School of Psychology
Ysgol Seicoleg

An Investigation into Positive Behavioural Support and Quality of Life

Thesis submitted in partial fulfilment of the requirement for the degree of:

Doctorate of Clinical Psychology (DClinPsy)

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Cardiff University

Amber Simler

Supervised by: Dr Christopher Hartwright & Dr Bronwen Davies

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Thesis Abstract

This thesis is submitted in partial fulfilment of the requirement for the degree of Doctorate of Clinical Psychology (DClinPsy). It is a portfolio thesis and as such consists of three separate papers. The first paper is a systematic review that aimed to examine whether Positive Behavioural Support (PBS) is effective for adult service users. The second paper is an empirical research study in which the validity of the English version of the Forensic Quality of Life Questionnaire - Short Version was explored using a cross-sectional qualitative research design. The third and final paper is a critical evaluation of both the systematic review and the empirical research study. The systematic review and empirical research study have been prepared in accordance with the author guidelines of a targeted journal for publication.

How Effective is Positive Behavioural Support for Adult Service Users?

A Systematic Review

Amber Simler, Dr Bronwen Davies and Dr Christopher Hartwright

School of Psychology, Cardiff University

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This systematic review has been prepared for submission to *Clinical Psychology Review* (please see Appendix 1 for further author guidance).

Abstract

Positive Behavioural Support (PBS) is purported to be an evidence-based approach to support individuals whose behaviour challenges those around them. A systematic review was undertaken that aimed to examine whether PBS is effective for adult service users based on the stated aims of PBS: improving challenging behaviour, enhancing quality of life, teaching adaptive skills, and reducing the use of restrictive practices. Searches for peer-reviewed, quantitative outcome studies were conducted across five databases. After inclusion and exclusion criteria were applied, 15 studies were retained for review. The quality of studies was assessed using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD; Sirriyeh, Lawton, Gardner, & Armitage, 2011). The majority of the studies (73.33%) were assessed to be of 'low' quality based on a score of <50% on the QATSDD. Whilst there is some 'high' quality evidence to suggest that PBS is effective at improving challenging behaviour up to 6-months follow-up, there is little empirical basis to suggest that PBS is effective at improving challenging behaviour beyond this. Overall, there is insufficient high-quality empirical evidence to suggest that PBS is effective at: enhancing quality of life, teaching adaptive skills, or reducing the use of restrictive practices. More research of high methodological quality that examines large samples with diverse clinical presentations over long periods of time is required before the effectiveness of PBS can be established empirically.

Keywords: behaviour, Positive Behavioural Support, PBS, outcomes, effectiveness

Introduction

Society may term an individual's behaviour as 'challenging' if it puts them or others around them at risk of harm or limits them from opportunities that enhance their quality of life (Emerson & Bromley, 1995). The costs of 'challenging behaviour' to individuals, their families, health and social care services can be extremely high. Data from a review of case files from 19 Local Authority commissioning teams and 18 associated NHS Trusts in the UK found that the majority of adults with intellectual disabilities (ID), complex needs and challenging behaviour were placed in residential care, on average 79 miles away from home and at a mean cost of £200,000 per annum (Deveau, McGill, & Poynter, 2015). Challenging behaviour is a risk factor for placement breakdown (Phillips & Rose, 2010). Johnson (2012) examined incidents in a secure forensic mental health service for adults with ID and found that most staff injuries occurred as a direct consequence of challenging behaviour or subsequent physical intervention.

According to Emerson et al. (2001), challenging behaviour functions as an attempt by an individual to serve their unmet need(s). Hastings et al. (2013) extended this definition through the development of a conceptual framework for understanding why challenging behaviour occurs in individuals with ID. Challenging behaviour may be best understood as a product of a complex interplay of intrapersonal (psychological, biological) and contextual (social, environmental) factors (Royal College of Psychiatrists, British Psychological Society & Royal College of Speech and Language Therapists, 2007).

Recognition that challenging behaviour develops to serve important functions for individuals corresponds with the 'aversives' debate in the late 1980s and early 1990s. The use of aversive approaches was criticised for being dehumanising and unethical (Horner et al., 1990). Following a decline in the use of aversive approaches, behaviourist approaches that seek to understand the function of challenging behaviour in context have steadily gained

traction, particularly over the last three decades. Examples include Applied Behaviour Analysis (ABA; Lovaas, Koegel, Simmons, & Long, 1973) functional analysis (O'Neill, Horner, Albin, Storey, & Sprague, 1990) and, more recently, Positive Behavioural Support (PBS; Horner et al., 1990). The latter is of particular significance as interest in PBS continues to grow exponentially. PBS is recommended in national guidance for application across multiple service contexts with various clinical populations who are at risk of being exposed to restrictive practices including "people with mental health conditions, autistic spectrum conditions, learning disability, dementia and/ or personality disorder, older people and detained patients" (Department of Health, 2014a, p.12).

Carr et al. (2002) defined PBS as "an applied science that uses educational methods to expand an individual's behaviour repertoire and systems change methods to redesign an individual's living environment to first enhance the individual's quality of life and, second, to minimize his or her problem behaviour" (p. 4). Gore et al. (2013) later explicated the definition and scope of PBS for a UK context. Three key components were identified: the values base of the 'inclusion movement' (O'Brien, 1987); the application of ABA and other evidence-based interventions to support behaviour change; and the data-driven process to support, monitor, and evaluate multi-component intervention over time. Neither component is sufficient in isolation. Utilising all three components together is necessary for an intervention to constitute PBS (Gore et al., 2013).

PBS is widely regarded as an effective (LaVigna & Willis, 2012; MacDonald, McGill, & Murphy, 2018) and an evidence-based approach (Allen et al., 2011a; British Institute of Learning Disabilities, 2016; Scior, Jackson Brown, Gore, Morris, & Armstrong, 2017). Although originally developed for individuals with ID, PBS has since been used to support individuals with diverse clinical presentations whose behaviour presents a challenge to services. Examples include individuals with brain injuries (Arco & Bishop, 2009), mental

health difficulties (Toogood, 2017), mental health difficulties and forensic histories (Davies, Lowe, Morgan, John-Evans, & Fitoussi, 2018), and dementia (McGill, 2013). In the USA, PBS has been applied to general educational settings for children who are otherwise at risk of exposure to punitive or restrictive approaches to behaviour management (Sugai & Horner, 2006).

According to the Department of Health (2014a), restrictive practices are "deliberate acts on the part of other person(s) that restrict an individual's movement, liberty and/ or freedom to act independently" (p.14). Examples of restrictive practices include physical and mechanical restraint, seclusion, and misuse of medication. Several UK policies advocate the use of PBS across varied health and social care settings to reduce the use of restrictive practices (Department of Health, 2014a; Department of Health, 2014b; Department of Health, 2014c). The Royal College of Psychiatrists and the British Psychological Society recently issued guidance endorsing PBS as an evidence-based approach to practitioners and service commissioners (Royal College of Psychiatrists & British Psychological Society, 2016). As PBS featured in 38 Transforming Care Partnership plans across England in 2017 (Denne, 2017), this appears to have had a substantial impact.

Despite its growing presence and recognition in UK health policy, there are no recent published systematic reviews of the effectiveness of PBS for individual service users. Related reviews have been published, including a literature review of the efficacy of PBS with severe and high rate challenging behaviour (Lavigna & Willis, 2012) and a systematic review of outcomes of staff training in PBS (MacDonald & McGill, 2013). Neither of these reviews, however, evaluated the rigour of the published literature included.

The efficacy of PBS has been the subject of two book chapters. Firstly, Carr et al. (1999) published a narrative synthesis of the research literature on PBS between 1985 to 1996. Secondly, Marquis et al. (2000) used the same database of research literature as Carr et

al. (1999) to produce a meta-analysis using quantitative measures. Neither review appears to have been updated. Given that both of these publications contain studies that are at least 23 years old, a contemporaneous systematic review is considered timely.

More recent reviews have been published on the efficacy of general behavioural approaches for challenging behaviour. Didden, Korzilius, van Oorsouw and Sturmey (2006) found meta-analytic evidence that behavioural interventions for challenging behaviour are effective for adults with mild ID. The extent to which PBS is any different from ABA and other general behavioural approaches has been the topic of much debate (see Johnston, Foxx, Jacobson, Green, & Mulick, 2006 for an overview). Johnston et al. (2006) stated that there is no basis for asserting that PBS is a new science distinct from ABA as it does not address any new phenomena or subject matter. LaVigna and Willis (2012) appear to have agreed with Johnston et al. (2006) and declared that PBS is fundamentally an application of ABA. In contrast, Carr et al. (2002) asserted that PBS is different from ABA because it blends behaviour analysis with systems analysis, ecological psychology, environmental psychology, and community psychology. Knoster, Anderson, Carr, Dunlap and Horner (2003) went further to describe PBS as an entirely unique approach that has evolved from ABA. Notwithstanding this debate, there is cause to evaluate the efficacy of PBS in its own right. After all, it is PBS and not general behavioural approaches that is explicitly endorsed in UK policy. It is specifically PBS services that are being commissioned and developed in the UK. A systematic review of service user outcomes that assessed the rigour of published studies would bridge an apparent gap in the literature. It was considered that this would be particularly timely given that PBS is increasingly being used with diverse clinical presentations, across a range of settings.

In summary, the need for an objective and comprehensive review of the evidence for PBS with adult service users was identified due to the personal and financial costs of

challenging behaviour and the UK health policy directive to implement PBS in the context of there being no recent systematic review that quality-appraised the published literature.

Aims and Objectives

The overall review question is: how effective is PBS for adult service users? The aim of this review was to locate and critically examine the available empirical evidence in order to address the aforementioned review question. There are considerable differences in how PBS is implemented across adult and child contexts (Buschbacher & Fox, 2003). Therefore, to enhance the specificity of this review, the decision was taken to focus exclusively on adult service users.

Gore et al. (2013) outlined a number of desirable outcomes for service users whilst providing the definition and scope for PBS. In order to fulfil the aim of the review, effectiveness was considered in respect of each of the following outcomes for service users:

1. Does PBS lead to improvements in challenging behaviour?
2. Does PBS lead to enhancements to quality of life?
3. Does PBS reduce the extent to which restrictive practices are used?
4. Does PBS lead to the enhancement of adaptive skills?

Addressing each of the questions above, it was anticipated that this review would be of relevance to service users, their families, clinicians, and commissioners alike.

Methodology

Search Strategy

The databases EMBASE, MEDLINE, PsycINFO, Web of Science, and Cochrane Library were searched on the 9th December 2018. “Positive Behavio* Support” was used as

both a keyword and topic to search across all five databases. Searches were limited to peer-reviewed journals published in the English language.

Alongside the two existing review papers (LaVigna & Willis, 2012; MacDonald & McGill, 2013), references within the studies identified for inclusion were screened in order to identify any further appropriate studies. Leading authors in the field of PBS were also contacted by email to request any further studies that might be appropriate for inclusion.

Eligibility Criteria

A number of inclusion and exclusion criteria were used to guide the selection of studies relevant to this review. MacDonald and McGill (2013) in their systematic review of staff training in PBS recognised that a degree of controversy exists over what exactly constitutes PBS. Therefore, MacDonald and McGill (2013) only included studies that self-identified as PBS. Hence, in this review, studies were only eligible for inclusion if they self-identified as PBS and met the following inclusion criteria:

1. Participants were adults over the age of 18.
2. PBS was individualised, based upon a functional assessment of behaviour.
3. At least one of the following service user outcomes were reported: challenging behaviour, quality of life, restrictive practices, and skills enhancement.
4. Quantitative outcomes are reported.

According to Gore et al. (2013), PBS may be implemented in multiple ways. Therefore, providing that PBS was individualised (in other words, intervention constituted a personalised PBS plan based upon a functional assessment of an individual's behaviour), there were no further exclusions on the format through which it was delivered. This meant that PBS studies were appropriate for inclusion provided they included implementation of individualised PBS by either: a single practitioner; a staff team trained to produce an

individualised PBS plan based upon a functional assessment of an individual's behaviour; a whole system wherein staff produce individualised PBS plans based on a functional assessment of an individual's behaviour as part of the service delivery model.

Studies that reported outcomes for both adult and child participants were considered appropriate for inclusion only if the data for adults was clearly differentiable and therefore extractable. Studies that only reported on outcomes for staff were excluded. Studies that erroneously self-identified as PBS, for example, those with only a single component intervention, were also excluded.

Selection of Studies

Figure 1 illustrates the full process for selecting studies within the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram (PRISMA; Moher, Liberati, Tetzlaff, & Altman, 2009).

The titles and abstracts of all records identified through searching all five databases were screened for eligibility by the first author (AS) and second author (BD). The full-text articles of those identified as potentially eligible for inclusion were obtained and considered against the inclusion and exclusion criteria. Assessment of eligibility for inclusion was done by both the first and second author. Through discussion, an agreement of 100% was reached between the first and second authors. This suggests a high level of agreement between authors. Had any discrepancies arisen, they would have been discussed with the third author (CH) to reach a consensus.

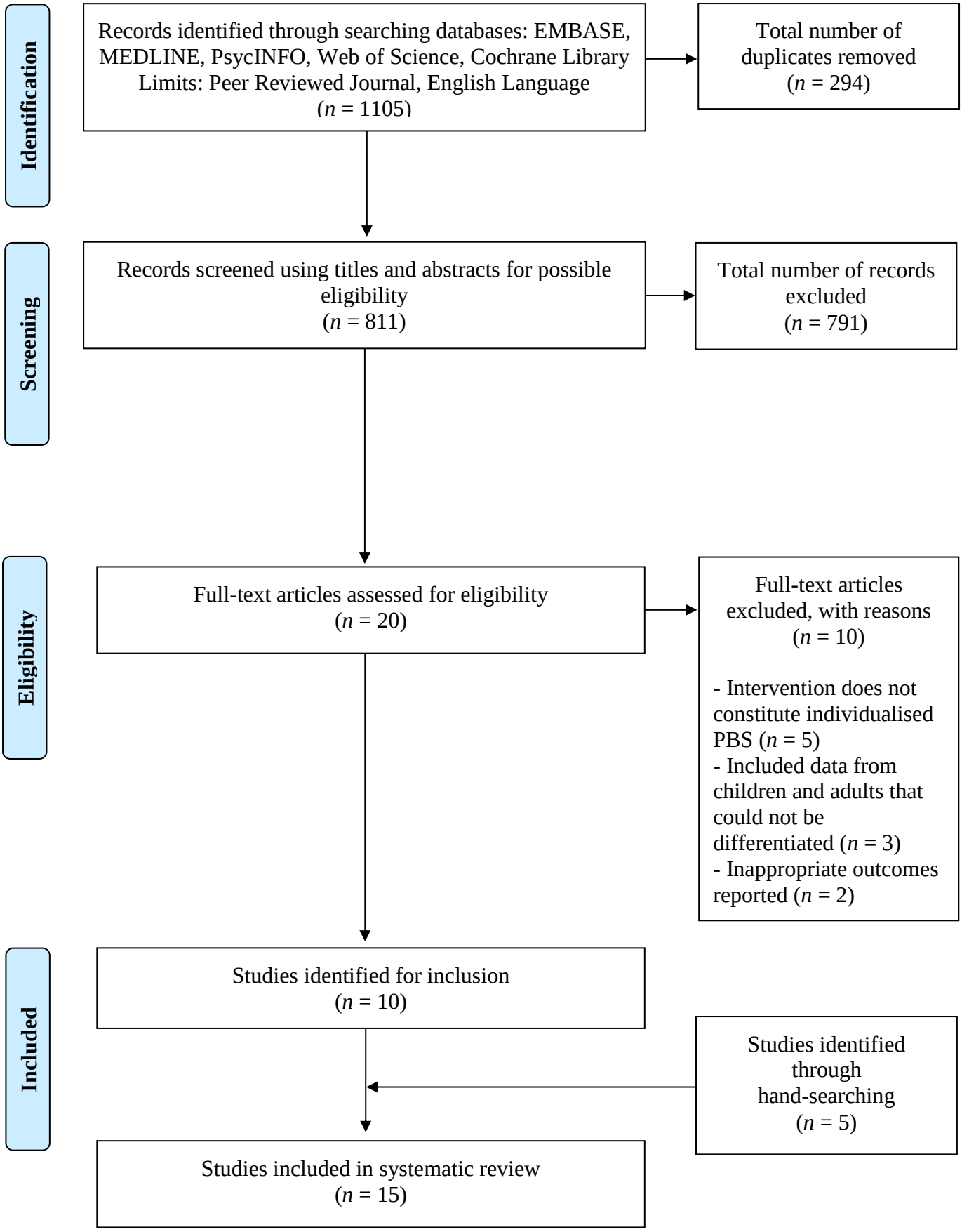

Figure 1. PRISMA flow chart illustrating study selection

Results

A summary of the characteristics of the included studies can be found in Table 1. Fifteen studies were identified for inclusion.

Study Setting

The majority of the studies were undertaken in the UK (*n* = 9). Studies were undertaken across a range of community and inpatient ID services as well as a medium secure forensic mental health service. The remaining studies were undertaken across day centre and residential ID services in Ireland (*n* = 3), community and day centre ID services in the USA (*n* = 2), and in a service user's home in Australia (*n* = 1).

Study Design

All studies were longitudinal. Two of the 15 studies used a randomised control trial design. Three studies used a non-randomised control group design and a further three studies used a repeated measures within-subjects design. Six of the remaining seven studies were case series (either single-case or small-*n* design), which made this the most commonly employed study design. The remaining study used an organisational case study design.

Sample Characteristics

Across the 15 studies, a total of *n* = 663 adult participants were studied, including those in control groups. Of these, a total of *n* = 434 participants received a PBS intervention. The size of the sample of interest (that is, adult participants who received a form of PBS intervention) varied between *n* = 1 to *n* = 108. In 13 of the 15 studies, the sample of interest consisted of participants with ID and/ or developmental disorders/ disabilities with/ without comorbid mental and/ or physical health difficulties (*n* = 416). In one of the remaining two

studies, the sample of interest consisted of participants with mental health diagnoses in secure services (*n* = 17) and the other consisted of a participant with acquired brain injury (*n* = 1). All participants (*n* = 663) were considered to exhibit challenging behaviour. Forms of challenging behaviour were classifiable according to the measurement tool used and included: psychiatric and behavioural disturbance (*n* = 297), violence and aggression (*n* = 95), self-injurious behaviour (*n* = 27), non-compliance (*n* = 11), and challenging behaviour not otherwise specified (*n* = 4). Many participants exhibited more than one of these forms of challenging behaviour.

Mode of PBS Intervention

Direct intervention by a single practitioner or trained family member was the most common mode of PBS and featured in eight of the 15 studies. Four of the remaining seven studies involved staff training in PBS (whereby a team of staff were trained to produce and implement an individualised PBS plan based upon a functional assessment of a service user's behaviour). The remaining three studies involved the implementation of PBS at an organisational level (whereby staff produced individualised PBS plans for all service users based on a functional assessment of each service user's behaviour as part of the service delivery model).

Variable Measured

A variety of service user outcomes were reported, which included: challenging behaviour, quality of life, adaptive skills, and the use of restrictive practices.

With respect to challenging behaviour, this was measured in a variety of ways including through the use of behaviour recordings and psychometric instruments such as the Checklist of Challenging Behaviour (CBC; Harris, Humphreys, & Thomson, 1994) as well as

through the use of incident reports completed by staff. Quality of life was either measured using behaviour recordings or through psychometric instruments such as the Guernsey Community Participation and Leisure Assessment (GCPLA; Baker, 2000). Restrictive practices were measured either through the use of physical interventions or the amount of medication dispensed. Adaptive skills were measured using behaviour recordings.

Challenging behaviour was the variable measured most frequently in 12 out of 15 studies. Seven of the 12 studies measured challenging behaviour exclusively, whereas four studies measured challenging behaviour and quality of life. One study measured challenging behaviour, quality of life, and the use of restrictive practices. Of the three remaining studies that did not measure challenging behaviour, two measured skills enhancement and one measured the use of restrictive practices.

