	All group meetings or interviews were recorded and transcribed verbatim	**Very good**	Each interview was recorded using a Dictaphone. Audio data were subsequently transcribed verbatim by a Cardiff University approved independent transcription provider. During the observation step of the interviews, interviewers made notes on facial expressions or comments.
23	Was an appropriate approach used to analyse the data?	A widely recognized or well justified approach was used	**Very good**	Analysis followed the thematic analytical model of cognitive interviewing.
24	Were at least two researchers involved in the analysis?	At least two researchers involved in the analysis	**Very good**	Two researchers (RP and NTS) were involved in the data analysis. RP independently coded the

COSMIN standard		Requirement	Rating	Details
				data. The analysis was checked by NTS and issues were discussed and resolved.
25	Were problems regarding the comprehensibility of the PROM instructions, items, response options, and recall period appropriately addressed by adapting the PROM?	No problems found or problems appropriately addressed, and PROM was adapted and re-tested if necessary	**Very good**	After each round of interviews, PRIDD was adapted to address problems found and re-tested in the next round of interviews.
26	Were patients asked about the comprehensiveness of the PROM?	Patients asked whether the items together comprehensively cover the construct the PROM (or subscale) intends to measure.	**Very good**	Patients were asked whether the items together comprehensively cover the impact of dermatological conditions.
27	Was the final set of items tested?	The final set of items was tested	**Very good**	All items were tested in their final form. No edits were made to PRIDD during the fourth and final round of interviews Table 27.
28	Was an appropriate method used for assessing the comprehensiveness of the PROM?	Widely recognised or well justified method used	**Very good**	The Three-Step Test-Interview method was employed to test PRIDD's comprehensiveness (see Appendix 15).

COSMIN standard		Requirement	Rating	Details
29	Was each item tested in an appropriate number of patients?	≥7 patients	**Very good**	Each item was tested by 12 participants.
30	Were skilled interviewers used?	Skilled interviewers used	**Very good**	All interviews were conducted by a skilled interviewer (RP, RH or ML). All interviewers had experience in conducting dermatological and qualitative research and were trained in cognitive interviewing techniques.
31	Were the interviews based on an appropriate interview guide?	Appropriate topic or interview guide	**Very good**	A topic guide, including the semi-structured interview guide, was developed to structure interviews (Appendix 15). The interview questions were developed based on ISPOR and other guidance. The guide was continually adapted to reflect refinements made to PRIDD or new topics or themes that needed further probing.
32	Were the interviews recorded and transcribed verbatim?	All group meetings or interviews were recorded and transcribed verbatim	**Very good**	Each interview was recorded using a Dictaphone. Audio data were subsequently transcribed verbatim by a Cardiff University approved independent transcription provider. During the

COSMIN standard		Requirement	Rating	Details
				observation step of the interviews, interviewers made notes on facial expressions or comments.
33	Was an appropriate approach used to analyse the data?	A widely recognised or well justified approach was used	**Very good**	Analysis followed the thematic analytical model of cognitive interviewing.
34	Were at least two researchers involved in the analysis?	At least two researchers involved in the analysis	**Very good**	All items were tested in their final form. No edits were made to PRIDD during the fourth and final round of interviews Table 27.
35	Were problems regarding the comprehensiveness of the PROM appropriately addressed by adapting the PROM?	No problems found or problems appropriately addressed, and PROM was adapted and re-tested if necessary	**Very good**	After each round of interviews, PRIDD was adapted to address problems found and re-tested in the next round of interviews.
		Overall score	**Very good**	

Appendix 19: Item definition list (version 2)

Item no.	Item	Domain	Description
1	…the quality, look or feel of my skin has bothered me	Physical	This item is intended to capture how bothersome the physical symptoms of the patient's dermatological condition have been. It is worded broadly so that it applies across dermatological conditions, but patients should understand that this item relates also to their disease-specific symptoms. For example, we would expect that patients with psoriasis would think about their plaques when answering this item.
2	…I have experienced physical discomfort, soreness or irritation	Physical	This item is intended to assess the patient's degree of physical discomfort which includes pain and itch.
3	…my skin has been sensitive to external factors (for example, to touch, light or temperature)	Physical	This item assesses how sensitive the patient's skin has been to external stimuli. This should not include pain or itch captured in item 2.
4	…my sleep has been disturbed	Physical	This item assesses the extent to which their patient's dermatological condition has affected their sleep. This includes their sleep quality, duration, disturbances and onset.
5	…I have felt tired, fatigued or lacked energy	Physical	This item is intended to assess the degree to which the patient's dermatological condition negatively affects their energy levels.
6	…my general physical health has been negatively affected	Physical	This item is intended to assess the extent to which the patient's dermatological condition has affected their general physical health whether directly (e.g. treatment consequences and comorbidities) or indirectly (e.g. unhealthy coping strategies). This should not include mental health which is assessed via other items.