Table 1.
Characteristics of Studies Included in the Systematic Review

Study	**Setting; Country**	**Aim(s)**	**Study Design**	**Total Sample Size (*N*); Subsample Size (*n*)***	**Sample Characteristics**	**Mode of Intervention**	**Variable Measured; Outcome Measured (including Outcome Measurement Tool, as applicable)**
Allen et al. (2011b)	Specialist PBS service for adults with ID; South Wales, UK	To test the proposition that the adoption of PBS at an organisational level might reduce the use of restrictive practices.	Non-experimental; Observational study; Organisational case study	The study reports on the 24 and 40 long-stay adult beds over a seven-year period. Figures were averaged by bed space, that is, the total figure was abstracted for each measure, month on month, and then divided by 64.	Adults with ID and complex, challenging behaviour and/ or mental health needs.	Service-wide PBS. A clear, evidence-based reactive management model was in place and all service users had an individualised PBS plan that contained proactive and reactive strategies.	Restrictive practices; Measured total frequency (*M*) of the use of physical interventions for the service (1, self-defensive 'breakaway' techniques; 2, temporary holds for removing a person from one location to another; 3, restrictive seated or supine restraint) using a bespoke measurement tool, '…a standard pro forma that listed the types of physical interventions'.
Arco and Bishop (2009)	In-home, parent-implemented PBS; Perth, Australia	To report on single participant studies on parent-implemented PBS for sons and daughters (children or adult) who had sustained a brain injury.	Case series; Multiple baseline design single case study	*N* = 3; *n* = 1 (The sample consisted of 1 adult and 2 children all of whom received PBS)	Adult male (aged 43 years) with an acquired brain injury and subsequent difficulties with challenging behaviour by way of poor initiative and motivation for completing certain daily routines.	Parent-implemented PBS. An individualised, multicomponent PBS plan based upon functional analysis of behaviour.	Skills enhancement; Measured total frequency (*M*) of independent behaviour across target routines using behaviour recording sheets and self-recording sheets for the participant.
Baker (1998)	Residential and vocational support agency; USA	To report on the direct and indirect outcomes of non-directive training/ consultation to teams of managerial and direct care staff on positive behavioural support strategies in order to evaluate the	Repeated measures within subjects design; pre- and post-	*n* = 5 (The sample consisted of 5 adults all of whom received PBS)	Adults (aged 28 - 69 years) with moderate to profound ID (with/ without ASD, cerebral palsy, visual impairment) and challenging behaviour.	Staff training in PBS. Staff were given three training sessions that lasted three hours each. Content included completing a functional assessment of challenging behaviour, developing a behaviour support plan, teaching skills	Challenging behaviour; Measured the frequency of challenging behaviour using incident reports completed by staff pre- and post-training.

		effectiveness of the training/ consultation.				enhancement, maintenance and evaluation of behaviour support plans for service users (*n* = 5).	
Bird and Luiselli (2000)	Behavioural healthcare centre for children and adults with developmental disabilities and severe behaviour disorders; Massachusetts, USA	To describe five adults with developmental disabilities who had been exposed to multiple, aversive treatments in a previous service setting and who subsequently were discharged to an alternative habilitation program in which the former interventions were discontinued in favour of PBS.	Uncontrolled longitudinal study; Case series	*n* = 5 (The sample consisted of 5 adults all of whom received PBS)	Adult males (aged 24 - 34 years) with developmental disabilities (with/ without OCD, ASD, BPD, Tourette's disorder, bipolar disorder, depression) and challenging behaviour.	Direct PBS intervention. An individualised, multicomponent PBS plan based upon a functional analysis of behaviour.	Challenging behaviour; Measured the frequency of target challenging behaviour at pre-discharge, transition, 6-month, 12-month, and 24-month intervals using SPR.
Davies et al. (2018)	Medium secure forensic mental health service; South Wales, UK	To evaluate the effectiveness of PBS in reducing the frequency, management difficulty, and severity of challenging behaviour within a forensic mental health context and to assess the longer-term impact of PBS over a period of one year.	Non-randomised control group design (PBS vs. TAU)	*N* = 34; *n* = 17 (The sample consisted of 34 adults, 17 of whom received PBS and the remainder of whom received TAU)	Adult males (88%) and female (12%) service users (*M* age = 35 years) with mental health diagnoses (with/ without BPD, ASPD, bipolar disorder, depression, schizophrenia, schizoaffective disorder) and challenging behaviour.	Direct PBS intervention. An individualised, multicomponent PBS plan based upon a functional analysis of behaviour.	Challenging behaviour; Measured the frequency, management difficulty, and severity of challenging behaviour at baseline, 3-month, 6-month, 9-month, and 12-month intervals using the CBC.
Gray et al. (2013)	Acute assessment and treatment service for adults with ID; South Wales, UK	To describe the service user outcomes of an acute assessment and treatment service in South Wales that has adopted PBS at an organisational level.	Repeated measures within-subject design; pre- and post-	*n* = 75 (The sample consisted of 75 adults all of whom received PBS)	Adult male (53%) and female (47%) service users with developmental disabilities (with/ without an ID, ASD, mental health condition, specific behavioural phenotype) admitted to the unit (*M* length of stay = 140 days) with/	Service-wide PBS. A clear, evidence-based reactive management model was in place and all service users had an individualised PBS plan that contained proactive and reactive strategies.	Challenging behaviour; Measured the degree of challenging behaviour pre- and post-admission using the ABC.

					without formal detention under the Mental Health Act (33% and 67%, respectively).		
Hassiotis et al. (2009)	Specialist behaviour therapy service for adults with ID; South Essex, UK	To test the hypothesis that the use of applied behaviour analysis and PBS via the specialist behaviour therapy team, in combination with standard treatment, was more effective than standard treatment alone in reducing challenging behaviour and costs.	Randomised controlled trial design (PBS vs. TAU)	*N* = 63; *n* = 32 (The sample consisted of 63 adults, 32 of whom received PBS and the remainder of whom received TAU)	Adult male (59.4%) and female (40.6%) service users (93.8% Caucasian, 6.2% other) with an ID (with/ without sensory impairment, communication impairment, epilepsy, other health problems, mental health difficulties) and challenging behaviour.	Direct PBS intervention. An individualised, multicomponent PBS plan based upon a functional analysis of behaviour.	Challenging behaviour; Measured the degree of challenging behaviour at baseline, 3-month and 6-month intervals using the ABC.
Hassiotis et al. (2018)	Twenty-three specialist community ID services; England, UK	To compare the clinical effectiveness of staff training in PBS with TAU alone over 12-months.	Randomised controlled trial design (PBS vs. TAU)	*N* = 245; *n* = 108 (The sample consisted of 245 adults, 108 of whom received PBS and the remainder of whom received TAU)	Adult male (62%) and female (38%) service users (75% Caucasian, 25% other) with an ID (with/ without mental health difficulties, ASD, physical health problems) and challenging behaviour.	Staff training in PBS. Services were randomly allocated to manual-assisted staff training in PBS or TAU. Training included three two-day training sessions. Content included functional behavioural assessment and formulation using the BBAT, primary, secondary prevention and reactive strategies, PSR, problem-solving and troubleshooting.	Challenging behaviour; Measured the degree of challenging behaviour at baseline, 6-month and 12-month intervals using the ABC. Quality of Life; Measured the frequency of community participation using the GCPLA over 12-months.
Inchley-Mort et al. (2014)	Complex behaviour service for adults with ID; London, UK	To report on the clinical outcomes and social care costs associated with the delivery of PBS over 12-months.	Non-randomised control group design (PBS vs. TAU)	*N* = 46; *n* = 24 (The sample consisted of 46 adults, 24 of whom received PBS and the remainder of whom received TAU)	Adult male (70.8%) and female (29.2%) service users (*M* age = 33.83 years) with an ID (with/ without ASD, mental health difficulties, physical health difficulties) and challenging behaviour.	Service-wide PBS. The complex behaviour service delivered PBS including functional analysis of behaviours and the implementation of individualised proactive and reactive strategies.	Challenging behaviour; Measured the degree of challenging behaviour at baseline and time (6-month or 12-months) using the ABC.

MacDonald et al. (2010)	Specialist PBS service; Scotland, UK	To report on the outcomes of a PBS intervention for a service user with severe ID and challenging behaviour.	Uncontrolled longitudinal study; Single case study	*n* = 1 (The sample consisted of 1 adult who received PBS)	Adult male with severe ID and challenging behaviour by way of self-injury, aggression, and property destruction.	Direct PBS intervention. An individualised, multicomponent PBS plan based upon a functional analysis of behaviour.	Challenging behaviour; Measured the frequency of challenging behaviour (self-injury, aggressive, destructive) on a monthly basis for 22-months using behaviour recording on a bespoke record form. Measured the episodic severity of challenging behaviour pre- and post- PBS intervention using a SRS. Quality of Life; Measured the frequency of activity participation over a 15-month period using behaviour recordings to calculate the percentage of times the participant participated when offered the opportunity to participate in an activity.
MacDonald et al. (2018)	A community-based social care provider for people with ID; Scotland, UK	To investigate whether training service managers in PBS resulted in skilled teams who are able to provide better support to service users with ID and challenging behaviour.	Non-randomised control group design (PBS vs. TAU)	*N* = 72; *n* = 50 (The sample consisted of 72 adults, 50 of whom received PBS and the remainder of whom received TAU)	Adult male (70%) and female (30%) service users (*M* age = 41 years) with an ID (with/ without ASD (46% and 54%, respectively) and challenging behaviour.	Staff training in PBS. Service managers (*N* = 72) were allocated to year-long training in PBS (*n* = 50) or TAU (*n* = 22). Training consisted of a two-day introduction and eight one-day workshops, six weeks apart. Content included functional assessment, behaviour support planning, PSR, primary, secondary prevention and reactive strategies, and skills development.	Challenging behaviour; Measured the degree of challenging behaviour pre-training, post-training, and 6-months after the training was complete using the ABC, BRF, and MTS. Quality of Life; Measured the frequency of community participation pre-training, post-training, and 12-months after the training using the GCPLA and MTS.
McClean et al. (2005)	A day and residential service provider for	To evaluate the effectiveness of staff training in PBS in	Repeated measures within subject	*N* = 138; *n* = 105 (The sample	Adults male and female service users (aged 24 - 34 years) with ID and	Staff training in PBS. Staff (*N* = 132) were given training in PBS. The	Challenging behaviour; Measured the frequency of challenging behaviour using

	children and adults with ID; Ireland	reducing the challenging behaviour of a large group of service users with ID.	design; baseline, intervention and follow-up	consisted of 105 adults and 33 children all of whom received PBS)	challenging behaviour.	training lasted 6 months in duration over 5 teaching blocks and included 4 assignments and at least one quarterly progress report. Content included functional assessment, skills teaching, proactive and reactive strategies, PSR, and case review.	behaviour recordings 4-6 weeks prior and on average 22.5 months after the implementation of staff training in PBS.
McClean et al. (2007)	A state-funded voluntary service provider for children and adults with ID; Ireland	To evaluate the implementation of PBS for five service users with ID and severe challenging behaviour.	Case series; Uncontrolled longitudinal study; Multiple baseline design single case study	*n* = 5 (The sample consisted of 5 adults all of whom received PBS)	Adult male (60%) and female (40%) service users (aged 21 - 38) with ID (with/ without ASD, mental health difficulties, cerebral palsy) and challenging behaviour.	Direct PBS intervention. An individualised, multicomponent PBS plan based upon a functional analysis of behaviour.	Challenging behaviour; Measured the frequency of challenging behaviour using behaviour recordings over a 24-month period. Quality of Life; Measured quality of life pre- and post- PBS intervention using the QoL-Q. Restrictive practices; Measured the daily units of medication dispensed to each service user over a 24-month period.
McClean and Grey (2012)	A state-funded voluntary service provider for children and adults with ID; Ireland	To evaluate a PBS approach across individuals with ID, ASD, and severe challenging behaviour.	Case series; Uncontrolled longitudinal study; Multiple baseline design single case study	*N* = 4; *n* = 2 (The sample consisted of 2 adults and 2 children all of whom received PBS)	Adult male service users (aged 21 - 23) with ID, ASD, and challenging behaviour.	Direct PBS intervention. An individualised, multicomponent PBS plan based upon a functional analysis of behaviour.	Challenging behaviour; Measured the frequency of challenging behaviour using behaviour recordings over 156-weeks. Measured the episodic severity of the most severe behavioural incidents in a 1-month period using the severity subtest of the CBC. Quality of Life; Measured the quality of life at baseline, intervention, and follow up using the QoLS.
West	A community	To test the hypothesis	Case series;	*n* = 4	Adult male (50%) and	Direct PBS intervention. An	Skills enhancement; Measured

and Patton (2010)	service organisation; Washington, USA	that if meaningful life opportunities were provided to service users, their challenging behaviour would decrease.	Uncontrolled longitudinal study; Multiple baseline design single case study	(The sample consisted of 4 adults all of whom received PBS)	female (50%) service users (aged 34 – 41) with ID (with/ without cerebral palsy, Rhett syndrome) and challenging behaviour.	individualised, multicomponent PBS plan based upon a functional analysis of behaviour.	total frequency of correct, independent behaviour across job training sessions target routines using a behaviour recording system.

*Subsample here refers to the sample of interest, that is, those who received a form of PBS intervention

Note.
ABC = The Aberrant Behaviour Checklist (Aman, Burrow, & Wolford, 1995); ASD = Autism spectrum disorder; ASPD = Antisocial personality disorder; BPD = Borderline personality disorder; BRF = Behaviour Recording Forms (Emerson & Einfield, 2012); CBC = The Checklist of Challenging Behaviour (Harris, Humphreys, & Thomson, 1994); GCPLA = The Guernsey Community Participation and Leisure Assessment (Baker, 2000); ID = Intellectual disability; MTS = Momentary Time Sampling (Mansell, Beadle-Brown, Macdonald, & Ashman, 2003); PBS = Positive Behaviour Support; PSR = Periodic Service Review (LaVigna, Willis, Shaull, Abedi, & Sweitzer, 1994); SPR = Scatterplot Recording (Touchette, MacDonald, & Langer, 1985); SRS = Severity Rating Scale (La Vigna & Willis 2005); QoL-Q = Quality of Life Questionnaire (Schalock, Keith, Hoffman, & Karan, 1989); QoLS = Quality of Life Scale (Kincaid, Knoster, Harrower, Shannon, & Bustamante, 2002).

Assessment of Quality of Included Studies

Quality assessment was used to evaluate the methodological rigour of the studies. The designs of the studies identified for inclusion are very diverse. It was decided that a tool capable of evaluating diverse designs would be preferable to using a variety of tools, which would make an accurate comparison of quality across studies difficult. Therefore, the quality of each study was assessed using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD; Sirriyeh, Lawton, Gardner, & Armitage, 2011). The QATSDD has 16 items and was selected as it has been shown to have good reliability and validity for use in the assessment of studies with diverse methodological designs (Sirriyeh et al., 2011). The QATSDD comprises a four-point rating scale: 0, 'Not at all'; 1, 'Very slightly'; 2, 'Moderately'; and 3, 'Complete' (see Appendix 2). Of the 16 items, 14 are relevant to quantitative studies. The total score for each study is then converted into a percentage. Higher percentages indicate higher quality studies. The assessment of each study was undertaken by the first author. An independent reviewer (KW) quality assessed a random selection of four studies (25%) using the QATSDD. Inter-rater reliability was assessed using Cohen's kappa (k = .630). According to Altman's (1991) benchmark scale, this suggests a 'good' level of agreement between raters. The quality of the methodology was then used to guide the extent to which meaningful conclusions could be drawn from the studies.

Summary of Quality Assessment of Included Studies

Scores on the QATSDD for each study can be viewed in Appendix 3. Studies scoring between 0-25% were considered to be of 'very low' quality. Studies scoring between 26-50% of 'low' quality. The quality of studies scoring between 51-75% were considered to be 'moderate' quality and for those scoring between 76-100% of 'high' quality. The decision to categorise the studies in this way was informed by the GRADE approach (GRADE Working

Group, 2004). The rationale for categorising the studies in this way is that is provides a clear structure and way of organising the data on the basis of methodological quality. The categories serve to emphasise the importance of the methodological quality of the studies in the extent to which meaningful conclusions can be drawn from the findings.

Overall, one study by MacDonald et al. (2018) and another by Hassiotis et al. (2009) were rated as being of 'high' quality, having scored 78.57% and 76.91% on the QATSDD respectively. A further study by Hassiotis et al. (2018) and one by Davies et al. (2018) were rated as being of 'moderate' quality, having both scored 73.81%. Ten of the remaining studies were rated as being of 'low' quality: McClean et al. (2005) and West and Patton (2010), both having scored 47.62%; McClean and Grey (2012) and Inchley-Mort, Rantell, Wahlich and Hassiotis (2014), both having scored 45.24%; Arco and Bishop (2009), having scored 42.86%; McClean, Grey and McCracken (2007), having scored 40.47%; Allen, Kaye, Horwood, Gray and Mines (2011b), Bird and Luiselli (2000), and Gray, Smith, Nethall, Allen and Lowe (2013), each having scored 38.10%; and Baker (1998), having scored 30.95%. The final study by MacDonald, Hume and McGill (2010) was rated as being of 'very low' quality, having scored 21.43%.

Almost all studies (93%) provided a specific description of the research setting having scored 3 on QATSDD criterion, '*Clear description of the research setting*'. All studies (100%) were adept at providing a detailed description of the procedure for data collection having each scored 3 on QATSDD criterion, '*Description of procedure for data collection*'.

Conversely, 66.66% of the studies scored 0 on the following QATSDD criteria: '*Statistical assessment of reliability and validity of measurement tools*'; '*Fit between stated research question and method of data collection*'; and, '*Fit between research question and method of analysis*'. Just over half of the studies (53.33%) scored 0 on the QATSDD criterion, '*Good justification for analytical method selected*'.

Furthermore, the majority of the studies (93.33%) scored 0 on QATSDD criterion, '*Evidence of user involvement in design*'. A large proportion of the studies (80%) also scored 0 on the QATSDD criterion, '*Evidence of sample size considered in terms of analysis*'. This is more important in particular study designs, such as randomised controlled trials.

The main strength of this body of literature is that all of the studies described their procedure for data collection in replicable detail. Another strength is that since many studies were undertaken in UK health and social care settings with service users, there is evidence of high ecological and population validity. The main weakness of this body of literature is the size of the sample. Sample sizes are small throughout most of the studies, which is largely due to the preponderance of single case and small-*n* designs. The main implication of this is that smaller sample sizes are less likely to be representative of the population, which limits the generalisability of the findings. The findings of studies with small sample sizes require careful interpretation as they can produce false-positive results (Hackshaw, 2008).

Primary Findings of Included Studies

The primary findings of the studies can be found in Table 2. As per the stated aims of the review, the following information has been organised by service user outcomes: challenging behaviour, quality of life, restrictive practices, and enhancement of adaptive skills. One study (MacDonald et al., 2010) was excluded altogether on the basis that it was assessed to be of 'very low' quality. The methodological quality of the remaining studies was used to govern the extent to which conclusions could be drawn from the findings.

Considering that the studies identified for inclusion were of diverse designs (i.e. single-case and small-*n* design, repeated measures within-subjects design, non-randomised control design, randomised control trial design, organisational case study design), some were more biased than others by definition of their design (Mann, 2003).

Challenging Behaviour

According to the QATSDD assessment, two studies that reported on challenging behaviour were considered to be of 'high' quality. The first, undertaken by MacDonald et al. (2018), investigated whether training service managers in PBS would have an impact on the quality of life and challenging behaviour of service users with ID. Challenging behaviour was measured using the Aberrant Behaviour Checklist (ABC; Aman, Burrow, & Wolford, 1995), Behaviour Recording Forms (Emerson & Einfield, 2012) and Momentary Time Sampling (MTS; Mansell, Beadle-Brown, Macdonald, & Ashman, 2003). A non-randomised control group design with both between- and within-group comparison was used to compare year-long manager training in PBS to TAU. MacDonald et al. (2018) found significant differences between groups post-training for challenging behaviour according to ABC scores (ABC Total and ABC Severity) and Behaviour Recording Forms, but not for MTS. A sub-sample of the PBS group (n = 22) were followed up 6 months after training at which time improvements to challenging behaviour had begun to reduce. Although this reduction in improvements did not reach statistical significance, it brings into question the longevity of the improvements. This constitutes a limitation of the study. A follow up over a longer time period would have helped to clarify this. Other limitations include the fact that the participants from the PBS group exhibited challenging behaviour of a higher frequency and severity than the control group to start with. There was also no measurement of the episodic severity of challenging behaviour. MacDonald et al. (2018) acknowledged the increased potential for bias as the study was an internal evaluation. Reasonable efforts were taken to address potential sources of bias, including: blind ratings of behaviour recordings; blind inter-rater reliability checks for observation data; and double scoring of 5% of all evaluation questionnaires. An intention to

treat approach to analyses was also utilised, which may have mitigated the risk of bias across group comparisons. This is a strength of the study.

The second study of 'high' quality was that by Hassiotis et al. (2009) in which a randomised controlled trial design was used to compare participants who received TAU as well as PBS to participants who received TAU alone. All participants recruited to the study were service users with ID. Just as in the MacDonald et al. (2018) study, challenging behaviour was measured using the ABC (Aman et al., 1995). Hassiotis et al. (2009) found that participants in the intervention arm showed a greater improvement in challenging behaviour according to ABC scores (ABC Total and ABC Lethargy and Hyperactivity Subscales) at 3 and 6 months. Again, a limitation of the study is that the final measurement was taken at 6 months and so the longevity of improvements is difficult to ascertain. The strengths of the study include the steps taken to mitigate potential sources of bias: recruitment of all eligible service users to mitigate recruitment bias; randomisation to mitigate selection bias; and adjustment to the outcome model for participant characteristics to help reduce the risk of systematic bias. Furthermore, the ecological validity of the study was enhanced by the recruitment of a reasonably sized and representative sample of service users in an NHS community ID service. Fidelity to the model of PBS intervention was also high.

A further two studies reporting on challenging behaviour were assessed as 'moderate' quality. The first of which by Hassiotis et al. (2018) utilised a randomised controlled trial design to compare the effects of TAU as well as staff training in PBS to TAU alone. Participants were service users with ID. Challenging behaviour was measured using the ABC (Aman et al., 1995). When compared to TAU, the PBS intervention was found to be no more effective in reducing challenging behaviour over 12 months. Strengths of the study include the measures taken to reduce the risk of bias. Such efforts included: the use of an a priori analysis plan; randomisation to mitigate the risk of selection bias; and protocol registration to

mitigate the risk of publication bias. Enough participants were recruited and retained such that the analyses were sufficiently powered and the attrition rate was low. Participants were also followed up over a longer time period of 12 months. Limitations include poor fidelity to the model of PBS intervention with just 33/ 108 of participants reported to have received the optimal delivery.

The study by Davies et al (2018) was also found to be of 'moderate' quality. In this study, participants were service users with mental health diagnoses in a medium secure forensic mental health unit. Challenging behaviour was measured using the CBC (Harris et al., 1994) adapted for use within a forensic mental health context. A non-randomised control group design was used in order to compare the effectiveness of PBS to TAU. A sub-sample of the PBS group (n = 17) were followed up 12 months after the intervention. Whilst no differences in challenging behaviour were found for the control group over time, improvements to challenging behaviour were found for the PBS intervention group according to CBC scores. Significant differences in improvements to challenging behaviour were found between groups that were maintained at 6 months for the PBS intervention full group and 12 months for the sub-sample of the PBS intervention group. The main limitation is that it is not clear whether any efforts were made to address potential sources of bias. This is pertinent since the study was an internal evaluation. Another limitation was the sample, which, although fairly representative, was small.

Seven of the remaining studies that reported on challenging behaviour outcomes were assessed as 'low' quality. All studies included participants with ID. Inferential statistics were only utilised in three of these studies (Inchley-Mort et al., 2014; Gray et al., 2013; Baker, 1998). Inchley-Mort et al. (2014) compared service-wide PBS to TAU and found the challenging behaviour of participants had improved to a greater extent in the PBS group at 6 months, but not at 12 months follow up. Gray et al. (2013) also examined service-wide PBS

and found it to be associated with significant improvements to challenging behaviour for service users. Baker (1998) found staff training in PBS to be effective in reducing challenging behaviour for all participants examined. Due caution should be exercised when generalising these findings to the wider population given the methodological shortcomings.

Analyses that comprised of descriptive statistics were used in the remaining 'low' quality studies. McClean et al. (2005) described the relationship between the implementation of staff training in PBS and improvements to challenging behaviour. McClean and Grey (2012) and McClean et al. (2007) described how the direct implementation of PBS appeared to be associated with improvements to challenging behaviour. This was also described by Bird and Luiselli (2000) who added that improvements were maintained over a 24-month period. The statistical analyses employed in the studies render the results non-generalisable to any other group or population. When holding this in balance with the poor methodological quality of the studies, the conclusions that can be drawn are very limited.

Quality of Life

The aforementioned MacDonald et al. (2018) study reported on quality of life. Quality of life was measured using the GCPLA (Baker, 2000) along with the MTS (Mansell et al., 2003). A behaviour coding system informed by Jones et al. (1999) was applied to the MTS footage and used to discern participants' engagement in various behaviours considered indicative of quality of life. Although quality of life as determined by the MTS Total Engagement Score increased for participants in the PBS group, this did not reach statistical significance. In fact, no significant differences were found between the staff training in PBS group and the TAU group for either the GCPLA or the MTS measures of quality of life. MacDonald et al. (2018) asserted that levels of participant engagement prior to intervention for either group were higher than the average to start with. The average taken by MacDonald

et al. (2018) was from a literature review by Hatton and Emerson (1996). This constitutes another limitation of the study since this indicates that either the sample is non-representative or the comparison to levels of participant engagement from 23 years ago is intrinsically problematic.

Hassiotis et al. (2018) also used the GCPLA to measure quality of life and was assessed to be of 'moderate' quality. No significant differences were found between the TAU as well as PBS group to the TAU alone group on quality of life outcomes over 12 months.

The remaining studies that considered quality of life were those by McClean and Grey (2012) and McClean et al. (2007). These were assessed as 'low' quality and only utilised descriptive statistics. McClean and Grey (2012) measured quality of life using the Quality of Life Scale (QoLS; Kincaid, Knoster, Harrower, Shannon, & Bustamante, 2002). McClean et al. (2007) measured quality of life using the Quality of Life Questionnaire (QoL-Q; Schalock, Keith, Hoffman, & Karen, 1989). Whilst McClean and Grey (2012) described an overall positive trend in QoLS scores after direct PBS intervention over time, McClean et al. (2007) only described improvements in QoL-Q scores for three out of five participants. As for reasons stated above, limited conclusions can be drawn from these studies.

Restrictive Practices

McClean et al. (2007) reported on restrictive practices using descriptive statistics, as did Allen et al. (2011b). McClean et al. (2007) operationalised restrictive practices as the daily units of medication dispensed to each participant. For the four participants taking medication, the overall daily units of medication reduced by an average of 66% after direct PBS intervention. Allen et al. (2011b) examined the relationship between service-wide PBS and restrictive practices by way of the number of physical interventions used by staff. A negative trend in the use of physical intervention was described over time following the

implementation of service-wide PBS. Given the methodology that both studies employed, the findings have little basis for scientific generalisation.

Enhancement of Adaptive Skills

Of the two studies that reported on the enhancement of participants' adaptive skills, both were assessed to be of 'low' quality. The first, undertaken by West and Patton (2010), utilised descriptive statistics to explore the relationship between direct PBS intervention and the employment-based skills of service users with ID. Adaptive skills were conceptualised as the frequency of independent correct responses during job training sessions. West and Patton (2010) described that, following PBS intervention, each participant had performed complete independent responses by the end of the training. Likewise, Arco and Bishop (2009) reported on the relationship between direct, parent-implemented PBS intervention and the adaptive skills of a participant with acquired brain injury. Adaptive skills consisted of the frequency of the participants' independent behaviour across three breakfast routines. The relationship between direct PBS intervention and enhancement of adaptive skills was unclear given that the frequency of behaviour remained unchanged, had increased and had decreased across the three respective routines. As the methodological rigour of the studies is compromised, so are the credibility of the findings.

Table 2.
Primary Findings and Quality Assessment of Studies Included in the Systematic Review

Study	Analysis	Summary of Findings	Quality Assessment (%)
MacDonald et al. (2018)	Descriptive statistics; *M* and *SD* of ABC, BRF challenging behaviour, GCPLA and MTS scores before (pre-) and after (post-) the implementation of either staff training in PBS or TAU and at follow up 6-months after training was complete. Inferential statistics; a Mixed Factorial ANOVA was conducted with the 2 groups as the between-subjects factor and 2 time points as a within-subjects factor, as well as parametric *t* tests or Mann-Whitney *U* tests. Correlations were used to examine the relationship between group and scores.	There was a significant difference between PBS and TAU groups pre- and post-training in ABC total scores ($F = 16.837$, $p < .001$), ABC severity ($U = 271$, $p < .001$) and BRF challenging behaviour ($t = 4.851$, $p < .001$). There were no significant differences between PBS and TAU groups for MTS or GCPLA scores. At 6-month follow up, there were no further statistically significant differences. Data suggests that staff training in PBS was more effective than TAU in reducing challenging behaviour, but had no effect on QoL.	78.57%; the study is of 'high' quality.
Hassiotis et al. (2009)	Descriptive statistics; Median and IQR of total and subscale raw scores on ABC checklist at baseline, 3-, and 6-months for PBS and TAU groups. Inferential statistics; a multilevel (two-levels) linear regression model was used to compare square root transformations of ABC scores between PBS and TAU groups.	Statistically significant differences in primary multilevel analysis showed a greater reduction in (transformed) total ABC scores in participants in the intervention arm before and after adjustment for total score at baseline (difference = -0.89, 95% CI = -1.74 to - 0.04) and transformed lethargy and hyperactivity subscale scores (common intervention effect = -0.56, 95% CI = -0.97 to -0.15). Data suggests the use of PBS in addition to TAU leads to a greater reduction in challenging behaviour than TAU alone.	76.19%; the study is of 'high' quality.
Hassiotis et al. (2018)	Descriptive statistics; *M*, *SD*, Median, IQR of total ABC scores over 12-months for PBS and TAU groups. Inferential statistics; a multilevel (three-levels) random effects regression model (adjusted for baseline score, time period, staff/ patient ratio, effects	No treatment effects were found between for challenging behaviour over 12-months (adjusted mean difference = -2.14, 95% CI: -8.79, 4.51) or QoL outcomes. In the PBS group, baseline total ABC score (*M*) was 61.8 (*SD* = 27.7) compared with 68.5 (*SD* = 29.0) in the TAU group. In the PBS group, total ABC score (*M*) reduced to 55.5 (*SD* = 32.5) at 6 months and to 54.0 (*SD* = 32.1) at 12-months compared with 60.6 (*SD* = 32.6) at 6 months and 59.2 (*SD* = 28.8) at 12 months for the TAU group. The PBS intervention was not statistically significant compared with TAU in terms of the total ABC score (adjusted mean difference =-2.4; 95% CI: -8.7, 4.5; $p = 0.528$). There were no differences between the groups on GCPLAS outcomes over 12 months.	73.81%; the study is of 'moderate' quality.

	of clustering by services) repeated measures, within participants was used to compare total ABC score (*M*) between PBS and TAU groups.	Data suggests that staff training in PBS was no more effective than TAU in reducing challenging behaviour.	
Davies et al. (2018)	Descriptive statistics; CBC scores (*M*) over time for control and PBS intervention groups. Inferential statistics; a Wilcoxon Matched Pairs, Signed Ranks test (two-tailed) was used to measure within-group differences in CBC scores over time, and a Mann-Whitney U test (two-tailed) was used to assess between control and intervention group differences.	No statistically significant changes in CBC were observed for the control group. Statistically significant decreases were seen in the PBS full group between baseline and 3-months in aggression frequency and management difficulty (p <.05) as well as aggression severity, other challenging behaviour frequency, and management difficulty (p < 0.01). Aggression frequency between 3- and 6-months also reached statistical significance (p < 0.01). Statistically significant decreases were seen in the PBS subgroup between baseline and 3-months in aggression frequency and severity (p < 0.05), as well as aggression management difficulty, other challenging behaviour frequency and management difficulty (p < 0.01). Reduction in aggression frequency between 3- and 6-months was statistically significant (p < 0.05). Comparison between baseline and 12-months revealed statistically significant decreases in aggression frequency, management difficulty and severity (p < 0.01), as well as other challenging behaviours (p < 0.01). Reduction in other challenging behaviour management difficulty between baseline and 12-months was not statistically significant. Statistically significant differences were found between control group CBC scores at T2 (12-months) when compared to: PBS full group at 6-months for other challenging behaviour frequency and management difficulty (p < 0.01), aggression frequency and management difficulty (p < 0.05), but not severity; and PBS subgroup at 12-months for other challenging behaviour frequency (p < 0.01) and for aggression frequency, management difficulty, and other challenging behaviour management difficulty (p < 0.05), but not severity. Challenging behaviour appears to have been reduced and maintained over a 12-month period in the PBS groups.	73.81%; the study is of 'moderate' quality.
West and Patton (2010)	Descriptive statistics; The total frequency of correct, independent behaviour was measured at baseline, assessment and PBS intervention.	Pre-intervention, participants were performing 0 independent complete responses during job training. PBS intervention commenced at session 7 and lasted until session 16. Post-intervention, all participants had performed independent complete responses during training by session 15, 14, 15 and 15. Data suggests that the direct implementation of PBS appears to be associated with employment-based skills development.	47.62%; the study is of 'low' quality.
McClean et al. (2005)	Descriptive statistics; *M* and *SD* of percentage reduction in the frequency of challenging behaviour recordings 4-6 weeks before (pre-) and on average 22.5 months after (range: 3-months - 5.5 years) the implementation of staff training in PBS (post-).	Post-training, challenging behaviour had reduced on average by 74.6% (*SD* = 36.4) for participants aged 20-22 years and by 68.3% for those aged 30 years or over (*SD* = 33.9). It appears that following the implementation of staff training in PBS, the frequency of participants' challenging behaviour has reduced.	47.62%; the study is of 'low' quality.
McClean and Grey (2012)	Descriptive statistics; % of the baseline	Post-intervention, challenging behaviour had reduced to 0 for both participants and maintained	45.24%; the study is of

	rate of challenging behaviour ratings, CBC episodic severity and management difficulty sub-scores on a monthly basis, and QoLS at baseline, intervention, and follow up.	at 156 weeks. The % of the baseline rate of behaviour suggests that intervention was associated with a reduction to 0% of baseline. One out of two participants showed significant reductions in staff-rated episodic severity and management difficulty maintained at 154 weeks. Visual inspection of QoLS scores suggests a positive trend in QoLS scores over time. Direct implementation of PBS appears to be associated with reductions in challenging behaviour and enhancement to QoL.	'low' quality.
Inchley-Mort et al. (2014)	Descriptive statistics; *M* and *SD* of ABC scores at baseline, 6- and 12-month follow up for PBS and TAU groups. Inferential statistics; two types of multilevel regression models: unadjusted, outcome values at baseline, time (6- or 12-months), group and the interaction between time and group; adjusted, included participant characteristics as predictor variables; were used to compare ABC scores between PBS and TAU groups.	At 6-months, both groups improved on all ABC domains (with greater improvement in irritability and stereotypy domains for the PBS group). The PBS group showed a significant reduction in ABC total and domain (*M*) scores for irritability and stereotypy. *M* differences (95% CI) based on the adjusted analysis were: 4.7 (0.6, 8.8); 2.0 (0.4, 3.7) and 11.8 (0, 23.6), respectively. The only difference between PBS and TAU groups after 12-months was for stereotypy scores, which was significantly lower in the PBS group (*M* difference = 1.5; 95 per cent CI 0.2, 2.9). Besides for stereotypy, data suggests that service-wide PBS was no more effective than TAU in reducing challenging behaviour over 12-months.	45.24%; the study is of 'low' quality.
Arco and Bishop (2009)	Descriptive statistics; The total frequency (*M*) of participants' independent behaviour across routines over time (%) after parent-implemented PBS.	During baseline, total frequency (*M*) of independent behaviour across three routines (PB, SDT, EB) was 97%, 80%, and 69%, respectively. During generalisation phase (SDT, EB), total frequency (*M*) of independent behaviour decreased to 61% and 77%, respectively. During intervention (PB, SDT, EB), total frequency (*M*) of independent behaviour was 98%, 66%, and 91%, respectively. Data is mixed and inconclusive. The participants' total frequency (*M*) of independent behaviour across PB remained fairly stable, increased for EB, whilst it decreased for STD. The effects of parent-implemented PBS appear unclear.	42.86%; the study is of 'low' quality.
McClean et al. (2007)	Descriptive statistics; The frequency of challenging behaviour and daily units of medication was measured using behaviour recordings at baseline (pre-), which ranged from 1 to 6 months, up to 24-months (post-) direct PBS intervention. Baseline (pre-) and 24-month follow up (post-) percentile QoL-Q scores are compared.	Post-intervention, challenging behaviour had reduced to near-zero for all participants and were sustained over 24-months. For the four participants taking medication, overall levels of medication reduced for three of them by an average of 66%. Visual inspection of the data suggests a negative trend in challenging behaviour and medication use over time. Percentile QoL-Q scores increased significantly for three out of five participants, from below the 1st percentile to above the 50th percentile. The direct implementation of PBS appears to be associated with reductions in challenging behaviour and medication. The data is mixed and inconclusive for QoL.	40.47%; the study is of 'low' quality.
Allen et al. (2011b)	Descriptive statistics; The total frequency (*M*) use of physical	After the establishment of service-wide PBS, the average likelihood of a service user being subject to physical intervention by way of 'breakaway' techniques, temporary holds, and	38.10%; the study is of 'low' quality.

	interventions over time and reductions (%) after the implementation of PBS at an organisational level.	restrictive seating or restraint reduced by 73%, 70%, and 73% respectively. This was based on a comparison of figures from 2004 and equivalent figures for 2010-2011. Visual inspection of the data suggests a negative trend in the use of physical intervention over time. The implementation of PBS at an organisational level appears to be associated with reductions in physical intervention.	
Bird and Luiselli (2000)	Descriptive statistics; The frequency of challenging behaviour at pre-discharge (from the highly restrictive facility), transition, 6-month, 12-month, and 24-month intervals after the implementation of direct PBS intervention.	Direct PBS intervention was implemented during the transition phase. When participants' challenging behaviour is compared from transition to 24-month follow up, it reduced by 90.91%, 71.43%, 0%, 92.31%, and 0%, respectively (M = 50.93%). Data suggests that after the participants' restrictive intervention programmes were terminated in favour of PBS intervention, challenging behaviour appears to have reduced and maintained over a 24-month period.	38.10%; the study is of 'low' quality.
Gray et al. (2013)	Descriptive statistics; ABC (M) scores before (pre-) and after (post-) the implementation of service-wide PBS. Inferential statistics; a Wilcoxon Matched Pairs, Signed Ranks test was used to measure within-subject differences in ABC scores pre- and post- PBS intervention.	Statistically significant differences were found on the ABC: total score (M), decreased from 59 (range: 4 - 103) to 28 (range: 0 - 88); number of behaviours (M), decreased from 29 (range: 4 - 56) to 20 (range: 0 - 54); and in highest level severity behaviours (M), decreased from 11 (range: 0 - 30) to 2 (range: 0 - 17), pre- and post-intervention ($p < 0.000$). Data suggests that the implementation of service-wide PBS was associated with reductions in challenging behaviour for participants.	38.10%; the study is of 'low' quality.
Baker (1998)	Descriptive statistics; The frequency of challenging behaviour incident reports 2-months before (pre-) and in 2-months after (post-) the implementation of PBS training/ consultation to staff. Inferential statistics; a Wilcoxon Matched Pairs, Signed Ranks Test to compare the frequency of challenging behaviour incident reports pre- and post-training.	Post-training, each participants' challenging behaviour had reduced by 88.89%, 71.43%, 88.33%, 100%, and 100%, respectively (M = 88.73%). A Wilcoxon Matched Pairs, Signed Rank Test analysis revealed the number of incident reports involving challenging behaviour decreased to a statistically significant degree pre- and post-training (T = 0, p <.05). Data suggests that staff training in PBS was effective in reducing challenging behaviour for all participants.	30.95%; the study is of 'low' quality.
MacDonald et al. (2010)	Descriptive statistics; The frequency of challenging behaviour at monthly intervals over a 22-period and episodic severity of challenging behaviour scores pre- and post- the implementation of direct PBS	Visual inspection of the frequency data suggests a negative trend in challenging behaviour over time. Episodic severity of aggression destruction reduced from 6 to 2.7 (55% reduction), and self-injury reduced from 4.5 to 2.5 (44.44% reduction) post-intervention. A Pearson's correlation coefficient of 0.90 indicates there is a relationship between PBS implementation and participation in activities (a proxy measure of QoL). Direct PBS implementation appears to be associated with reductions in the frequency and episodic severity of challenging behaviour.	21.43%; the study is of 'very low' quality.

	intervention Inferential statistics; the relationship between consistent PBS implementation and participation in activity over 15-months was examined by Pearson's correlation coefficient.		

Note.
ABC = The Aberrant Behaviour Checklist (Aman, Burrow, & Wolford, 1995); BRF = Behaviour Recording Forms (Emerson & Einfield, 2012); CBC = The Checklist of Challenging Behaviour (Harris, Humphreys, & Thomson, 1994); GCPLA = The Guernsey Community Participation and Leisure Assessment (Baker, 2000); MTS = Momentary Time Sampling (Mansell, Beadle-Brown, Macdonald, & Ashman, 2003); PBS = Positive Behaviour Support; QoL = Quality of life; QoL-Q = Quality of Life Questionnaire (Schalock, Keith, Hoffman, & Karan, 1989); QoLS = Quality of Life Scale (Kincaid, Knoster, Harrower, Shannon, & Bustamante, 2002)

Discussion

The aim of this review was to locate outcome studies and evaluate their rigour to examine the effectiveness of PBS for adult service users. A total of 15 studies were identified. Studies varied considerably in terms of methodological design and quality. Overall, just two studies were assessed to be of 'high' quality and a further two were assessed to be of 'moderate' quality. As studies of sufficient rigour were lacking, there is insufficient high-quality empirical research to suggest that PBS is effective for service users. Notwithstanding this, each question set out in the aims of this review is now returned to so that the status of the current evidence can inform directives for future research and clinical practice.

Does PBS Lead to Improvements in Challenging Behaviour?

Challenging behaviour was the most frequently measured outcome. Two studies assessed to be of 'high' quality (MacDonald et al., 2018; Hassiotis et al., 2009) and one study assessed to be of 'moderate' quality (Davies et al., 2018) reported improvements in challenging behaviour. However, two of these were limited by insufficient follow-up times (MacDonald et al., 2018; Hassiotis et al., 2009) and one of these did not appear to address potential sources of bias (Davies et al., 2018). The remaining study assessed to be of 'moderate' quality found PBS to be no more effective than TAU, however, this may have been affected by the reported poor implementation fidelity (Hassiotis et al., 2018). Therefore, the available evidence is mixed and equivocal. At present, it is not clear whether PBS leads to improvements in challenging behaviour. This is because although most of the evidence suggests that PBS does lead to improvements in challenging behaviour, the identified methodological weaknesses limit confidence in the generalisability of these findings. This finding is broadly consistent with the review undertaken by Carr et al. (1999) who found PBS

to be effective in reducing challenging behaviour in one half to two-thirds of the cases considered. Furthermore, a review undertaken by MacDonald and McGill (2013) reported that training staff in PBS yielded considerable reductions in challenging behaviour. Whilst this is true, it was again based upon a selection of non-quality appraised studies of both children and adults, one of which was subsequently assessed as 'low' quality in this review (McClean et al., 2005). It is also the case that the findings of the current review are broadly consistent with Lavigna and Willis (2012), who reported that PBS is effective at improving both less and more severe challenging behaviour. However, Lavigna and Willis's (2012) findings were based upon just twelve outcome studies, whose quality were also not formally assessed. Therefore, what is common between this and the current review is the conclusion that as such few studies exist, it is difficult to say with confidence that PBS leads to improvements in challenging behaviour for adults with a diagnosis of ID and more research is needed to validate these findings. There is a distinct lack of evidence to suggest that PBS leads to improvements in challenging behaviour for other clinical populations who are at risk of being exposed to restrictive practices including adults with mental health difficulties/ a diagnosis of personality disorder with/ without forensic histories who are detained in inpatient/ secure services and older people with/ without dementia.

Does PBS Lead to Enhancements to Quality of Life?

Just five studies measured quality of life in this review. This is despite the fact that enhancement to quality of life is considered the primary aim of PBS (Carr et al., 2002). There was also considerable variation in the measures of quality of life employed (GCPLA; Baker, 2000; MTS; Mansell et al., 2003; QoLS; Kincaid et al., 2002; QoL-Q; Schalock et al., 1989; behaviour recordings). Neither the study assessed to be of 'high' quality (MacDonald et al., 2018) nor the study assessed to be of 'moderate' quality (Hassiotis et al., 2018) that reported

on quality of life found evidence of enhancement to quality of life. At present, there is no sufficiently rigorous evidence to suggest that PBS leads to quality of life enhancement. This finding corresponds with that of Carr et al. (1999) who noted that data for enhancement to quality of life (as defined by increased engagement in community activities) was only available for two of the 230 participants in the sample. Similarly, MacDonald and McGill (2013) found that just one of the 14 studies of staff training in PBS (Dench, 2005) measured enhancements to quality of life using the QoL-Q (Schalock et al., 1989). Dench (2005) found no evidence to substantiate quality of life enhancement, besides positive anecdotal changes. Moreover, it is apparent that the ways in which quality of life have been understood, operationalised and measured are variable. In this way, previously published research dovetails with the finding of this review.

Does PBS Reduce the Extent to Which Restrictive Practices are Used?

This review did not identify any serviceable outcome studies examining the extent to which PBS reduced the use of restrictive practices. Therefore, knowledge of the extent to which PBS may reduce the use of restrictive practices is lacking. This is consistent with the outputs of Carr et al. (1999) who recognised the need for systematic examination of the relationship between PBS and the use of medication. This neglected area continues to be of relevance twenty years later because healthcare professionals continue to overuse psychotropic medication when caring for adults with ID (Sheehan et al., 2015) and overuse of antipsychotic medication constitutes a particularly hazardous restrictive practice (Matson & Mahan, 2010). There is a distinct lack of evidence to suggest that PBS leads to reduced use of other forms of restrictive practices including physical interventions, segregation/ seclusion, the use of punitive sanctions/ consequences and mechanical restraint.

Does PBS Lead to the Enhancement of Adaptive Skills?

As was the case for restrictive practices, this review did not identify any serviceable outcome studies that measured enhancement of adaptive skills. To the best of our knowledge, no previously published reviews have examined the enhancement of adaptive skills in a systematic manner. Knowledge of whether PBS leads to the enhancement of adaptive skills is considerably lacking.

Recommendations for Future Research

A clearer understanding of whether PBS is effective for adult service users is contingent upon publication of future research. In particular, studies of sufficient rigour such that they examine large samples over a longer period of time and take clear steps to mitigate the risk of bias.

Future studies should examine the feasibility of PBS since at least one study in this review had difficulties with sustained implementation (Hassiotis et al., 2018). LaVigna, Willis, Shaull, Abedi and Sweitzer (1994) have emphasised the need for Periodic Service Review (PSR) to address implementation fidelity issues, whilst Gore et al. (2013) have emphasised the need to implement support, monitoring and evaluation of interventions over the long term as a core component of PBS. The relationship between PSR and service user outcomes could be the subject of future empirical investigation.

Future research should also examine the relationship between PBS and the many different forms of restrictive and punitive practices. As well as medication, other types of restrictive practices include the use of long-term segregation/ seclusion, physical intervention, sanctions/ punitive practices and restrictions on the use of Section 17 leave. This research is particularly important because recommendations for positive approaches to the management of challenging behaviour came from the recognition that services needed to

reduce their reliance on restrictive practices during the management of challenging behaviour. Therefore, if PBS cannot be established as able to do this then other approaches need to be identified as a matter of priority.