Item no.	Item	Domain	Description
7	…my treatment has caused practical problems (for example, by taking up time or being messy)	Daily life and responsibilities	This item assesses the extent to which the patient's treatments affect their daily life. For example, by being time consuming, ruining possessions or resulting in extra cleaning chores.
8	...my preferred daily routine has been negatively affected	Daily life and responsibilities	This item is intended to capture the extent to which the patient has had to change or adapt their daily routine to accommodate their dermatological condition. For example, the sun may dictate when a patient can leave their home.
9	…my leisure time (for example, hobbies, sports or exercise) has been negatively affected	Daily life and responsibilities	This item assesses the extent to which the patient's dermatological condition negatively affects their ability to engage in or enjoy their preferred leisure activities.
10	…my everyday choices have been affected (for example, choice of clothes, hair style or products)	Daily life and responsibilities	This item assesses the extent to which the patient's dermatological condition restricts their everyday choices. This may include how they chose to style themselves (e.g. choice of clothes, makeup and hair styles), the products they use and food or drink they consume.
11	…my life goals and choices have been affected (for example, career choice or having children)	Daily life and responsibilities	This item is intended to capture the cumulative life course impairment of the patient's dermatological condition or its impact of major life decisions such as choice of career or decision to have children.
12	…I have struggled to perform roles important to me (for example, to be caregiver / parent / partner / employee / student)	Daily life and responsibilities	This item assesses the extent to which the patient's dermatological condition negatively affects their ability to perform their social or caring roles or responsibilities. Overall, their ability to function in society.
13	…I have had extra medical or non-medical financial costs	Financial	This item assesses the financial impact of the patient's dermatological condition. This may include medical (e.g. consultations and

Item no.	Item	Domain	Description
			prescriptions) or related non-medical expenses (e.g. products that cover or do not trigger their condition).
14	……I have felt anxious, worried or nervous	Psychological	This item assesses the extent to which the patient's dermatological condition causes anxiety or related emotions
15	…my condition has dominated my thoughts	Psychological	This item is intended to capture the extent to which the patient is preoccupied by or obsesses or ruminates over their dermatological condition. For example, overly focused on their condition, checking in the mirror.
16	…I have felt depressed or low in mood	Psychological	This item assesses the extent to which the patient expresses depression or low mood as a result of their dermatological condition.
17	…I have felt angry, annoyed or frustrated	Psychological	This item assesses the extent to which the patient experiences anger, frustration or hostility as a result of their dermatological condition.
18	…I have felt shame or embarrassment	Psychological	This item assesses the extent to which the patient has felt embarrassed, ashamed, humiliated or self-conscious as a result of their dermatological condition.
19	…I have felt unattractive	Psychological	This item assesses the extent to which the patient has felt unattractive, low in confidence or 'disgusting' as a result of their dermatological condition.
20	…I have been focused on hiding, covering or concealing my condition	Psychological	This item assesses the extent to which the patient copes by hiding their dermatological condition.

Item no.	Item	Domain	Description
21	…I have struggled to concentrate	Psychological	This item is intended to capture the extent to which the patient's dermatological condition has negatively affected their ability to concentrate.
22	…I have felt like I've lost some control over my life	Psychological	This item assesses the extent to which the patient feels that they have lost control as a result of their condition. This may include feeling at the mercy of their condition or reliant on others.
23	…my social life or interactions have been negatively affected	Social	This item assesses the extent to which the patient's dermatological condition has negatively affected their social life.
24	…my relationships with those close to me have been negatively affected	Social	This item assesses the extent to which the patient's dermatological condition has negatively affected their relationships with their close ones such as partners, friends or family.
25	…I have been prevented from or found it difficult to be intimate with another person	Social	This item assesses the extent to which the patient's dermatological condition negatively affects their sex life.
26	…I have been excluded, bullied or discriminated against	Social	This item assesses the extent to which the patient has been stigmatised or discriminated against as a result of their dermatological condition. Overall, other people's reactions to the condition.