It is surprising how few studies measured quality of life given that the primary objective of PBS is to enhance quality of life. The studies in this review that did measure quality of life used various tools that rely on staff as proxy respondents (QoL-Q; Schalock et al., 1989; GCPLA; Baker, 2000; QoLS; Kincaid et al., 2002). One tool (GCPLA; Baker, 2000) measures participation in activities and not whether service users value or enjoy participating in activities. Future research should aim to establish consensus on the selection of the most appropriate outcome measures to capture quality of life in a meaningful way. Failure to establish a consistent way to capture quality of life may belie discrepant findings in future research. Furthermore, rigorously validated measures of quality of life do not yet exist for some clinical populations such as individuals with ID and challenging behaviour (Townsend-White, Pham, & Vassos, 2012) and individuals with mental health difficulties and forensic histories (O'Flynn, O'Regan, O'Reilly, & Kennedy, 2018). Future research should develop such measures.

Strengths and Limitations

The main strength of this review is that it examined the methodological rigour of included studies using the QATSDD, a reliable and valid quality appraisal tool (Sirriyeh et al., 2011). Yet, the QATSDD has come under criticism for its vague language, which has led to discrepancies in its application between reviewers (Fenton, Lauckner, & Gilbert, 2015). However, the results from the statistical assessment of inter-rater reliability may engender confidence in its application during this review. Furthermore, there are a number of strengths and limitations of the categories used for the QATSDD. One strength is that the use of

explicit categories ensured that methodological quality was at the fore. Another strength is that the use of categories provided a way in which to be selective when reporting findings on the basis of methodological quality. Studies that fell within the 'very low' category, for example, were excluded altogether. A limitation of the approach of categorising is that categories impose meaning on behalf of the reader who might disagree with the categories used. Another limitation is that the authors of the QATSDD themselves have not provided any guidance on how to benchmark quality nor what categories might be appropriate to use. The limitations of the categories used are tempered by inclusion of all individual QATSDD scores and percentages on page 125. A narrative overview of quality could have been used as an alternative.

Another strength is that this review is the first to examine service user outcomes across multiple clinical populations. The main limitation of this review relates to the definition of PBS. On account of the controversy surrounding what exactly constitutes PBS, the decision was taken to replicate MacDonald and McGill (2013) and only include studies that self-identified as PBS. Studies of interventions that constitute PBS may otherwise exist but evaded inclusion due to being under a different name. If such studies exist and are of high calibre, it is not clear what impact this may have had on the findings of this review. Another limitation is that using a meta-analysis design would have helped to derive firmer conclusions on the efficacy of PBS. However, this was not feasible due to the small number of identified studies and the heterogeneity of outcome measures employed within them. This review has limited generalisability given the small number of included studies, especially as so few studies examined clinical populations beyond adults with ID.

Implications

Although the Challenging Behaviour Foundation (2019) attest to their being "strong evidence that PBS is effective in producing positive outcomes, such as increasing the person's skills and positive life opportunities", this was not substantiated for adult service users in this review. The main output of this review for service users, their families, clinicians, services and policymakers, is that there is a lack of scientific knowledge on the extent to which PBS is effective for adult service users. This is consistent with the evidence review undertaken by NICE (2015) who did not explicate PBS in clinical guidance due to the scarcity of evidence. It is important to recognise this as PBS features heavily in UK government guidance and policy in the promotion of positive and proactive approaches to the management of behaviours that challenge (Department of Health, 2014a; Department of Health, 2014b; Department of Health, 2014c), which could be at the expense of other approaches that may be of equal or greater utility to service users. It is also important since there has been substantial investment in the workforce of UK clinical psychologists and allied healthcare professionals to develop competence in PBS (Department of Health, 2014c; Noone & Chaplin, 2017).

The evidence does not support the assertion that any reduction in challenging behaviour occurs as a secondary consequence of enhancement to quality of life (Carr et al., 2002). This could indicate that the theoretical or conceptual basis of PBS requires some revision. However, the lack of evidence may well be related to other factors, such as inadequate means of determining and measuring quality of life.

The level of investment in PBS has transformed the landscape of ID services in the UK. It is, perhaps, surprising that an approach as influential as this appears to have been so on the basis of very few high-quality empirical studies. There is an argument for continuing to use PBS because of its strong values-based approach, which is important for any approach

used with vulnerable clinical populations. The findings of Hassiotis et al. (2018) call into question the feasibility of sustaining PBS implementation over the long-term. Issues with consistent implementation with due fidelity to the PBS framework are likely to be paralleled, if not amplified, in real life clinical settings where staff turnover is high, and staff are working with multiple individuals with challenging behaviour with limited opportunities for training/mentoring and/or supervision. There is some evidence to suggest that when services receive intensive systemic or organisational support that includes recruiting a full capacity staff team and providing them with regular, structured formal coaching and training, that this can maintain the improvements achieved through PBS over the long-term (McGill et al., 2018). This indicates that services are likely to require considerable investment and sustained support in order to maintain improvements achieved by PBS.

Finally, there is a need to delineate PBS and whether any constituent parts are associated with positive clinical change and explore the utility of other behavioural or evidence-based interventions from other modalities to reduce the use of restrictive practices and enhance quality of life.

Conclusion

This review is the first of its kind. At present, there is little empirical basis to suggest that PBS is effective at improving challenging behaviour when used with adult service users. Furthermore, there is no empirical basis to suggest that PBS reduces the use of restrictive practices nor that it enhances quality of life or teaches adaptive skills. This is despite the presence and popularity of PBS in the UK. This is not to say that PBS is ineffective, but that further research is necessary before its status can be determined either way.

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Cognitive Interview-Based Validation of the English Version of the Forensic Quality of Life Questionnaire - Short Version (EFQL-SV)

Amber Simler, Dr Bronwen Davies and Dr Christopher Hartwright

School of Psychology, Cardiff University

Word Count: 5449

This empirical research study has been prepared for submission to *The Journal of Forensic Psychiatry & Psychology*. To provide some additional contextual information, the word count has been extended slightly from 5000 words (see Appendix 4 for further author guidance).

Abstract

In recent years, quality of life for inpatients in forensic services has been the topic of increased empirical and clinical inquiry. Despite this, no well-validated quality of life measure exists for use with this specific clinical population in the UK. The Forensic Quality of Life Questionnaire - Short Version (FQL-SV) is a psychometrically valid quality of life measure developed in the Netherlands and translated into English (Schel, Bouman, Vorstenbosch, & Bulten, 2017). This study aimed to explore the validity of the English version of the FQL-SV (EFQL-SV) using a think aloud and concurrent probing cognitive interviewing procedure. Fifteen inpatients in UK forensic services participated. Comprehension of the EFQL-SV was evaluated systematically using Conrad and Blair's (1996) respondent problem matrix. Findings indicated that participants had the most difficulty understanding the wording of EFQL-SV items. This meant that the EFQL-SV was limited in the extent to which it measured what it purports to. A number of revisions to the EFQL-SV were proposed, however, these require further validation.

Keywords: cognitive interviewing, questionnaire, translation, quality of life, forensic

Introduction

In the UK, many individuals with mental health difficulties and a history of serious violent or other 'challenging behaviours' (Emerson & Bromley, 1995) may be subject to compulsory detention in secure units under the Mental Health Act (1983, amended 2007). Such facilities provide therapeutic conditions of either low, medium or high security. Many of the individuals who receive care and treatment in secure units have been in contact with the Criminal Justice System; therefore, service providers have an ethical and statutory duty to support mental health recovery (see The Good Lives Model; Ward & Brown, 2004) as well as reduce the risk of recidivism and challenging behaviours.

Secure units are, by definition, highly restrictive environments. After the Winterbourne View scandal (Department of Health, 2012) and several restraint-related deaths (Mind, 2013), the UK government published a number of policy documents pledging to reduce the use of restrictive practices across health and social care settings (Department of Health, 2014a; Department of Health, 2014b; Department of Health, 2014c). Despite this, there are figures to suggest that the use of restraint remains high. A total of 468 physical restraints occurred across medium secure units in England in January 2016 alone (The National Health Service Benchmarking Network, as cited in Sethi, Parkes, Baskind, Paterson, & O'Brien, 2018). Therefore, there continues to be demand for a less restrictive, values-led approach to the management of violence and other behaviours that present a challenge to forensic health services. The Department of Health (2014a) identified Positive Behavioural Support (PBS; Horner et al., 1990) as an approach capable of this and advocated its use across a range of settings, including UK forensic services. Carr et al. (2002) defined PBS as "an applied science that uses educational methods to expand an individual's behaviour repertoire and systems change methods to redesign an individual's living environment to first enhance the individual's quality of life and, second, to minimize his or her problem

behaviour" (p. 4). The underlying theory being that through enhancing an individual's quality of life, services should see a reduction in challenging behaviour (Carr et al., 2002). Although there is some evidence to suggest that PBS is effective at reducing aggression and other forms of challenging behaviour in secure settings (Davies, Lowe, Morgan, John-Evans, & Fitoussi, 2018), the extent to which PBS is effective at enhancing the quality of life of inpatients in UK forensic services is poorly understood.

The World Health Organisation (WHO; 1998) defined quality of life as: "…the individuals' perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns" (p.12). Although this is one of the most widely used definitions, it is not exhaustive. Post (2014) acknowledged that quality of life is an elusive construct that has been defined and measured in many ways. These include use of self-report psychometric measures of quality of life to inquire about individual's subjective experience, as well as the use of other measures that invite staff or family members to act as proxy respondents (Post, 2014). A number of problems exist with proxy respondent measures of quality of life, including the influence of positive response bias (Ncube, Perry, & Weiss, 2018).

O'Flynn, O'Regan, O'Reilly and Kennedy (2018) recognised that despite increased interest in quality of life following the recovery-focused practice movement, few studies appeared to have considered factors associated with quality of life in forensic settings (Swinton, Oliver, & Carlisle, 1999; Long, McLean, & Boothby, 2008; Trizna & Adamowski, 2016). O'Flynn et al. (2018) examined predictors of quality of life using the World Health Organisation QOL Bref (WHO, 2004), Engagement in Meaningful Activity Survey (EMAS; Goldberg, Brintnell, & Goldberg, 2002) and the EssenCES (Schalast, Redies, Collins, Stacey, & Howells, 2008). Neither the WHOQOL-Bref nor the EMAS are designed for use in a

forensic inpatient context and whilst the EssenCES is, it is a measure of the ward climate rather than quality of life.

To the best of our knowledge, no well-validated self-report measures of quality of life for inpatients in UK forensic services exist. This is a problem because without valid quality of life measures, the extent to which the effectiveness of PBS and other therapeutic approaches can be understood is limited (in other words, whether these interventions do enhance quality of life). The development of a well-validated self-report measure of quality of life may also be of use to the research community who could use this to examine the relationship between quality of life and challenging behaviour, as well as quality of life and mental health recovery.

Schel, Bouman, Vorstenbosch and Bulten (2017) developed the Forensic Quality of Life Questionnaire - Short Version (FQL-SV). This is a psychometrically valid measure of quality of life for use in forensic services in the Netherlands. Although the FQL-SV was translated into English in 2017, to date there has been no attempt to validate the English translation of the FQL-SV (EFQL-SV) with a UK sample.

Aims

The principal aim of the study was to ascertain whether the EFQL-SV is sufficiently valid for use with inpatients in low or medium secure UK forensic services. In order to fulfil this aim, the EFQL-SV's construct validity, the extent to which it measures what it purports to, was examined. The following research questions were informed by those posed by Walden (2008) during cognitive interview-based validation of a novel questionnaire.

Research Questions

1. Does the content of participants' responses to the EFQL-SV suggest that the tool is valid for inpatients in UK forensic services?
2. When compared to the intent of the EFQL-SV's developers, can any types of problem be identified in the content of participants' responses?
3. What revisions might be necessary in order to improve the validity of the EFQL-SV?

Addressing the research questions was thought to be important because where no appropriate measures currently exist in the UK, the EFQL-SV has the potential to be a valid instrument through which quality of life can be measured. Establishing the EFQL-SV as a valid measure would be of direct relevance to inpatients in UK forensic services. It would also be of relevance to clinicians and commissioners who could use the measure to improve reporting of whether therapeutic approaches, such as PBS, enhance quality of life as intended. Finally, it would be of benefit to the research community who could use the measure to empirically examine the proposed link between self-reported quality of life, recovery, and challenging behaviour in inpatients in UK forensic services.

Methodology

Study Design

A cross-sectional qualitative research design using cognitive interviewing was considered the most appropriate for addressing the research questions as it elicits rich data on the cognitive processes by which participants arrive at their answers.

In the context of survey or questionnaire testing, Willis (2005) asserted that cognitive interviewing seeks to elucidate respondent's cognitive processes through which they arrive at their answer. Discrepancy between the way in which respondents comprehend and respond to

items on a questionnaire versus how the questionnaire's developers intended them to is a threat to the questionnaire's validity (Willis, Lessler, & Caspar, 1999).

The procedure for cognitive interviewing can take different forms: think aloud, whereby respondents are only asked to verbalise their thought processes whilst responding to questionnaire items; and verbal probing, whereby respondents think aloud and are also asked scripted or unscripted probing questions by the interviewer (Willis, 2005). Verbal probing can be done concurrently after each item or retrospectively after the whole questionnaire (Willis et al., 1999).

As noted by Belzer et al. (2013), even after a questionnaire has had its psychometric properties established statistically with due rigour, this is not always a sufficient indicator of its comprehensibility. Moreover, whilst traditional quantitative methods provide useful information about many facets of construct validity, such methods are limited in the extent to which they can guide the selection of items that minimise comprehension problems (Belzer et al., 2013).

It is plausible that a translated measure may present further challenges to the construct validity and comprehensibility (Willis, 2015), hence the decision to examine the EFQL-SV's construct validity in respect of its comprehensibility and whether participants answer in the intended way using a think aloud and concurrent probing cognitive interviewing procedure.

Target Population

The target population for the study was forensic inpatients aged 18 or over detained in conditions of low or medium security in the UK under the Mental Health Act (1983, amended 2007).

Calculation of Sample Size

There is a lack of consensus on how to calculate sample size for cognitive interview studies. A number of researchers advocate using small sample sizes (Sheatsley, 1983; Willis, 2005; Beatty & Willis, 2007), whereas others suggest that using larger sample sizes will increase the likelihood that all problems will be identified (Blair & Conrad, 2011). Some proponents of cognitive interviewing aim for traditional data 'saturation', to test until no further meaningful results are obtained (Emmel, 2013). Saturation has also been defined by Sudman (1976) to mean until sufficient data has been gathered that renders further interviews no longer time or cost-effective (Sudman 1976, in Willis, 2015). With the latter borne in mind, the current study sought to interview a sample of 15 participants to reveal any serious problems. This is in accordance with Peterson, Peterson and Powell (2017) who asserted small numbers of cognitive interviews expose proportionately more serious than minor problems and who also advocate conducting 5-15 interviews.

Recruitment Strategy

Participants were recruited from either of six wards across two hospital sites. Wards comprised of one medium secure female ward, two low secure female wards, two medium secure male wards and one low secure male ward. One of the medium secure male wards was also a high dependency unit.

In accordance with The National Research Ethics Service (NRES) guidance, the process of identifying prospective participants was executed by the patient's direct care team (Appendix 5). Recruitment aimed to select a sample to reflect the diversity found within the target population. A non-probability sampling technique (purposive sampling) was used to ensure adequate representation of the diverse characteristics found within the target population such as gender, mental health difficulties, and cognitive ability.

Participants

As was stipulated by the eligibility criteria, participants were inpatients detained under the Mental Health Act (1983, amended 2007) in conditions of low or medium security. All participants had been detained in an independent hospital in the UK for at least three months duration. Eligibility criteria also required participants to be able to provide valid informed consent, as well as be able to understand and communicate responses in the English language. Exclusion criteria required participants not to be acutely unwell or have significant cognitive impairments such that would prevent them from engaging within an interview.

Measures

The EFQL-SV is the English translation of the FQL-SV (Appendix 6). The FQL-SV is a 20 item (20 items plus a further 9 questions to gather demographic information) abbreviation of the 131 item Forensic Quality of Life questionnaire (FQL; Vorstenbosch, Bulten, Bouman, & Braun, 2007). It is comprised of 15 domains (Activities, Leave, Residence, Nutrition, Hygiene, Health, Sexuality, Social Relations, Other Residents, Daily Staff, Affection, Autonomy, Self-Actualisation, Religion, Overall Quality of Life) identified through statistical cluster analysis in a concept-mapping study (Vorstenbosch, Bouman, Braun, & Bulten, 2010). Respondents are asked to indicate their subjective level of agreement to individual items, such as: '*In general, do you derive enjoyment from your day-to-day activities?*', on 100-mm Visual Analogue Scales (VAS). This ranged from no agreement at all, 'Not at all' (0-mm) to complete agreement, 'Completely' (100-mm).

Schel et al. (2017) reported coherent intra-scale correlations between the FQL-SV and the WHOQOL-Bref as well as moderate to strong correlations between the FQL-SV and the EssenCES. Schel et al. (2017) also found the FQL-SV to demonstrate good internal consistency (Cronbach's $\alpha = .79$).

Interview Procedure

Interviews took place between the 9th November 2018 and the 18th January 2019. All interviews were held in the visitor's lounge of each participants' respective ward in the hospital. To standardise the interview procedure, the first author (AS), who had prior experience and formal training in cognitive interviewing, interviewed each participant. Participants were provided with an information sheet (Appendix 7) and consent form (Appendix 8). As well as the purpose of the study, confidentiality and its limitations were explained to participants who were given the opportunity to ask any questions and reminded that they could terminate the interview at any point. Written informed consent was obtained from participants in the presence of a member of staff with whom they were familiar with. All interviews were audio-recorded to ensure the integrity of the data. Interviews were semi-structured and took place on a single occasion, each lasting up to 60 minutes in duration. Use of a protocol comprising standardised instructions and a training task (Appendix 9) helped achieve consistency across interviews. After the training task, participants were given the EFQL-SV and asked to read each question aloud, thinking aloud as they responded. The decision to ask participants to read the EFQL-SV aloud was based on the EFQL-SV being a self-administered measure. It was also considered that if the interviewer read the EFQL-SV aloud, variability in their speech intonation/ inflection and emphasis could constitute something of an extraneous variable or source of bias. In accordance with guidelines developed by Willis (2005), the interviewer used a series of pre-determined (Appendix 10) and spontaneous probes during interviews. Spontaneous probes were reactive in nature and used if there was any indication of a problem with a question. Participants received a verbal and written debrief (Appendix 11) including on how they could access any emotional support or exercise their right to withdraw from the study once the interview had finished.

Participants were also thanked for their participation and compensated for their time with a £5.00 Amazon voucher.

Ethical Approval

Health and Care Research Wales awarded ethical approval for this study (REC Reference: 18/WA/0163, Appendix 12).

Data Analysis

Conrad and Blair (1996) developed a systematic method of analysing cognitive interview data. This method is derived from Tourangeau's (1984) cognitive model of the survey response process, which assumes that respondents go through four distinct stages in a fixed sequence when responding. Conrad and Blair's (1996) modification of Tourangeau's (1984) model consists of three distinct response stages: (1) understanding what information is being asked for and how to provide it, (2) executing the task with the cognitive processes necessary (i.e. retrieval, comparison, deduction, arithmetic, evaluation) and (3) mapping the results of the task onto the response options available. Problems can occur at any stage of the response process. By examining the content of verbal responses, the stage at which the problem occurred can be discerned (Conrad & Blair, 1996).

To increase the objectivity of data analysis, Conrad and Blair (1996) suggested that problems occurring across the three response stages (i.e. understanding, task performance, response mapping) could be classified further into five types of problem: (1) lexical, to do with understanding the meaning of certain words or question, (2) temporal, to do with the time period to which the question applies, (3) logical, to do with use of connectives, false pre-suppositions, contradictions and tautologies in the question, (4) computational, to do with

processing and manipulating information, (5) omission/ inclusion, to do with understanding whether certain concepts are within or outside of the scope of a word or question.

In this study, the first author transcribed each cognitive interview verbatim and used Conrad and Blair's (1996) respondent problem matrix to compare participant responses to the EFQL-SV's developers intended meaning of items (see Appendix 13) in order to systematically code for the presence or absence of problems. As participants read each EFQL-SV question before thinking aloud, it was clear to which question each response belonged. When participants' responses contained evidence of successful understanding, task performance and response formatting, the first author coded them as problem free. When the first author found evidence to the contrary, they coded the response with one of 15 problems from the taxonomy (see Appendix 14 for illustrative example). An additional category of problem sensitivity was added to the taxonomy after it became clear from the data that a number of participants considered the questionnaire to involve sensitive topics, such as sexual behaviour and mental health treatment.

Reflexivity

A number of steps were taken to increase the objectivity of data collection and analysis. Steps included use of a protocol to enhance consistency of interviews and use of a Dictaphone to mitigate the risk of impressionistic data collection. The method of analysis used (Conrad & Blair, 1996) was itself developed to address concerns about the objectivity of cognitive interview data analysis (Conrad, Blair, & Tracy, 1999). Furthermore, an independent reviewer (EH) coded a random selection of three transcripts (20%). The aim of this was to further enhance the rigour and objectivity of the analysis. A Cohen's kappa was calculated to assess agreement between raters on the presence or absence of one or more problem (k = .968) and to assess agreement on the type of problem(s) coded (k = .505). Using

Altman's (1991) scale this can be interpreted as 'very good' and 'moderate' agreement, respectively.

Results

Demographic Information

Direct care teams identified and approached 47 out of 85 inpatients across six wards in two forensic hospitals who met the eligibility criteria. Fifteen out of the 47 inpatients who were eligible to participate were then interviewed on the basis that they provided informed consent, their mental state had remained stable and they were available at the time of interview. Participants were 8 females (53.33%) and 7 males (46.67%) aged between 20 to 62 years (M = 37.2, SD = 11.52). Table 1 summarises participant demographic information.

Table 1
Summary of Participant Demographic Information

Age	**Count (%)**
20-30	6 (40%)
31-40	5 (33.33%)
41-50	3 (20%)
51-60	-
60-62	1 (6.67%)
Ethnic Background	
White British	13 (86.66%)
White Welsh	1 (6.67%)
White European	1 (6.67%)
Highest Level of Education Completed	
None	7 (46.67%)
GCSEs	3 (20%)
A Levels	1 (6.67%)
Vocational	4 (26.66%)
Months/ Years in Forensic Services	
<1 year	3 (20%)
1-5 years	5 (33.33%)
6-10 years	3 (20%)
11-15 years	3 (20%)
16-20 years	-
21-25 years	-
26-30 years	-
31-35 years	-
36-40 years	-
41-45 years	-
46-50 years	1 (6.67%)
Ward Type	
Low Secure Female	5 (33.33%)
Medium Secure Female	3 (20%)
Low Secure Male	2 (13.33%)
Medium Secure Male	4 (26.66%)
Medium Secure Male High Dependency Unit	1 (6.67%)

Overall Frequency of Respondent Problems

Inspection of the data revealed 426 verbal responses from 15 participants to the EFQL-SV that were appropriate for analysis. The maximum number of responses possible was 435, therefore nine responses were excluded from the analysis. The reason for this was that participants did not think aloud whilst responding.

Types of Respondent Problems

Table 2 illustrates all problems identified and at which stage they occurred (*n* = 144). Aside from sensitivity problems, all problems were categorised according to the stage at which they occurred (*n* = 141). The most problems (73.05%) occurred at the understanding stage (*n* = 103). The second most problems (17.73%) occurred at the response formatting stage (*n* = 25). The least problems (9.22%) occurred at the task performance stage (*n* = 13).

It is important to note that the data for response formatting is skewed due to one participant having a consistent difficulty using the VAS. This participants' response formatting problems (*n* = 17) account for many of the total response formatting problems identified (68%). This inflates the total number of response formatting problems substantially.

Identified as the most commonly occurring problem category was omission/ inclusion (*n* = 85), followed by lexical (*n* = 39), computational (*n* = 9), logical (*n* = 6), sensitivity (*n* = 3) and temporal problem categories (*n* = 2).

Table 3 provides illustrative examples of participants' responses to the EFQL-SV, each demonstrating one of the six types of problems.

Table 2

Overview of All Types of Respondent Problems Using Conrad & Blair's (1996) Respondent Problem Taxonomy

	Response Stage		
Classification of Problem	Understanding	Task Performance	Response Formatting
Lexical	(P1:Q2) (P1: Q10) (P2: Q1.6) (P2: Q10) (P3: Q7) (P4: Q1.2) (P4: Q2) (P4: Q10) (P5: Q1.2) (P5: Q10) (P6: Q2) (P6: Q12) (P6: Q13) (P7: Q1.6) (P7: Q18) (P8: Q10) (P8: Q18) (P9: Q1.2) (P9: Q2) (P9: Q10) (P9: Q17) (P10: Q2) (P10: Q10) (P10: Q18) (P11: Q1.2) (P11: Q1.3) (P11: Q10) (P12: Q2) (P12: Q14) (P13: Q1.2) (P13: Q1.4b) (P13: Q1.6) (P13: Q10) (P14: Q2) (P14: Q10) (P15: Q1.3) (P15: Q1.6) (P15: Q2) (P15: Q10)		
Temporal	(P3: Q2)		(P3: Q2)
Logical		(P2: Q14) (P2: Q16) (P6: Q19) (P10: Q19) (P15: Q8) (P15: Q19)	
Computational	(P4: Q17) (P8: Q3.2) (P8: Q12)	(P2: Q1.4a) (P2: Q18) (P3: Q1.3) (P6: 1.3) (P9: Q5) (P15: Q7)	
Omission/ Inclusion	(P1: Q4) (P1: Q8) (P1: Q15) (P2: Q3.1) (P2: Q8) (P2: Q11) (P3: Q1.2b) (P3: Q1.3) (P3: Q1.5) (P3: Q7) (P3: Q8) (P3: Q11) (P4:Q1.2b) (P5: Q1.3) (P5: Q2) (P5: Q15) (P6: Q1.3) (P6: Q4) (P6: Q5) (P6: Q7) (P6: Q8) (P6: Q13) (P6: Q15) (P6: Q17) (P7: Q1.3) (P7: Q4) (P7: Q7) (P7: Q8) (P7: Q9) (P7: Q12) (P7: Q15) (P7: Q17) (P8: Q1.3) (P8: Q1.4a) (P8: Q4) (P8: Q5) (P9: Q5) (P9: Q11) (P10: Q1.4a) (P10: Q1.5) (P10: Q9) (P10: Q12) (P10: Q15) (P11: Q1.4a) (P12: Q5) (P12: Q11) (P12: Q12) (P12: Q15) (P13: Q1.3) (P13: Q1.4a) (P13: Q11) (P13: Q13) (P13: Q15) (P14: Q1.4a) (P14: Q5) (P14: Q15) (P15: Q1.5) (P15: Q4) (P15: Q5) (P15: Q15)	(P3: Q1.2)	(P3: Q4) (P3: Q5) (P3: Q11) (P3: Q12) (P3: Q13) (P9: Q1.5) (P9: Q2) (P9: Q3.2) (P9: Q4) (P9: Q5) (P9: Q6) (P9: Q7) (P9: Q8) (P9: Q9) (P9: Q10) (P9: Q11) (P9: Q12) (P9: Q14) (P9: Q15) (P9: Q16) (P9: Q17) (P9: Q18) (P12: Q11) (P13: Q11)
Sensitivity	(P2: 1.6) (P7: Q10) (P13: Q8)		
Does Not Think Aloud	(P8: Q14) (P8: Q17) (P9: Q1.1) (P9: Q13) (P9: Q19) (P9: Q20) (P10: Q3.2) (P10: Q14) (P15: Q3.1)		

Note. P = participant, Q = question. Different colours indicate each participant 1-15.

Table 3
Examples of Types of Respondent Problems Identified During Cognitive Interviews

Classification of Problem	Illustrative Quotation
Lexical	Q1.3: "I ain't got a clue. I don't, I don't really understand it myself."
Temporal	Q2: "Are you asking me to write currently or in general, because there'd be two different answers."
Logical	Q19: "Well, depends on where your recovery is, because, like, I'm on my way out soon, so…"
Computational	Q1.4a: "So, it's just, sort of, like my memory. I might be slightly out by one, you know, 'cause people come and go, but I'm pretty sure it's about fourteen or fifteen"
Omission/ Inclusion	Q8: "I think, it's more to do with the, uh, drug treatment you get. Um, sort of, like, from your doctor."
Sensitivity	Q10: "I'm declining to answer that question, because I feel that it's, um, I don't need to answer anything to do with my sexuality."

Overall Distribution of Respondent Problems

Figure 1 presents the frequency distribution of the identified problems. It is clear from visual inspection of the data that cognitive interviewing did not detect any problems with three FQL-SV items (Q1.1, Q1.2a, Q20), but four items had upwards of ten problems (Q1.3, Q2, Q10, Q15). The distribution of the problems is such that they do not appear to be on account of fatigue effects.

Figure 2 presents all EFQL-SV items in order from the least problematic to the most problematic.

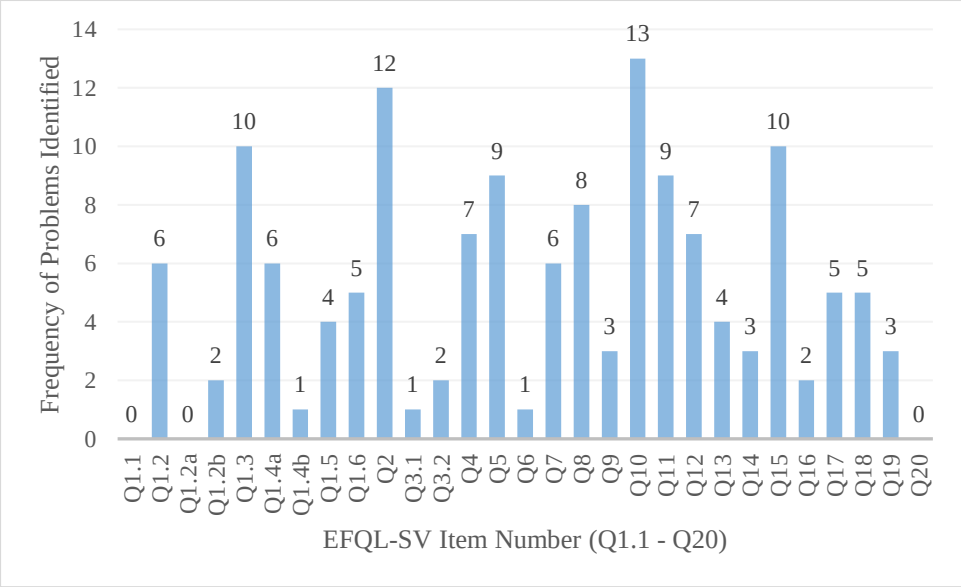

Figure 1. Distribution of all respondent problems across all EFQL-SV items identified.

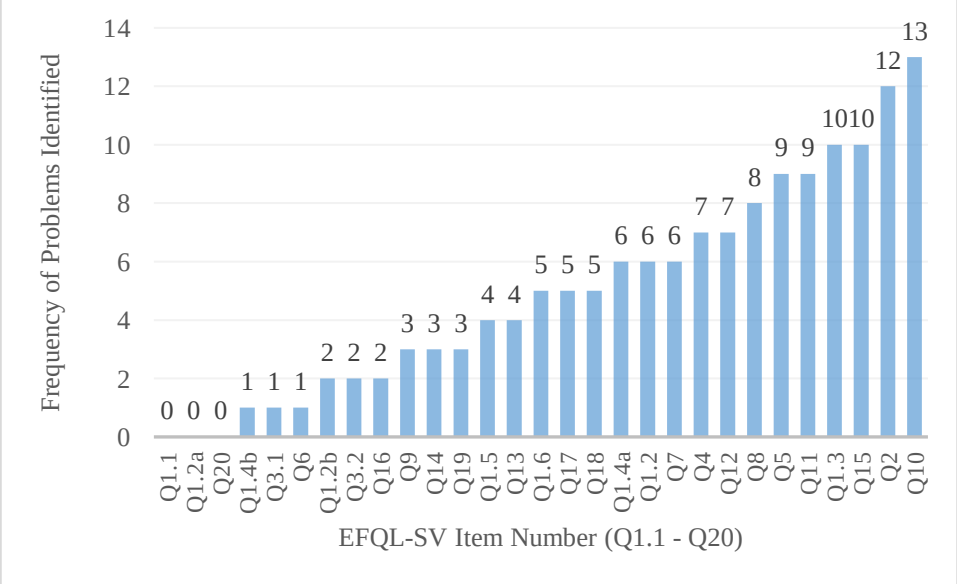

Figure 2. All respondent problems across all EFQL-SV items ordered from least to most problematic.

Suggested Revisions to the EFQL-SV

Table 4 provides a summary of the problems identified alongside a number of suggestions to improve the EFQL-SV. Suggested revisions are re-wordings or re-ordering of words.

Table 4
Summary of All Types of Respondent Problems Identified During Cognitive Interviews and Suggested FQL-SV Revisions

Original EFQL-SV Item	**Classification of Problem(s) (Lexical, Omission/ Inclusion, Temporal, Logical, Computational) and Response Stages (Understanding, Task Performance, Response Formatting)**	**Suggested Revisions to EFQL-SV Item**
1.1. What is your Date of Birth?	None identified	Original item unchanged
1.2. What is your ethnic background?	A total of six problems were identified with this question Lexical/ Understanding: Five participants misunderstood or were confused by the meaning of the words 'ethnic background' Omission/ Inclusion Task Performance: One participant had difficulty performing the implied task of deciding whether they were British or English in the absence of an explicit decision rule	1.2. What is your ethnic background? **White** • Welsh/ English/ Scottish/ Northern Irish/ British • Irish • Gypsy or Irish Traveller • Any other White background **Mixed/ Multiple ethnic groups** • White and Black Caribbean • White and Black African • White and Asian • Any other Mixed/ Multiple ethnic backgrounds **Asian/ Asian British** • Indian • Pakistani

		• Bangladeshi • Chinese • Any other Asian background **Black/ African/ Caribbean/ Black British** • African • Caribbean • Any other Black/ African/ Caribbean background **Other ethnic groups** • Arab • Any other ethnic group
1.2.a. Where were you born?	None identified	Original item unchanged
1.2.b. How long have lived in the UK?	A total of two problems were identified with this question Omission/ Inclusion Understanding: One participant was unsure of whether Wales was included as part of the UK. One participant omitted to answer the question as they thought it applied to non-UK nationals only	1.2.b. How long have you lived in the UK? • Since birth • Other (please specify)
1.3. How many *months/ years** have you been an inpatient in forensic services?	A total of ten problems were identified with this question Omission/ Inclusion Understanding: Six participants misunderstood or were uncertain of the scope of 'inpatient in forensic services'. Responses erroneously included the time between admissions, care received from community/ outpatient services, non-forensic mental health hospitals, and prison Computational Task Performance: Two	1.3. How many months/ years have you lived in this secure hospital for? 1.3.a. Have you come to this secure hospital straight from another secure hospital? • Yes • No If yes, how long have you been in secure hospitals for all together?

	participants had difficulty recalling information from a long period of time so gave approximate answers Lexical Understanding: Two participants did not understand the meaning of 'forensic services'	
1.4.a. How many other residents live with you in the unit?	A total of six problems were identified with this question Omission/ Inclusion Understanding: Five participants were uncertain of the scope of 'unit' and whether this included the whole hospital 'unit' or their ward. Computational Task Performance: One participant had difficulty retrieving information from memory so responded with an approximate answer	1.4.a. How many other patients live with you on the ward?
1.5. What is the highest level of education you have completed?	A total of four problems were identified with this question Omission/ Inclusion Understanding: Two participants omitted their vocational qualifications or highest level of schooling completed believing that only academic qualifications were appropriate for inclusion. One participant omitted their qualifications or highest level of schooling believing that only education completed in hospital was appropriate for inclusion Omission/ Inclusion Response Formatting: One participant introduced their own response category,	1.5. What is the highest level of education you have completed? • No qualifications • O levels/ CSEs/ GCSEs (any grades) • AS levels, A levels • College course (please specify) • University (please specify) • Other vocational/ work related qualifications • Other (please specify)

	'poor', which deviates from the categories intended by the developers	
1.6. What is your gender?	A total of five problems were identified with this question Lexical Understanding: Four participants misunderstood the word 'gender' Sensitivity: One participant misunderstood the word 'gender' and subsequently indicated the question was of a sensitive nature	1.6. What is your gender? • Male • Female • Transgender • Gender Variant/ Non-Confirming • Other (please specify) • Prefer not to say
2. In general, do you derive enjoyment from your day-to-day activities?	A total of twelve problems were identified with this question Lexical Understanding: Seven participants were unsure of the meaning of 'derive' and one participant rated how many activities they were doing, rather than their enjoyment of them Temporal Understanding: One participant had difficulty understanding the time period to which 'in general' applies Temporal Response Formatting: One participant had difficulty mapping their response to the singular response option Omission/ Inclusion Understanding: One participant included enjoyment of the hospital environment, as well as of day-to-day activities in their response Omission/ Inclusion Response Formatting:	2. In general, do you enjoy your day-to-day activities?

	One participant provided a 'Yes/ No' response, which differs from the response option available	
3.1. Do you have leave?	One problem was identified with this question. Omission/ Inclusion Understanding: One participant sought clarity on whether grounds leave was considered within the scope of 'leave' in this question	Original item unchanged
3.2. Are you satisfied with your current leave? (Supervised leave or no leave outside the hospital)	Two problems were identified with this question. Computational Understanding: One participant had difficulty processing the question due to its syntax Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	3.2. Are you satisfied with your current leave? (This can be supervised leave, unsupervised leave, or no leave outside the hospital)
4. Do you feel safe on the unit?	A total of seven problems were identified with this question. Omission/ Inclusion Understanding: Three participants included whether they were safe enough with themselves in their responses. Two participants focused exclusively on physical safety and omitted to consider 'safe' in terms of therapeutic/ psychological containment Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response	4. Do you feel physically and emotionally safe on the ward? (For example, safe from being physically attacked and safe from bullying and being pressured)

	option available. One participant had difficulty mapping their response to the singular response option	
5. In your opinion, do you live in a pleasant environment?	A total of nine problems were identified with this question Omission/ Inclusion Understanding: Five participants understood 'pleasant environment' to be about the quality of their relationships within the environment and omitted the physical attributes of the ward in their response. One participant understood this as to whether they found the environment 'comfortable' but it was unclear whether this was in respect of relationships and/or physical attributes and/ or something else Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available. One participant had difficulty mapping their response to the singular response option Computational Task Performance: One participant responded 'Yes', however, was unable to retrieve any examples	5. Are you satisfied with the ward atmosphere and the ward environment?
6. Are you satisfied with the quality of the food?	A total of one problem was identified with this question Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	Original item unchanged

7. Are you satisfied with your opportunities to look after your personal hygiene?	A total of six problems were identified with this question Omission/ Inclusion Understanding: Three participants included hygiene of their bedroom or living space to be within the scope of 'personal hygiene' Lexical Understanding: One participant expressed dissatisfaction with the opportunities available however rated their satisfaction as high, misunderstanding the question to be asking about their ability to utilise 'opportunities to look after your personal hygiene' Computational Task Performance: One participant appeared to be holding information in mind from the previous question Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	7. Are you satisfied with your opportunities to keep yourself and your clothes clean?
8. Are you satisfied with the treatment you receive for your mental health symptoms?	A total of eight problems were identified with this question. Omission/ Inclusion Understanding: Two participants included medical treatment and omitted psychological or therapeutic intervention or other forms of care. One participant included psychological intervention and omitted medical treatment, therapeutic or other care. One participant	8. Are you satisfied with the therapeutic and other forms of treatment you receive for your mental health symptoms?

	included 'treatment programmes' in the scope of 'treatment' but excluded 'talking to people'. One participant included medical treatment and psychological intervention but not other forms of care. Sensitivity: One participant indicated the question was of a sensitive nature Logical Task Performance: One participant was unable to perform the implied task as, in their view, the presupposition that they have mental health problems and receive treatment for mental health symptoms is false Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	
9. Do you rate yourself as healthy?	A total of three problems were identified with this question Omission/ Inclusion Understanding: Two participants included mental health as well as physical health in their responses Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	9. Do you rate yourself as physically fit and healthy?
10. Are you satisfied with the opportunities you receive with regards to your sexuality?	A total of thirteen problems were identified with this question Lexical Understanding:	10.a. Do staff try and support you with any sexual needs you might have? • Yes

	Eleven participants misunderstood 'opportunities you receive with regards to your sexuality' Sensitivity: One participant declined to respond Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	• No • Not applicable 10.b. Are you satisfied with the amount that staff try and support you with any sexual needs you might have?
11. Are you satisfied with the relationship with people outside the unit?	A total of nine problems were identified with this question Omission/ Inclusion Understanding: Four participants either sought clarity on the scope of 'people outside the unit' or expressed uncertainty of who to include. One participant understood the question literally and included two patients whom they regularly see outside the front of the unit in their response Omission/ Inclusion Response Formatting: Four participants provided a response that differed from the response option available	11.a. Are you satisfied with your relationships with family? 11.b. Are you satisfied with your relationships with friends? 11.c. Are you satisfied with your relationships with professionals outside of the hospital?
12. Do you enjoy the contact with the other residents?	A total of seven problems were identified with this question Omission/ Inclusion Understanding: Two participants included patients from other wards in the hospital. One participant included patients inside and outside the hospital	12. Are you satisfied with your relationships with other patients on the ward?

	including those in the community Omission/ Inclusion Response Formatting: Two participants provided a response that differed from the response option available Lexical Understanding: One participant misunderstands 'contact' as physical touching Computational Understanding: One participant had difficulty processing the question due to its syntax	
13. Are you appreciated by the ward staff?	A total of four problems were identified with this question. Omission/ Inclusion Understanding: Two participants included multi-disciplinary team staff to be within the scope of 'ward staff' Lexical Understanding: One participant misunderstood the meaning of the question as asking whether they appreciated the ward staff Omission/ Inclusion Response Formatting: One participant provided a response that differed from the response option available	13. Do you feel valued by the nurses and support workers on the ward?
14. Are there enough people you can turn to when you are having a bad time?	A total of three problems were identified with this question. Logical Task Performance: One participant was unable to perform the task as they	14. Are there enough people to help and support you if you are having a bad time?

	had no information on the matter since the presupposition that they have had 'a bad time' was false Lexical Understanding: One participant misunderstood the question as asking whether they could turn to people, rather than whether there are enough people to turn to Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	
15. Are you satisfied with the degree to which you are able to move freely in the hospital? (For example supervised or unsupervised)	A total of ten problems were identified with this question. Omission/ Inclusion Understanding: Nine participants understood moving from inside to outside of the hospital (i.e. leave) to be within the scope of 'in the hospital' Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	15. Are you satisfied with the freedom you have to move around the ward and inside the hospital?
16. Are you satisfied with the degree to which you are able to make your own decisions in here?	A total of two problems were identified with this question. Logical Task Performance: One participant had difficulty performing the task due to the logic of the question and tension between decision making and being a sentenced prisoner on a hospital order	Original item unchanged

	Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	
17. Are you of the opinion that you have tried to do your utmost?	A total of five problems were identified with this question. Omission/ Inclusion Understanding: Two participants were unsure of what to include whilst considering if they had tried to do their utmost Computational Understanding: One participant considered the influence of other people on their ability to do their utmost Omission/ Inclusion Response Formatting: One participant provided a 'Yes/ No' response, which differs from the response option available	17. Have you done all you can to move on from hospital?
18. Are you able to discuss questions around life, death and religion with a chaplain?	A total of five problems were identified with this question. Lexical Understanding: Three participants misunderstood the question as asking whether they felt personally able to, rather than whether the option was available to them Computational Task Performance: One participant had difficulty performing the task and therefore provided a guess Omission/ Inclusion Response Formatting: One	18. Is a chaplain available to discuss questions around life, death and religion?

	participant provided a 'Yes/ No' response, which differs from the response option available	
19. Have you accepted that you will be living on a secure unit for some time?	A total of three problems were identified with this question. Logical Task Performance: Three participants had difficulty performing the implied task since the presupposition that they would be living on a secure unit for some time was false	19.a. Do you think you will be living in a secure hospital for some time? • Yes • No 19.b. If yes, have you come to terms with this?
20. How would you rate your life in general over the past three months?	None identified	Original item unchanged

Discussion

The aim of the study was to examine the extent to which the EFQL-SV measures what it purports to. Therefore, the study sought to address three research questions:

1. Does the content of participants' responses to the EFQL-SV suggest that the tool is valid for inpatients in UK forensic services?
2. When compared to the intent of the EFQL-SV's developers, can any types of problem be identified in the content of participants' responses?
3. What revisions might be necessary in order to improve the validity of the EFQL-SV?

To address these questions, 15 inpatients in low or medium secure UK forensic services were interviewed using cognitive interviewing. The stated research questions are now returned to in light of findings from the analysis of the cognitive interview data using Conrad and Blair's (1996) respondent problem matrix.

Does the Content of Participants' Responses to the EFQL-SV Suggest That the Tool Is Valid for Inpatients in UK Forensic Services?

The analysis revealed problems in the content of just over a third of total responses from participants (33.8%). This means the EFQL-SV elicited problem-free responses a little under two-thirds of the time (66.2%). Overall, the EFQL-SV elicited more valid than it did problematic responses.

Fewer problems occurred at the task performance stage and the response formatting stage combined (26.95%) than they did at the understanding stage (73.05%). This suggests that when participants were able to parse the questions, they were generally able to perform the implied task using the necessary cognitive processes. The majority of participants (73.3%) were able to subsequently map their responses onto the VAS without encountering difficulty. This may be considered a strength of the tool; however, this would require further investigation because this study did not explore the extent to which participants' responses and justification for their VAS score was consistent with the score itself.

Nonetheless, specific items on the EFQL-SV were particularly problematic (Q1.3, Q2, Q10, Q15) having elicited 10 or more problematic responses from participants. This appears likely to constitute a threat to the overall validity of the EFQL-SV.

When Compared to the Intent of the EFQL-SV's Developers, Can Any Types of Problem Be Identified in the Content of Participants' Responses?

A number of problems emerged through cognitive interviewing with use of the EFQL-SV (*n* = 144). Classifying the problems according to Conrad and Blair's (1996) respondent problem taxonomy yielded omission/ inclusion problems (*n* = 85), lexical problems (*n* = 39), computational problems (*n* = 9), logical problems (*n* = 6), sensitivity problems (*n* = 3) and temporal problems (*n* = 2).

Most problems occurred at the understanding stage (*n* = 103) and were either lexical problems or omission/ inclusion problems, which are also a particular type of lexical problem. This is perhaps unsurprising given that this is a translated measure and more so since the EFQL-SV was not 'back-translated' from Dutch to English (E. C. W. Vorstenbosch, personal communication, February 11th, 2019). This finding is consistent with Drennan's (2003) assertion that problems identified in translated measures may arise from the word meanings of translated items to respondents from another cultural group. The current findings also replicate those of Levin et al. (2009) who used cognitive interviewing to evaluate a Spanish translation of an English questionnaire. Levin et al. (2009) yielded findings to suggest that some words did not convey the intended constructs when translated because word meanings were sometimes different between nationalities.

Willis (2005) acknowledged that when translating questionnaires for use across cultures or nationalities, culturally specific issues may occur that cause problems. Culturally specific issues perhaps belie the number of problems with Q10: '*Are you satisfied with the opportunities you receive with regards to your sexuality?*' In the Netherlands, sexual relationships are permitted in secure units. Many opportunities for sexual expression exist, including access to sex workers, explicit materials, and use of a conjugal visiting suite (Tiwana, McDonald, & Vollm, 2016). This is not the case in the UK where sexual relationships are prohibited in secure units. Tiwana et al. (2016) identified few opportunities for sexual expression in the UK. These consisted of minor forms of physical contact without intimacy and, depending on circumstance, access to erotic novels. These opportunities are less overt than those in the Netherlands and may not have been recognised as such. It seems plausible that Q10 would be more easily understood in the context of the Netherlands, which appears to have a more progressive approach to patient sexuality. No other apparent

culturally specific issues were identified, which is also consistent with Willis (2005) and Levin et al. (2009) who found these to be relatively rare.

What Revisions Might Be Necessary in Order to Improve the Validity of the EFQL-SV?

Not all of the cognitive interviewing data indicated a need for item repair. However, a number of suggestions for revisions were made to try to ensure the items are capable of being easily understood (Appendix 15). This was thought to be of particular importance since forensic inpatients often have lower levels of literacy than the general population (Greenberg, Dunleavy, & Kutner, 2007).

Although suggestions for revisions were made in this study, within the literature there is little consensus on how to determine when a revision to an item might be necessary. There is no robust specification that a certain number of problems be identified beforehand. Willis (2015) reasoned, "Whether the damage is repaired is up to the researcher" (p. 113). Furthermore, some proponents of cognitive interviewing do not set out to make any revisions, rather their methods are purely descriptive in nature (Ridolfo & Schoua-Glusberg, 2011).

Given that the initial process of back-translation was not conducted (E. C. W. Vorstenbosch, personal communication, February 11th, 2019) the recommendations on what might be necessary in order to improve the validity of the measure should be met with a degree of caution. It would have been beneficial for back-translation to have been conducted in the first instance. It may also have been beneficial to have first examined the factor structure of the translated measure in a statistical validation study. One future possibility is that on account of the number of identified issues with the comprehensibility of the items, back-translation is conducted in retrospect. Another future possibility is that the authors of the measure are consulted with to determine whether the recommendations to change the wording of some items appear to have face validity. Factor analysis could then be used to

determine whether the reworded questions measure what they purport to. Re-examining the factor structure of the measure could present a further opportunity to examine those items that have been found to pose significant difficulties with comprehension for participants (for example, items 2 and 10).

Strengths and Limitations

This study has a number of strengths. Firstly, it is of direct clinical relevance as it examined the comprehensibility of the EFQL-SV with a sample somewhat representative of the diversity found in the target population. Although the sample is slightly over-representative of females in a predominantly male clinical population (Somers & Bartlett, 2014), representation of both genders was important to reduce the potential for gender differences in understanding/ responding to act as a confounding variable. Secondly, a number of steps were taken to improve the study's methodological rigour. The first author attended training in the practice of cognitive interviewing and assessed inter-rater reliability to examine agreement of coding problems in the content of participants' responses. Agreement for classification of types of problems although 'moderate' was much lower than agreement for the presence of a problem, which was 'very good'. This may in part be explained by the second rater's relative lack of familiarity with analysis using Conrad & Blair's (1996) respondent problem matrix. Finally, the analysis was reparative in nature such that the study has the potential to quickly influence clinical practice.

There are a number of limitations to the study. Firstly, there are limitations to the recruitment method and sample size. There is potential for undercoverage bias given that direct care teams only identified 47 out of 85 inpatients (55.29%) as being eligible for participation. The potential for undercoverage bias may be even greater since direct care teams only recruited from six out of a possible 13 wards across the two hospitals. This is not

to say that inpatients from the other 7 wards would be unable to complete the EFQL-SV, but rather that their direct care teams did not identify them as eligible to participate in research. There is also the potential for voluntary response bias since only inpatients whom opted-in and provided their ongoing consent were interviewed. Overall, the extent to which inferences can be drawn from the sample given the recruitment method is limited. One reason for there being no recruitment from a particular ward was that the ward provides conditions of security for individuals with cognitive impairment or intellectual disabilities. A review of inpatients on the ward by the direct care team determined no one met eligibility criteria on account of substantial reading difficulties. This begs the question of how best to measure quality of life in those who cannot access self-report measures. One option may be to have ward staff offer guidance on how items on the EFQL-SV should be comprehended, however, this assumes staff have a clear understanding of the developer's intended meaning of questions. Another limitation with the sample is due to its size of 15. This number is at the upper limit of what is by some considered as convention (Peterson et al., 2017). It is also more than 12, which Guest, Bunce and Johnson (2006) concluded is sufficient for 'saturating' cognitive interview results. However, Blair, Conrad, Ackerman and Claxton (2006) asserted that some problems may not be identified until upwards of 50 cognitive interviews have taken place. As the aims of the current study were to identify and repair any problematic items, it was considered that efforts were best placed interviewing a smaller sample so that major problems could be identified and repaired before further iterations of cognitive interviewing. This is consistent with the position that Willis (2015) has taken who argued that the number of interviews necessary depends on the aims of the research. Secondly, the process of deciding whether identified problems required revision was highly subjective on account of there being little guidance on this within the literature (Willis, 2015). One way to counter this might have been to adopt a purely descriptive approach to problem classification as practised by Behr, Braun,

Kaczmirek and Bandilla (2014), however, this would not have allowed for addressing the study's third research question. Finally, it may be that the proposed reworded questions do not help with response errors in the way that is intended. However, this can only be determined through further iterations of cognitive interviewing.

Implications

In this study, the EFQL-SV sometimes elicited responses that suggested that what was actually being measured differed to the constructs intended to be measured. This empirically derived knowledge was used to repair a number of items on the EFQL-SV. Therefore, the main implication is that a serviceable quality of life measure may now exist. If the validity of the revised measure is substantiated through further iterations of cognitive interviewing and factor analysis, this will be of potential benefit to thousands of inpatients across UK forensic services. It will also be of benefit to services who will be able to use the measure to capture whether approaches that purport to enhance quality of life are doing so.

Directions for Future Research

A future study comprising a further iteration of cognitive interviewing and the use of statistical methods is required to rigorously validate the EFQL-SV. Future research may wish to harness the EFQL-SV to delineate the relationship between quality of life, challenging behaviour, leave status, mental state and other variables of interest. Consideration of how best to measure quality of life in those who cannot access self-report measures should also be the target of future research. It may be that ward staff could guide completion of the EFQL-SV, but the assumption that staff understand the developer's intended meaning should first be determined empirically in a further iteration of cognitive interviewing.

Conclusion

Findings from this study indicate participants had difficulty with a number of items on the EFQL-SV. Most problems occurred at the level of understanding and were to do with either the meaning of particular words or determining whether certain concepts were within the scope of words in the question. Hence, the EFQL-SV was found unlikely to be sufficiently valid for use in UK forensic services. With the view to improve the measure's construct validity, revisions to a number of items were proposed. Future research should statistically assess the revised EFQL-SV's factor structure to compare against that of the original FQL-SV (Schel et al., 2017). It should also comprise a further iteration of cognitive interviewing to examine whether these revisions have been successful. Further work is needed to rigorously validate the revised EFQL-SV. Nonetheless, this study has contributed to the development of a tool that could be used as a benchmark against which to routinely measure changes in quality of life for inpatients in UK forensic services.

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Critical Evaluation of the Systematic Review and Empirical Research Study

Amber Simler

School of Psychology, Cardiff University

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Introduction

The overarching aim of this review is to critically evaluate the research process as a whole. To realise this aim, I will firstly provide a description of the inception of the project. This will include how the systematic review and empirical paper relate to one another. Following this, I will consider some of the key strengths and weaknesses of the systematic review. Lastly, I will consider some of the key strengths and weaknesses of the empirical research study.

Link Between the Systematic Review and Empirical Research Study

The Department of Health (2014) produced guidance for all UK health and social care settings wherein individuals are known to be at risk of exposure to restrictive practices, including secure forensic services. The guidance advocates for the use of Positive Behavioural Support (PBS; Horner et al., 1990) as an approach to minimise the use of restrictive practices. The systematic review set out to examine the effectiveness of PBS for adult service users across secure and other health and social care settings. The empirical research study set out to validate the English translation of the Forensic Quality of Life Questionnaire - Short Version (FQL-SV; Schel, Bouman, Vorstenbosch, & Bulten, 2017). The study developed from the recognition that the extent to which the effectiveness of PBS for adults in secure services could be understood was limited by the lack of valid and reliable measures of quality of life. Given that PBS is an approach that purports to be effective via enhancing quality of life, I hoped this empirical research study would be of relevance and potential utility to service users and clinicians alike.

Systematic Review

Within this section, I aim to provide a critical appraisal of the systematic review process. This will include how I identified a review question, developed a search strategy identified relevant studies, selected and applied a quality appraisal tool, and extracted and reported data from the studies. I aim to consider the strengths and weaknesses of some of the key decisions I took during the process. Finally, I will discuss the review's implications for research, clinical practice and service development.

Identification of the Systematic Review Question

I was interested to hear of the application of PBS to a range of novel settings, including secure inpatient services. It was as a Healthcare Assistant in secure inpatient services where I first began to notice how certain contextual variables appeared to predict instances of 'challenging behaviour'. At around the same time, I noticed that challenging behaviour and other related problems were all too often located entirely within the service user. During clinical psychology training I have continued to be interested in approaches that recognise challenging behaviour and other problems to exist between and not within people. I came to realise that as well as behavioural change, PBS involved systemic change (Carr et al., 2002). This piqued my interest. One thing in particular that drew me to this broad area of research was the will to understand how the implementation of PBS in secure services worked in practice. I found it difficult to reconcile the ethos of PBS with the UK model of secure service delivery because they seemed to oppose one another in many ways.

After learning that UK health and policy guidance recommended PBS for use in secure services, I assumed that high-quality published studies and practice-based evidence would underpin this. This meant that I initially posed a systematic review question that would allow me to examine how effective PBS is for adult service users in secure or other inpatient

mental health services. After some provisional scoping searches, however, I realised that this topic was far too narrow as very few studies appeared to exist. I broadened my search to instead look at the effectiveness of PBS clinically. I was astonished to discover that no one had published a recent systematic review on the effectiveness of PBS for adult service users. When I discovered that the two most recent, most relevant systematic reviews (LaVigna & Willis, 2012; MacDonald & McGill, 2013) were at least seven years old and had not appraised the quality of the included studies, I decided that there was even more cause for me to try and bridge the gap in the literature. I thought that by doing so, the systematic review would be of relevance to service users, carers and/ or family members as well as clinicians, services and commissioners.

Search Strategy

After identifying the systematic review question, I began some initial searches. These searches were selective and included a search using the term, "Positive Behavio* Support" in combination with other terms such as, "efficacy", "effectiveness" or "outcome". I encountered difficulties with this search. It appeared to lack sensitivity as it had not captured various relevant papers that I had identified via Google Scholar. Therefore, I sought advice from the university's specialist subject librarian who suggested I should approach the searches using as wide a term as possible. I used one term, "Positive Behavio* Support", which yielded 1105 papers. At this time, I was concerned that the search lacked specificity. I sought further advice on this from my research supervisors who reassured me that this was acceptable. With the benefit of hindsight, I recognise that a weakness of using a one-word search strategy is that it did not search for the abbreviation, "PBS". However, given that I searched for "Positive Behavio* Support" as a keyword and across all aspects of the published research, I hope that any published studies would have also defined "PBS" with the

full words “Positive Behaviour/ Behavior Support”. A strength of the search strategy was that it was able to recognise both English and American variations in spelling. I also hoped that the breadth of the search strategy would help to ensure that I did not overlook any suitable publications.

Inclusion/ Exclusion Criteria

I replicated the definition of PBS that MacDonald and McGill (2013) used in their systematic review of outcomes following staff training in PBS. This meant that studies were eligible if they identified themselves as delivering PBS somewhere in the text. This is a strength of the review because it reduced the risk of my own personal biases influencing whether an approach constituted PBS or not. However, defining PBS in this way may also be a weakness. There may have been studies of positive approaches/ interventions that fulfilled Gore’s (2013) definition of PBS, yet evaded inclusion because they went by another name.

I made the decision to not use any time period exclusions, however I did exclude studies published in languages other than English and I excluded ‘grey literature’. I excluded ‘grey literature’ because I thought it unlikely to be of high methodological rigour. This is a weakness of the review as by doing this I could have reduced the risk of the review’s susceptibility to publication bias. In hindsight, this may have been particularly worthwhile given the prevalence of $n = 1$ PBS studies. It seems unlikely that any peer-reviewed journal would accept and publish any $n = 1$ studies showing no effect or worsening effects of PBS.

Identification of Relevant Studies

To reduce the risk of reviewer bias, one of my research supervisors and I jointly identified studies for inclusion. This involved reviewing the titles and abstracts of all identified papers against the eligibility criteria following de-duplication. We did not disagree

on any of the decisions to include or exclude studies. Whilst this may be attributable to having a clearly defined set of inclusion and criteria, I now recognise this arrangement may have introduced conformity bias as I might not have disagreed with my supervisor who is far more knowledgeable about PBS than I am. This is a weakness of the study identification process. If I were to do this again, I would have identified the studies separately to my supervisor and met afterwards to determine whether there were any disagreements. To improve this process further, I would consider the suggestion made by Jadad et al (1996) that the process of identifying studies relevant to inclusion can be made more objective through ensuring that reviewers are blind to information that can otherwise introduce selection bias, including author name and academic institution.

Quality Assessment

After identifying studies for review, the diversity in both the quality and methodological design struck me. Given that previous systematic reviews of PBS had not assessed for quality, I knew this would be an important part of the process. I thought about using a number of tools for quality appraisal, each tool selected to suit the different designs of the studies. However, I realised this would make accurate comparison difficult because the weighting of items and scoring systems were different across the tools. Therefore, I searched for a tool capable of appraising diverse designs and found the Quality Assessment Tool for Studies with Diverse Designs (QATSDD; Sirriyeh, Lawton, Gardner, & Armitage, 2011).

I encountered some dilemmas and challenges whilst applying the QATSDD. It seemed to me unfair that when studies did not state a research question or hypothesis, they could not score more than 0 on some items. Application of the QATSDD required me to exercise my own judgement to a degree. At first, I found it difficult to strike a balance between being too permissive with the scoring and being too rigid. The wording of the items

on the QATSDD seemed to exacerbate this too. For example, to score more than 0 on criterion '*Statistical assessment of reliability and validity of the measurement tool(s)*' it is worded in such a way that implies both reliability and validity are required. A score of 0 seems unfair when a study has given a thorough assessment of either one but not the other. I was not surprised to learn that the QATSDD had come under criticism for its vague language (Fenton, Lauckner, & Gilbert, 2015). Similarly, on criterion '*Description of procedure for data collection'* studies had to include '*when, where and how data were gathered'*. Sometimes, I felt that the authors had implied this information although had not clearly stated it. In such cases, I wrestled with how rigidly to apply the criteria. Overall, it felt more justifiable and defensible to apply the criteria stringently. However, I had to keep checking to make sure that I had applied items in the same way across all of the studies to ensure consistency and equitability. I used an Excel spreadsheet to help me to do this. By doing this I also have a log of my justification of every score and a rationale for every decision that I made.

The QATSDD lacks an item that assesses for bias. This is a weakness of my decision to use this tool. I spent time thinking about how I could introduce an assessment of bias. Some ideas I had were to do a whole extra section after applying an assessment of bias tool. I also thought about merging items from an assessment of bias tool with the QATSDD. After some deliberation, I decided against an extra assessment of bias because many studies were bias by virtue of their design and the tools that appraise bias did not seem applicable to all of the studies. Therefore, I thought a compromise would be to review the higher quality studies and think about their susceptibility to bias without using a formal tool to do this.

All QATSDD criteria are of the same weighting. This is a weakness because in my opinion, some criteria are more important than others when determining methodological rigour or quality. To me, important criteria include '*Evidence of sample size considered in*

terms of analysis'. A statistical analysis that is under-powered seems to me to pose more of a threat to the methodological rigour of a study than whether there is '*Evidence of user involvement in design'*. This is not to say that I do not value or hold service user involvement in high regard, on the contrary in fact. I am a strong advocate for co-production wherever possible and I believe it to be especially important for research into PBS given the emphasis on stakeholder participation. It is just that I am not sure this criterion contributes to the methodological rigour of the study in the same way as some of the other criteria do, or in the same way that a criterion that examines risk of bias might. I recognise that had I used a different quality appraisal tool or perhaps developed a bespoke tool that weighed items differently I might have improved upon the quality appraisal process.

A strength of the quality appraisal process was the steps taken to ensure it was more reliable. This included that I asked another trainee clinical psychologist (KW) to act as an independent reviewer. I randomly generated four numbers between 1-15 (meaning 25% of the studies) and allocated these to KW who independently appraised the studies with the QATSDD. Just as I had kept an Excel spreadsheet, I asked KW to keep a log of their decision-making process. This was useful for when we met to discuss our ratings. Although there were a few instances where we clearly disagreed, we resolved these through discussion and recorded any subsequent changes to ratings. A weakness to this process was that KW only reviewed 25% of the studies. Had KW reviewed 100% of the studies this would have been better.

Another challenge I faced with application of the QATSDD tool was that besides providing a percentage out of 100, it does not give any guidance about how to benchmark quality of studies. I decided to add categories in myself to help me structure and organise the review. I came across the GRADE approach, which used 'very low', 'low', 'moderate' and 'high' categories. I thought using the same categories could enhance the specificity of my

review more so than my first idea of how to organise the studies, which was to use 'low', 'medium' and 'high' categories. I thought that by using four instead of three categories this would help me to be more selective in reporting outcomes from studies of lower methodological quality. For example, I used the 'very low' category to exclude one study from the review altogether.

I recognise that other options of structuring my review were available to me. I could have used 'low', 'medium' and 'high' as I first thought of doing. I could have not used any categories at all and described the findings of each study regardless. I could have used 'low', 'moderate', 'high' and 'very high'. In the absence of any clear guidance or consensus about how to organise the quality appraisal section following use of the QATSDD, I am not sure that any of the other options I considered seem to be any more defensible. I also made sure to include the percentage and the exact breakdown of QATSDD scoring to ensure transparency and for readers to be able to disregard the four categories that I imposed altogether if they wished.

Data Extraction

I undertook data extraction alone, which meant that I was more susceptible to the influence of bias than had I had done this with someone else. This is a weakness of the decision I took during this process. However, I hope that I took sufficient steps to mitigate the risk of bias through asking my supervisors to check that I had extracted the data accurately and drawn appropriate conclusions.

Findings and their Implications

The main finding of the review is that there is a paucity of high-quality empirical evidence. This means that we cannot draw any definite conclusions about the effectiveness of

PBS for adult service users. As it stands, the one firm conclusion that we can draw is the requirement for more high-quality research before the empirical status of PBS can be determined either way. In addition to this, there does appear to be some high-quality evidence for PBS leading to reductions to challenging behaviour until at least six months follow up. I hope that one implication of this review be that more funding becomes available for researchers and clinicians to conduct high-quality, well-resourced research. It seems unfair to me that many of the studies were rated as lower quality likely because the researchers and clinicians lacked appropriate resources and infrastructure to support high-quality clinical studies. I hope that the outputs of the review allow researchers to secure funding to conduct RCTs and higher quality research across a variety of clinical settings, not just ID settings, which are able to follow up participants for longer than six months. As a matter of priority, research should examine the relationship between PBS and use of restrictive practices and quality of life.

In terms of implications for research, the findings of the review have made me think about the many questions we do not yet have answers to. These include: do PBS approaches need to include specific evidence-based behavioural interventions in order to be effective? If so, which? Is the lack of evidence for the effectiveness of PBS underpinned by poor implementation? If so, is there a way to improve the feasibility of PBS to implement and sustain? Which components of PBS most contribute to its effectiveness? Could these components be manualised in some way to improve the feasibility of sustained implementation? What is the relationship between the environment/ context and the effectiveness of PBS? These questions are in addition to the areas for further research identified in Paper 1.

Another implication for clinicians in services is that they may feel more able to question whether PBS is the best fit for the presenting situation, rather than see it as the only

available option or the 'go-to' approach because of its popularity and presence in UK health and social care policy. Of course, the values-base of PBS make it an appealing choice and may form part of the rationale for its continued use across services. However, just to play devil's advocate for a moment, I would argue that we work within systems of healthcare where values underpin everything that we do, and sound values also underpin other therapeutic approaches. The point I wish to make is that I am sure that PBS still very much has a place for use across services, but the findings of this review may help to ensure that other approaches are not overlooked whilst we are still determining the status of PBS as an effective or evidence-based intervention.

Theoretical Implications

The findings of this review do not appear to be consistent with PBS's purported mechanism of change, which is that reduction in challenging behaviour occurs are a secondary consequence of quality of life enhancement (Carr et al., 2002). However, it seems to me that quality of life is something of a slippery construct and the ways in which we understand and measure it require further refinement.

Dissemination of Findings

I hope to disseminate the findings of this review as widely as I can. My decision to target the journal Clinical Psychology Review for publication was based on a few factors. Firstly, the journal publishes reviews that either advance the science or clinical practice of clinical psychology. Secondly, it has a wide readership and a high impact factor. Finally, it accepts uninvited systematic reviews of up to 50 manuscript pages long.

I also hope to disseminate the findings at a conference or similar event. I contacted the British Institute of Learning Disabilities in March 2019 to ask whether they had any

forthcoming opportunities for me to talk about the review or present it in a poster format. As I have not yet heard back, I intend to approach the British Psychological Society or Association of Clinical Psychology and see whether I can talk or present a poster at one of their forthcoming conferences or events. I hope to disseminate the findings at a local level and intend to contact the South Wales Intellectual Disabilities Special Interest Group to see whether I might be able to come and talk about the review.

Empirical Research Study

Within this section, I set out to critically appraise the empirical research study. This will include how I identified the quality of life measure, issues of service user involvement, the methodological approach that I chose, the dilemmas I faced with the method of analysis and the limitations of the approach as a whole. I will discuss the study's implications for research, clinical practice and service development. To finish, I will outline my intentions for dissemination.

Identification of the Quality of Life Measure

Although the English version of the FQL-SV (EFQL-SV) was selected for cognitive interview-based validation, I recognise that other quality of life measures exist and could have been examined instead. These include quality of life measures that have been developed for other clinical populations, such as The Guernsey Community Participation and Leisure Assessment (Baker, 2000) and the World Health Organisation QOL Bref (WHO, 2004). The EFQL-SV was chosen above other quality of life measures because it has been developed specifically for use across forensic mental health inpatient services. This means it is considerate of some of the unique aspects of secure environments, including restrictions on leave of the hospital and restrictions on autonomy in the more general sense.

Service User Involvement

By virtue of the clinical population studied, access to service users to involve them in the design and conduct of the study was difficult. I was not able to directly involve service users as much as I would have liked to. This is a weakness of the study design. However, I was fortunate in that I was able to indirectly access service users through one of my supervisors. It was important that my supervisor did this on my behalf so as to comply with research and ethical governance processes. As a result of this, I was able to indirectly capture service user views on some of the proposed materials for the studies, such as participant information and consent forms. I finalised my selection of the materials based upon service user views.

Beyond the design and conduct of the research, the aim of the study itself was to ultimately influence and enhance clinical practice for service users. I thought that if the EFQL-SV appeared to be valid for the specific purpose of measuring quality of life in secure settings, it could form the basis of a standardised and routine way of measuring quality of life for service users. It seemed to me that the mechanisms by which information on quality of life was collected, if collected at all, varied across secure services in the UK. Standardised monitoring of quality of life would provide a clear benchmark against which any subsequent monitoring on quality of life could be considered. I hoped that this would ultimately be of direct benefit to service users and staff who could use the measure whilst care planning. With the benefit of hindsight, I recognise that I could have improved service user involvement further. I could, for example, have explored general adult mental health service user involvement groups locally and asked service users for their input into the design and conduct of the study.

Methodological Approach

The EFQL-SV had already been psychometrically validated by its authors in the Netherlands, but there were concerns from clinicians working in UK secure settings pertaining to its comprehensibility. Cognitive interviewing seemed to be the most feasible and appropriate way to gather the subjective data required to address each of the stated research questions in order to consider its comprehensibility and subsequently its validity. To the best of my knowledge, there is not a more appropriate qualitative nor quantitative research methodology that would have allowed me to consider the comprehensibility of the EFQLS-SV.

A strength of cognitive interviewing is that it asks participants to think aloud. This yields rich data that can elucidate the cognitive processes by which participants arrived at their responses to questionnaire items. A weakness of this approach is that it places cognitive demands on participants. In order for participants to think aloud, it first requires them to learn what thinking aloud is. Whilst some participants had a natural aptitude for this, others seemed to find it peculiar. It also requires participants to retain knowledge of what thinking aloud is long enough so that they are able to keep doing this consistently. Another weakness is that the practice of cognitive interviewing rests on the assumption that participants will be completely transparent when thinking aloud. Although I have no firm evidence to support this, it is plausible that participants did not always say exactly what was going through their mind during the interviews. I am certain that if I were taking part in a cognitive interviewing study, thoughts would pass through my own mind that I would not consider it appropriate or useful to share. There are also other reasons for why perhaps participants may not have been completely transparent when thinking aloud. Within the clinical population, a large proportion are likely to have faced considerable adversity and exposure to traumatic events. Difficulties with trust are likely to emanate from these experiences as well as underpin

clinical presentations including paranoid or suspicious thinking. I imagine that this could reduce the likelihood that participants would feel safe enough to be completely transparent when thinking aloud. It is also possible that response biases, such as social desirability bias, may have influenced participants' thinking aloud. Understandably, participants might not have wanted to share all of their thoughts with someone with whom they were not familiar. Conversely, participants might have felt comfortable to share their thoughts with someone with whom they were not familiar and unlikely to see again, but as a member of staff was present during interviews may not have felt comfortable to think aloud in their presence.

A weakness of selecting a cognitive interviewing methodology is that it does not concern itself with participants' experiences of the questionnaire in terms of whether they consider it to be of importance or relevance to them. Although this was not addressed in the study, it could be an important area for future research. Using semi-structured interviews and a thematic analysis methodology, participants' data could be examined for themes and patterns. This would perhaps yield a deeper understanding of the importance and relevance of the EFQL-SV.

Determining the EFQL-SV Developer's Intent

I was fortunate that the developers of the FQL-SV were kind enough to allow me to use the measure. In addition to this, one of the developers provided me with confirmation of their intent behind each of the items (E. C. W. Vorstenbosch, personal communication, March 27th, 2019). Without this, I would have encountered difficulty during analysis of the data as I would have to work from the assumption that I understood the items in the way the developers intended. Given the findings of the empirical research study, this might well have not been the case. I was also able to consult with a native Dutch speaker and professor of psychology to check the accuracy of the EFQL-SV against the original Dutch FQL-SV.

Analysis of Data

After some deliberation, I decided to use Conrad and Blair's (1996) respondent problem matrix for data analysis. I based this decision on a number of factors. Firstly, it appeared to address the criticism that other methods of analysing cognitive interview data had received: that they are too subjective and impression-driven. To the best of my knowledge, it is one of the more objective and rigorous approaches. Secondly, it was the method of analysis with which I was more familiar and confident with, having used this in a service evaluation project during the first year of the DClinPsy. This is a strength, but it is also a weakness because I understand that other analytic approaches exist that are far less time intensive than the one that I chose. If I had used another analytic approach, I may have saved considerable time and resources and potentially yielded the same findings.

Amongst the other analytic approaches that were available to me were those developed specifically for use with translated measures. I considered using one by Fitzgerald, Widdop, Gray and Collins (2011), however I determined this to be less comprehensive than Conrad and Blair's (1996). Some specific cross-cultural analytical methods required the interviewer to be bilingual, which made the use of these methods infeasible. I also felt justified in this decision after I found evidence to suggest that the problems identified during cognitive interview studies of translated measures tended to be derived from conceptual, retrieval, decision, and response processes errors, which are general and unrelated to culture (Miller et al., 2011).

Another weakness with the decision to take a reparative approach to the analysis of cognitive interview data is that one optimal version of the repaired question is unlikely to exist (Beatty & Willis, 2007). Perhaps this is why I found the process of making repairs to EFQL-SV questions unsatisfactory. In the absence of any guidance on how best to do this, I

wondered whether I was making the right sort of revisions. I recognise, however, that this can easily be determined empirically through a further iteration of cognitive interviewing.

Findings and their Implications

Given that many participants had difficulty with the EFQL-SV, I proposed a number of revisions to items. Therefore, further work is needed to rigorously validate the revised EFQL-SV. This research could be undertaken within the South Wales DClinPsy programme of training. For example, a future project that aims to examine the factor structure of the EFQL-SV with quantitative methods could be offered. Another project could comprise further iterations of cognitive interviewing with staff and service users.

Dissemination of Findings

I hope to disseminate the findings of this empirical research study widely. My decision to target The Journal of Forensic Psychiatry and Psychology came after I contacted the editor, who confirmed that the study would be appropriate to submit for their consideration. I also hope to disseminate the findings at a future Division of Forensic Psychology Annual Conference or similar event.

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Appendix 2.
QATSDD Tool

Table 1 Quality assessment tool and scoring guidance notes

Criteria	0 = Not at all	1 = Very slightly	2 = Moderately	3 = Complete
Explicit theoretical framework	No mention at all.	Reference to broad theoretical basis.	Reference to a specific theoretical basis.	Explicit statement of theoretical framework and/or constructs applied to the research.
Statement of aims/objectives in main body of report	No mention at all.	General reference to aim/objective at some point in the report including abstract.	Reference to broad aims/objectives in main body of report.	Explicit statement of aims/objectives in main body of report.
Clear description of research setting	No mention at all.	General description of research area and background, e.g. 'in primary care'.	General description of research problem in the target population, e.g. 'among GPs in primary care'.	Specific description of the research problem and target population in the context of the study, e.g. nurses and doctors from GP practices in the east midlands.
Evidence of sample size considered in terms of analysis	No mention at all.	Basic explanation for choice of sample size. Evidence that size of the sample has been considered in study design.	Evidence of consideration of sample size in terms of saturation/information redundancy or to fit generic analytical requirements.	Explicit statement of data being gathered until information redundancy/saturation was reached or to fit exact calculations for analytical requirements.
Representative sample of target group of a reasonable size	No statement of target group.	Sample is limited but represents some of the target group or representative but very small.	Sample is somewhat diverse but not entirely representative, e.g. inclusive of all age groups, experience but only one workplace. Requires discussion of target population to determine what sample is required to be representative.	Sample includes individuals to represent a cross section of the target population, considering factors such as experience, age and workplace.
Description of procedure for data collection	No mention at all.	Very basic and brief outline of data collection procedure, e.g. 'using a questionnaire distributed to staff'.	States each stage of data collection procedure but with limited detail, or states some stages in details but omits others.	Detailed description of each stage of the data collection procedure, including when, where and how data were gathered.
Rationale for choice of data collection tool(s)	No mention at all.	Very limited explanation for choice of data collection tool(s).	Basic explanation of rationale for choice of data collection tool(s), e.g. based on use in a prior similar study.	Detailed explanation of rationale for choice of data collection tool(s), e.g. relevance to the study aims and assessments of tool quality either statistically, e.g. for reliability & validity, or relevant qualitative assessment.
Detailed recruitment data	No mention at all.	Minimal recruitment data, e.g. no. of questionnaire sent and no. returned.	Some recruitment information but not complete account of the recruitment process, e.g. recruitment figures but no information on strategy used.	Complete data regarding no. approached, no. recruited, attrition data where relevant, method of recruitment.
Statistical assessment of reliability and validity of measurement tool(s) (Quantitative only)	No mention at all.	Reliability and validity of measurement tool(s) discussed, but not statistically assessed.	Some attempt to assess reliability and validity of measurement tool(s) but insufficient, e.g. attempt to establish test–retest reliability is unsuccessful but no action is taken.	Suitable and thorough statistical assessment of reliability and validity of measurement tool(s) with reference to the quality of evidence as a result of the measures used.
Fit between stated research question and method of data collection (Quantitative)	No research question stated.	Method of data collection can only address some aspects of the research question.	Method of data collection can address the research question but there is a more suitable alternative that could have been used or used in addition.	Method of data collection selected is the most suitable approach to attempt answer the research question
Fit between stated research question and format and content of data collection tool e.g. interview schedule (Qualitative)	No research question stated.	Structure and/or content only suitable to address the research question in some aspects or superficially.	Structure & content allows for data to be gathered broadly addressing the stated research question(s) but could benefit from greater detail.	Structure & content allows for detailed data to be gathered around all relevant issues required to address the stated research question(s).
Fit between research question and method of analysis	No mention at all.	Method of analysis can only address the research question basically or broadly.	Method of analysis can address the research question but there is a more suitable alternative that could have been used or used in addition to offer greater detail.	Method of analysis selected is the most suitable approach to attempt answer the research question in detail, e.g. for qualitative IPA preferable for experiences vs. content analysis to elicit frequency of occurrence of events, etc.
Good justification for analytical method selected	No mention at all.	Basic explanation for choice of analytical method	Fairly detailed explanation of choice of analytical method.	Detailed explanation for choice of analytical method based on nature of research question(s).
Assessment of reliability of analytical process (Qualitative only)	No mention at all.	More than one researcher involved in the analytical process but no further reliability assessment.	Limited attempt to assess reliability, e.g. reliance on one method.	Use of a range of methods to assess reliability, e.g. triangulation, multiple researchers, varying research backgrounds.
Evidence of user involvement in design	No mention at all.	Use of pilot study but no involvement in planning stages of study design.	Pilot study with feedback from users informing changes to the design.	Explicit consultation with steering group or statement or formal consultation with users in planning of study design.
Strengths and limitations critically discussed	No mention at all.	Very limited mention of strengths and limitations with omissions of many key issues.	Discussion of some of the key strengths and weaknesses of the study but not complete.	Discussion of strengths and limitations of all aspects of study including design, measures, procedure, sample & analysis.

Appendix 3.
QATSDD Criteria Scores for Studies Included in the Systematic Review

QATSDD Criteria	**Score (0 = Not at all; 1 = Very slightly; 2 = Moderately; 3 = Completely)**														
1. Explicit theoretical framework	2	3	0	0	3	1	0	3	1	0	1	1	3	3	3
2. Statement of aims/ objectives in main body of report	1	3	2	1	3	1	3	3	3	1	3	3	1	1	2
3. Clear description of research setting	3	3	2	3	3	3	3	3	3	3	3	3	3	3	3
4. Evidence of sample size considered in terms of analysis	0	0	0	0	0	0	3	3	0	0	3	0	0	0	0
5. Representative sample of target group of a reasonable size	1	1	1	1	1	3	3	3	1	1	3	3	1	1	1
6. Description of procedure for data collection	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
7. Rationale for choice of data collection tool(s)	1	0	0	1	2	2	2	2	1	1	2	0	1	2	1
8. Detailed recruitment data	3	3	1	1	3	1	3	3	3	0	2	3	3	1	1
9. Statistical assessment of reliability and validity of measurement tool(s)	0	0	0	0	2	0	1	1	0	0	1	0	0	3	0
10. Fit between stated research question and method of data collection	0	0	0	3	3	0	3	0	0	0	3	0	0	0	3
11. Fit between research question and method of analysis	0	0	0	1	3	0	3	0	0	0	3	0	0	0	1
12. Good justification for analytical method selected	0	0	1	0	3	0	3	2	2	0	3	2	0	0	0
13. Evidence of user involvement in design	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
14. Strengths and limitations critically discussed	2	2	3	2	2	2	2	2	2	0	3	2	2	2	2
Total Score (/ 42; % rating)	16/42; 38.10%	18/42; 42.86%	13/42; 30.95%	16/42; 38.10%	31/42; 73.81%	16/42; 38.10%	32/42; 76.19%	31/42; 73.81%	19/42; 45.24%	9/42; 21.43%	33/42; 78.57%	20/42; 47.62%	17/42; 40.48%	19/42; 45.24%	20/42; 47.62%
	Allen *et al.* (2011)	Arco & Bishop (2009)	Baker (1998)	Bird & Luiselli (2000)	Davies *et al.* (2018)	Gray *et al.* (2013)	Hassiotis *et al.* (2009)	Hassiotis *et al.* (2018)	Inchley-Mort *et al.* (2014)	MacDonald *et al.* (2010)	MacDonald *et al.* (2018)	McClean *et al.* (2005)	McClean *et al.* (2007)	McClean & Grey (2012)	West & Patton (2010)

Appendix 4.
Author Guidance for Journal of Forensic Psychiatry and Psychology Submissions

Instructions for Authors
Thank you for choosing to submit your paper to us. These instructions will ensure we have everything required so your paper can move through peer review, production and publication smoothly. Please take the time to read and follow them as closely as possible, as doing so will ensure your paper matches the journal's requirements. For general guidance on the publication process at Taylor & Francis please visit our Author Services website.

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- case reports
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Should be written with the following elements in the following order: title page (including Acknowledgements as well as Funding and grant-awarding bodies); abstract; keywords; main text; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figure caption(s) (as a list).
Should be no more than 5000 words, inclusive of the abstract, tables, figure captions, footnotes, endnotes.
Should contain an unstructured abstract of 200 words.
Between 3 and 6 keywords. Read making your article more discoverable, including information on choosing a title and search engine optimization. Please include a word count.

Should be written with the following elements in the following order: title page (including Acknowledgements as well as Funding and grant-awarding bodies); abstract; keywords; main text; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figure caption(s) (as a list).
Should contain an unstructured abstract of 200 words.

Between 3 and 6 keywords. Read making your article more discoverable, including information on choosing a title and search engine optimization. Case reports should be accompanied by the written consent of the subject. If a subject is not competent to give consent the report should be accompanied by the written consent of an authorized person. Please include a word count.

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References
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Checklist: What to Include

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2. You can opt to include a video abstract with your article. Find out how these can help your work reach a wider audience, and what to think about when filming.
3. Funding details. Please supply all details required by your funding and grant-awarding bodies as follows: For single agency grants
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Appendix 5.
Consent to be Contacted for Research Purposes Form

NHS WALES GIG CYMRU

School of Psychology
Ysgol Seicoleg

South Wales Doctoral Programme in Clinical Psychology
De Cymru Rhaglen Doctoraidd mewn Seicoleg Glinigol

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

Cardiff University
Tower Building
Park Place
Cardiff CF10 3AT
Wales UK
www.cardiff.ac.uk/psych

Prifysgol Caerdydd
Adeilad y Tŵr
Plas y Parc
Caerdydd CF10 3AT
Cymru Y Deyrnas Unedig

CONSENT TO BE CONTACTED FOR RESEARCH PURPOSES

TITLE: *How do inpatients in UK secure settings comprehend the Forensic Inpatient Quality of Life Questionnaire (FQL-SV)? Findings from a cognitive interview study.*

SPONSOR: *Cardiff University*

INVESTIGATORS: *Amber Simler, Dr Christopher Harwright, Dr Bronwen Davies*

What is the purpose of this consent?
We are interested to know how people who are cared for in UK secure services make sense of a particular questionnaire: the Forensic Inpatient Quality of Life Questionnaire (FQL-SV).

By signing this form, you will be providing your consent for Amber Simler, Principle Investigator, to contact you in the near future to invite you to participate in the above-named research project.

What happens if I sign this form?
If you decide to sign this form, you will be providing your consent for the investigators to have your full name, as well as details of the hospital providing your care, for example, the ward name and hospital name.

If you decide to sign this form, you have no obligation to actually participate in the above-named study and can withdraw your permission to be contacted at any time by contacting the investigators on: 02920870582.

What happens if I do not sign this form?
If you decide not to sign this form, we will not be able to contact you to ask whether you would like to participate in the above-named study. You do not need to do anything further.

What information will you have access to if I sign this form?
If you decide to sign this form, we will have access to your full name, as well as the name of the ward and hospital that are currently providing your care. This is so that we can make contact with you to tell you more about the above-named study.

What if I have questions about providing consent to be contacted?
You are welcome to contact the investigators on: 02920870582 if you have any questions or concerns about providing consent to be contacted.

NHS WALES GIG CYMRU
School of Psychology
Ysgol Seicoleg
South Wales Doctoral Programme in Clinical Psychology
De Cymru Rhaglen Doctoriaeth mewn Seicoleg Glinigol
CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
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Tower Building
Park Place
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Wales UK
www.cardiff.ac.uk/psych
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Caerdydd CF10 3AT
Cymru Y Deyrnas Unedig

REPLY SLIP

Are you willing to learn more about the *'How do inpatients in UK secure settings comprehend the Forensic Inpatient Quality of Life Questionnaire (FQL-SV)? Findings from a cognitive interview study' study?* (Circle one)

YES NO

If yes, you will be contacted at a later date. Please provide your full name, ward and hospital details below.

Name: _____

Ward and Hospital Name: _____

By signing this form, you are giving permission for your health care provider to disclose your full name, as well as the name of the ward and hospital that are currently providing your care, to the investigators for the purpose of being contacted to learn more about the research study, '*How do inpatients in UK secure settings comprehend the Forensic Inpatient Quality of Life Questionnaire (FQL-SV)? Findings from a cognitive interview study' study.'*

By signing this form, your consent is effective immediately. You can, however, withdraw your consent at any time by contacting the investigators on: 02920870582.

Patient's Signature: _____

Date: _____

Appendix 6.
English Translation of the FQL-SV

FQL-SV

Forensic Inpatient Quality of Life questionnaire – Short Version

Quality of Life Questionnaire *(Short Version)*

for patients

in long-term forensic psychiatric care

Client version

Client's name: _____

Date: _____

Address/location: _____

Name of staff member: _____

FQL-SV

Forensic Inpatient Quality of Life questionnaire – Short Version

Instruction

This questionnaire is aimed at creating a shared understanding of certain aspects of your everyday life, such as your daily routine, your health and your social life. In the questionnaire you are asked to rate YOUR level of satisfaction in each of these areas, there are no right or wrong answers. Once the questionnaire has been completed, it will be dealt with in a confidential manner.

You are asked to rate the extent to which you agree or disagree with certain statements. To do this, you are asked to put a small vertical mark on the horizontal line.

The more you disagree with the statement, the further to the left your mark will go.

Not at all —|— Completely

Similarly the further right you put the mark, the more you agree with the statement.

Not at all —|— Completely

You may find some questions quite difficult, if this is the case, you can discuss them with a member of staff.

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Personal Details

1.1. What is your Date of Birth? _____

1.2. What is your ethnic background? _____

1.2.a. Where were you born? _____

1.2.b. How long have lived in the UK? _____

1.3. How many *months/years** have you been an inpatient in forensic services? _____

1.4.a. How many other residents live with you in the unit? _____

1.4.b. With how many other residents do you share your bedroom? _____

1.5. What is the highest level of education you have completed? _____

1.6 What is your gender? _____

* *delete as appropriate*

FQL-SV
Forensic Inpatient Quality of Life questionnaire – Short Version

2. In general, do you derive enjoyment from your day-to-day activities?
Not at all _____ Completely

3.1 Do you have leave? Yes / No

3.2 Are you satisfied with your current leave? (Supervised leave or no leave outside the hospital)
Not at all _____ Completely

4. Do you feel safe on the unit?
Not at all _____ Completely

5. In your opinion do you live in a pleasant environment?
Not at all _____ Completely

6. Are you satisfied with the quality of the food?
Not at all _____ Completely

7. Are you satisfied with your opportunities to look after your personal hygiene?
Not at all _____ Completely

8. Are you satisfied with the treatment you receive for your mental health symptoms?
Not at all _____ Completely

9. Do you rate yourself as healthy?
Not at all _____ Completely

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10. Are you satisfied with the opportunities you receive with regards to your sexuality?
Not at all _____ Completely

11. Are you satisfied with the relationship with people outside the unit?
Not at all _____ Completely

12. Do you enjoy the contact with the other residents?
Not at all _____ Completely

13. Are you appreciated by the ward staff?
Not at all _____ Completely

14. Are there enough people you can turn to when you are having a bad time?
Not at all _____ Completely

15. Are you satisfied with the degree to which you are able to move freely in the hospital? (For example supervised or unsupervised)
Not at all _____ Completely

16. Are you satisfied with the degree to which you are able to make your own decisions in here?
Not at all _____ Completely

17. Are you of the opinion that you have tried to do your utmost?
Not at all _____ Completely

18. Are you able to discuss questions around life, death and religion with a chaplain?
Not at all _____ Completely

FQL-SV
Forensic Inpatient Quality of Life questionnaire – Short Version

19. Have you accepted that you will be living on a secure unit for some time?
Not at all _____ Completely

20. How would you rate your life in general over the past three months?
The best possible life _____ The worst possible life

Thank you very much for filling in this questionnaire.

If you were unable to complete any questions, please notify a member of staff when you return the questionnaire.

Comments:

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Appendix 7.
Participant Information Form(s)

School of Psychology
Ysgol Seicoleg

South Wales Doctoral Programme in Clinical Psychology
De Cymru Rhaglen Doethuriaeth mewn Seicoleg Glinigol

PARTICIPANT INFORMATION FORM

TITLE: *How do service users in secure settings understand the Forensic Inpatient Quality of Life Questionnaire (FQL-SV)? Findings from a cognitive interview study.*

SPONSOR: *Cardiff University*

INVESTIGATORS: *Amber Simler, Dr Christopher Harwright, Dr Bronwen Davies*

The study
Hello, and thank you for your interest in the project. My name is Amber Simler and I am a Trainee Clinical Psychologist on the South Wales Doctoral Programme in Clinical Psychology (DClinPsy).

I am looking to interview 20 service users in forensic settings to see how they make sense of the Forensic Inpatient Quality of Life Questionnaire (FQL-SV). Before you agree to take part in the study, please read the information below.

If you decide to take part in the study, I will meet with you for about an hour. As you work through the questionnaire I will ask you things like: (i) what you thought each question meant; (ii) how you decided on the score you gave; and (iii) how important you thought each question was to your quality of life.. This will help me to see whether the questionnaire is useful or not.

Keeping your information private
All information you give me will be kept *confidential*, this means that no one will know what you have said to me and your answers will only be seen by me. Your name will not be on the questionnaire so no one will know the answers are from you. The only time I would need to pass information about you to other people would be if you told me something that I thought was a risk to either yourself or someone else. If I need to pass on information to other people, I will do my best to let you know before I do this.

What will you do with my information?
I will be using a dictaphone to record our interview. This is to make sure that I record your answers correctly. The recording will be saved onto a secure computer and will be proteted by password so only I will access it. I will also give the saved file a number so your name is not linked with it to make sure your information is kept private and confidential. The final write-up of the study may include things you have said but your name will not be used.

Are there any risks to taking part?
Questions you are asked will get you to think about your quality of life, which you may feel sad about. If this happens you can take a break at any time. You may also want to stop the interview and this is okay. We will make sure you have support from ward staff during or after the interview if you need it.

Are there any benefits to taking part?
There is no direct benefit to you for taking part. However, if the questionnaire seems to be useful, it may become a routine way of asking service users in forensic settings about their quality of life so that it can be improved upon.

Can I stop being in the study?
You are able to stop being in the study at any time. If you want to do this, all of your information and the answers you gave me in the interview will be removed. The recorded file saved on the computer will also be deleted.

Results of the study
It is my hope that the results of the study will be published in a journal. This will help to make sure that servce users in forensic settings have ways to talk about their quality of life. Your name would not be printed in any journal. If you want information about the results of the study, let me know and I will send this to you when the study is finished.

Payment for taking part
To thank you for taking part in the study, you will receive a £5 Amazon gift voucher.

What if I have a question of a complaint?
If you wish to make a complaint or ask a question about the study, please contact my Supervisor, Dr Christopher Hartwright, on: 02920870582.

If you would like to raise a formal complaint, I can give you a leaflet called *'Putting Things Right'*. Any formal concerns will be looked at under the policy, '*NHS Concerns, Complaints and Redress Arrangements (Wales) Regulations'*.

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PARTICIPANT INFORMATION FORM – EASY READ

TITLE: *How do inpatients in UK secure settings comprehend the Forensic Inpatient Quality of Life Questionnaire (FQL-SV)? Findings from a cognitive interview study.*

SPONSOR: *Cardiff University*

INVESTIGATORS: *Amber Simler, Dr Christopher Harwright, Dr Bronwen Davies*

If you need help to read this form a person who is not part of the research team can read it to you. They will act as a witness who will sign this form to show it has been read to you. Please sign the form at the end to show you have read the form or that you have had this read to you.

Hello, my name is Amber and I am a trainee psychologist. I am talking to people in secure care to find out if a questionnaire works well.	
The questionnaire is called the Forensic Inpatient Quality of Life Questionnaire (FQL-SV). This is for a research project.	
It is important that you have all the information about the project before you decide if you want to be involved.	

It is up to you if you want to take part in the research. You will be able to say no without giving a reason. Your medical care will not be affected. If you decide to take part and later change your mind, this is OK and you do not have to give a reason. You will be able to withdraw from the study up until it is published.	
If you agree top take part, the interview could last for around 1 hour	
Your answers to my questions will be confidential. This means that I will not tell anyone else what you said, unless you tell me something that makes me worried that you or others are at risk. I might also need to tell others if you tell me about a crime that has not been reported. If I do need to tell someone else, I will try to talk to you first.	
I will be audio recording the interviews with a dictophone to make sure I record everything you say before typing it up. This will be stored securely. Once the interview has been typed up, the audio recording will be deleted.	
You may find that being asked to think about your quality of life is upsetting.	

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If you become upset, you can take a break or stop the interview at any time.	
The information you provide will be kept private. Any personal information that could identify you will be removed. No one will know it is you except us.	
You will receive a £5 Amazon voucher to say thank you for taking the time to be interviewed.	
If you would like a copy of the results when the project is finished, I can send you a summary. Please let me know if you would like this.	
NHS research needs to be agreed by a group of people called the Research Ethics Committee. This is to make sure you are protected. This study has been agreed by them. **(not obtained at present, IRAS to be completed)**	 
This research will be submitted as part of a Doctorate in Clinical Psychology. It will also be submitted for publication. No-one will be able to identify you in the project	

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or the publication.	
On of your care team will ask you if you want to take part in the project. Please let them know your decision. If you choose to take part an appointment will be arranged by myself (Amber). We will go through this information sheet and a consent form you will be asked to sign.	☑ **I Agree**
If you have any concerns about the study, you can call Dr Christopher Hartwright on 029 208 705 82.	

Name of Participant (Please Print):……
Date:……
Signature:……..

Name of Researcher (Please Print):……
Date:……
Signature……..

Name of Witness (Please Print):……
(*if applicable*)
Date:……
Signature……

Appendix 8.
Participant Consent Form

School of Psychology
Ysgol Seicoleg

South Wales Doctoral Programme in Clinical Psychology
De Cymru Rhaglen Doctoriaeth mewn Seicoleg Glinigol

INFORMED CONSENT FORM

TITLE: *How do service users in secure settings understand the Forensic Inpatient Quality of Life Questionnaire (FQL-SV)? Findings from a cognitive interview study.*

SPONSOR: *Cardiff University*

INVESTIGATORS: *Amber Simler, Dr Christopher Harwright, Dr Bronwen Davies*

Overview
If you wish to participate, please complete this consent form after you have carefully read the Participant Information Sheet and/ or have listened to an explanation of the research. After each statement, please write your initials in each of the boxes and provide your signature at the end.

Keeping your information private
All information you give me will be kept *confidential*, this means that no one will know what you have said to me and your answers will only be seen by me. Your name will not be on the questionnaire so no one will know the answers are from you. The only time I would need to pass information about you to other people would be if you told me something that I thought was a risk to either yourself or someone else. If I need to pass on information to other people, I will do my best to let you know before I do this.

Participant's statement
I agree that:

1.	I voluntarily agree to participate in the above named project.	
2.	I have read the Participant Information Sheet, and understand what the study involves.	
3.	I have been given the opportunity to ask questions about the study and my participation. Where applicable, questions about the purpose of the project have been answered sufficiently.	
4.	I agree to be interviewed for the study.	
5.	I understand that my participation will be audio-recorded and transcribed and I consent to the use of this material as part of the study.	
6.	I understand that I can withdraw at any time without needing to give an explanation and that I will not be penalised for withdrawing.	

Cardiff University
Tower Building
Park Place
Cardiff CF10 3AT
Wales UK
www.cardiff.ac.uk/psych
Prifysgol Caerdydd
Adeilad y Tŵr
Plas y Parc
Caerdydd CF10 3AT
Cymru Y Deyrnas Unedig

7.	The procedures regarding confidentiality have been clearly explained to me.	
8.	I understand that clinical supervisors and tutors from the South Wales Doctoral Programme in Clinical Psychology may view my anonymised data.	
9.	I understand that my anonymised data will be included in an assignment for the South Wales Doctoral Programme in Clinical Psychology. This data may include direct quotations.	
10.	I understand that the write up of this study, including my anonymised data, may be published.	
11	I agree to sign and date this informed consent form.	

Name of Participant (Please Print):……
Date:……
Signature:……..

Name of Researcher (Please Print):……
Date:……
Signature……..

Name of Witness (Please Print):……
(*if applicable*)
Date:……
Signature……

Appendix 9.
Standardised Cognitive Interviewing Instructions and Training Task

Introduction

What I would like you to do is to read and fill out this questionnaire. The only difference is I want you to say out loud what you are thinking and reading. This is called 'thinking aloud'. There are no right or wrong answers, I just want you to say, out loud, the thoughts that come into your mind when you are reading the question. After each question, I may ask you a couple of extra questions.

Is that all okay so far?

Practicing 'thinking aloud'

Thinking aloud may feel a bit strange, so it is best to practice first. I will also go through an example with you.

If I were asked, 'How many times have you spoken to a doctor in the last month?' and if I were thinking out aloud, I would say:

'Well, I've not been to the GP or spoken to one on the phone, but I might have spoken to doctors at work a couple of times… I'm not sure the question is meaning that, so I'll say none in the last month'

So, you can see how I got to my answer. Does that make sense?

Now let me ask you the same question, 'How many times have you spoken to a doctor in the last month?'

Second practice of 'thinking aloud' if necessary

I want you to tell me how many windows there are in your bedroom. Try to imagine what your bedroom looks like and think about how many windows there are. As you count up the windows, tell me what you are seeing and thinking about.

Appendix 10.
Cognitive Interview Probes

Forensic Inpatient Quality of Life Questionnaire – Short Version (FQL-SV)	**Pre-Prepared/ Scripted Probes**	**Spontaneous Probes**
1.1. What is your Date of Birth?		*Observation probe:* I noticed that you spent some time on that/ answered that quickly/ hesitated when you answered - can you tell me what you were thinking about? *General probe:* What were you thinking of when you answered that? *General probe:* What went through your mind when answering that question? *General probe:* How did you come up with that answer? *General probe:* How do you know that? *General probe:* What did you think of when you answered this? *General probe:* How did you go about working out the answer to that question? *General probe*: What were you thinking about when you read this? *General probe:* Was that easy or difficult to answer? Why was that? *General probe:* What were you thinking just then? *General probe:* What are you thinking about now?
1.2. What is your ethnic background?	*Comprehension probe*: What do you think 'ethnic background' means?	
1.2.a. Where were you born?		
1.2.b. How long have lived in the UK?		
1.3. How many *months/ years* have you been an inpatient in forensic services?		
1.4.a. How many other residents live with you in the unit?		
1.4.b. With how many other residents do you share your bedroom?		
1.5. What is the highest level of education you have completed?		
1.6. What is your gender?		
2. In general, do you derive enjoyment from your day-to-day activities?	*Comprehension probe:* What does 'derive' mean to you? *Specific probe:* How would you know if you had derived enjoyment from your day-to-day activities?	
3.1. Do you have leave?	*Comprehension probe:* What do you understand 'leave' to be?	
3.2. Are you satisfied with your current leave? (Supervised leave or no leave outside the hospital)		
4. Do you feel safe on the unit?	*Comprehension probe:* What does 'safe' mean to you? *Recall/ judgement probe:* What time period were you thinking of when you answered this?	
5. In your opinion do you live in a pleasant		

environment?		*Recall/ judgement probe:* How did you work that out? *Recall/ judgement probe:* How do you remember that? *Recall/ judgement probe:* Can you give an example of '---' ? *Recall/ judgement probe:* What brought that to mind? *Paraphrasing probe:* What would you say that question is asking of you? *Paraphrasing probe:* Using your own words, what do you think that question is asking? *Paraphrasing:* Can you repeat that question back to me using your own words? *Paraphrasing:* What would you say that question is getting at? *Specific probe:* How important is being able to '---'? *Specific probe:* What would '---' look like? *Confidence judgement probe:* How well do you remember this? *Confidence judgement probe:* How sure are you of this? *Comprehension probe:* What does '---' mean to you?
6. Are you satisfied with the quality of the food?		
7. Are you satisfied with your opportunities to look after your personal hygiene?	*Comprehension probe:* In your own words, what is 'personal hygiene'? *Specific probe:* Can you give me an example of an opportunity to look after your personal hygiene?	
8. Are you satisfied with the treatment you receive for your mental health symptoms?	*Comprehension probe:* What does 'treatment' mean to you?	
9. Do you rate yourself as healthy?	*Comprehension probe:* What, to you, does 'healthy' mean?	
10. Are you satisfied with the opportunities you receive with regards to your sexuality?		
11. Are you satisfied with the relationship with people outside of the unit?		
12. Do you enjoy the contact with the other residents?		
13. Are you appreciated by the ward staff?	*Comprehension probe:* What do you think 'appreciated' means here?	
14. Are there enough people you can turn to when you are having a bad time?	*Specific probe:* Can you give me an example of people you can turn to when you are having a bad time?	
15. Are you satisfied with the degree to which you are able to move freely in the hospital (for example, supervised or unsupervised)		
16. Are you satisfied with the degree to which you are able to make your own decisions here?		
17. Are you of the opinion that you have tried to do your utmost?	*Comprehension probe:* What do you think 'utmost' means here?	
18. Are you able to discuss questions around life, death and religion with a chaplain?		
19. Have you accepted that you will be living on a secure unit for some time?		
20. How would you rate your life in general over the past three months?		

Appendix 11.
Participant Debrief Form

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PARTICIPANT DEBRIEF SHEET

TITLE: *How do service users in secure settings understand the Forensic Inpatient Quality of Life Questionnaire (FQL-SV)? Findings from a cognitive interview study.*

SPONSOR: *Cardiff University*

INVESTIGATORS: *Amber Simler, Dr Christopher Harwright, Dr Bronwen Davies*

The study
Thank you very much for taking part in the study.

The purpose of the study is to find out whether the questionnaire is understood by service users in forensic settings in the way that we would hope them to.

If you would like a copy of the results when the study is finished, I can send you a sumamary. Please let me know if you would like me to do this.

Further support
Thinking about your quality of life may have been difficult for you. You may feel sad as a result of this. If you feel sad or as though you would like further support, ward staff are available to talk to.

What will you do with my information?
Your information will be kept confidential, this means that no one will know what you have said to me and your answers will only be seen by me. The final write-up of the study may include things you have said but your name will not be used.

What if I have a question or a complaint?
If you wish to make a complaint or ask a question about the study, please contact my Supervisor, Dr Christopher Hartwright, on: 02920870582.

If you would like to raise a formal complaint, I can give you a leaflet called 'Putting Things Right'. Any formal concerns will be looked at under the policy, 'NHS Concerns, Complaints and Redress Arrangements (Wales) Regulations'.

Thank you again for taking the time to participate in the study.

Appendix 12.
Confirmation of Ethical Approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Wales REC 3
Health and Care Research Wales Castlebridge 4
15 – 19 Cowbridge Road East
Cardiff CF11 9AB
Telephone : 029 2078 5735

E-mail : corinne.scott@wales.nhs.uk
Website : www.hra.nhs.uk

02 July 2018

Miss Amber Simler
South Wales Doctoral Programme in Clinical Psychology,
Cardiff University
11th Floor, Tower Building,
70 Park Place
Cardiff CF10 3AT

Dear Miss Simler

Study title:	**How do inpatients in UK secure services comprehend the Forensic Inpatient Quality of Life Questionnaire: Short Version (FQL-SV)? Findings from a cognitive interview study.**
REC reference:	**18/WA/0163**
Protocol number:	**SPON 1668-18**
IRAS project ID:	**240260**

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion
The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).
Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials
All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites
NHS sites
The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents
The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering letter on headed paper [Response to provisional REC opinion]	Version 1	06 June 2018
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only)]	Version 1	18 March 2018
IRAS Application Form [IRAS_Form_12042018]		12 April 2018
IRAS Checklist XML [Checklist_12042018]		12 April 2018
IRAS Checklist XML [Checklist_11062018]		11 June 2018
Letter from sponsor [Letter from sponsor]	Version 1	18 March 2018
Letters of invitation to participant [Tracked Changes Consent to be Contacted - Version 2 - Monday 11th June 2018]	Version 2	11 June 2018
Letters of invitation to participant [Consent to be Contacted - Version 2 - Monday 11th June 2018]	Version 2	11 June 2018
Other [Easy Read Participant Information Sheet]	Version 1	29 May 2018
Other [Participant Debrief]	Version 1	11 June 2018
Participant consent form [Tracked Changes Informed Consent Proforma - Version 2 - Monday 11th June 2018]	Version 2	11 June 2018
Participant consent form [Informed Consent Proforma - Version 2 - 11th June 2018]	Version 2	11 June 2018
Participant information sheet (PIS) [Tracked Changes Participant Information Form - Version 2 - Tuesday 29th May 2018]	Version 2	29 May 2018
Participant information sheet (PIS) [Participant Information Form - Version 2 - Tuesday 29th May 2018]	Version 2	29 May 2018
Referee's report or other scientific critique report [Evidence of Scientific Review]	Version 1	29 January 2018
Research protocol or project proposal [Amber Simler Protocol - Version 1 - Monday 12th March 2018]	Version 1	12 March 2018
Summary CV for Chief Investigator (CI) [Dr Christopher Hartwright CV]	Version 1	18 March 2018
Summary CV for student [Amber Simler Research CV - Version 1 - Sunday 18th March 2018.docx]	Version 1	18 March 2018
Summary CV for supervisor (student research) [Dr Christopher Hartwright CV]	Version 1	18 March 2018
Validated questionnaire [Copy of the FQL-SV English Version]	Version 1	03 April 2018

Statement of compliance
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review
Reporting requirements
The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training
We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

18/WA/0163 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr. Corinne Scott, Senior Ethics Service Manager, Health and Care Research Wales

pp **Mrs. Monika Hare, Vice Chair**

E-mail: corinne.scott@wales.nhs.uk

Appendix 13.
EFQL-SV Developer's Intended Meaning

1.1. What is your Date of Birth?	What is your Date of Birth? Meaning what date were you born on.
1.2. What is your ethnic background? 1.2. a. Where were you born? 1.2.b. How long have lived in the UK?	What is your ethnic background? 'Ethnic background' meaning the country, social or religious group that the patient's ancestors came from (not necessarily just the patient's race) Where were you born? Meaning what is the name of your place of birth. How many years in total have you lived in the UK for?
1.3. How many months/ years• have you been an inpatient in forensic services?	How many months/ years in total have you been in a secure hospital, under a forensic section? Meaning if a patient had been discharged from hospital for a period of time and been re-admitted, only count the time from their most recent admission. Meaning if a patient had moved from another hospital (for example, from high secure to medium secure) count the time in both hospitals. 'Forensic services' meaning only inpatient psychiatric care, not prison or community forensic services.
1.4.a. How many other residents live with you in the unit? 1.4.b. With how many other residents do you share your bedroom?	How many other patients live with you on your ward or unit? Not meaning the whole of the hospital. How many other patients share your bedroom?
1.5. What is the highest level of education you have completed?	What is your highest formal level of education?
	Meaning, for example, secondary school, college, university. Not necessarily meaning what is the highest qualification achieved.
1.6. What is your gender?	Which of the two binary gender categories do you identify with? Meaning, for example, male or female. Or meaning which non-binary gender do you identify with (for example, gender-neutral, polygender, other)
2. In general, do you derive enjoyment from your day-to-day activities?	How enjoyable are your day-to-day activities?
3.1. Do you have leave? 3.2. Are you satisfied with your current leave? (Supervised leave or no leave outside the hospital)	Do you have any leave at all from the ward? Meaning that the leave may be supervised or not-supervised. If you have leave, either supervised or not-supervised, are you satisfied with it? If you don't have leave, are you satisfied with not having leave?
4. Do you feel safe on the unit?	Do you feel safe on the unit? Meaning both in terms of physical safety and also psychological/ therapeutic safety. Meaning the ward or unit, not the whole hospital'
5. In your opinion do you live in a pleasant environment?	Is your environment pleasant? Meaning not just the décor and facilities, but the quality of the relationships and general atmosphere in the environment.
6. Are you satisfied with the quality of the food?	Are you satisfied with the quality of the food that is provided by the hospital?
7. Are you satisfied with your opportunities to look after your personal hygiene?	Is there enough access to ways to look after your personal hygiene? Meaning does the patient have access to baths/ showers etc
8. Are you satisfied with the treatment you receive for your mental health symptoms?	Are you satisfied with the treatment provided for your mental health symptoms?

Ellen Vorstenbosch
Indeed, only completed

Ellen Vorstenbosch
When I developed the questionnaire this wasn't yet such a theme, I agree that we shouldn't exclude any gender type

Ellen Vorstenbosch
And if the patient is satisfied with it, in some facilities patients can only access the showers during certain time slots.

	Meaning not just medication, but also psychological/ therapeutic support.
9. Do you rate yourself as healthy?	Do you rate yourself as physically healthy? Just meaning physical health here, not mental health.
10. Are you satisfied with the opportunities you receive with regards to your sexuality?	Are you satisfied with the opportunities you get to express your sexuality? Meaning do staff support patients to express their sexuality.
11. Are you satisfied with the relationship with people outside the unit?	Are you satisfied with your relationships outside the unit? Meaning relationships with anyone who isn't another resident for example friends, family members - romantic or social relationships
12. Do you enjoy the contact with the other residents?	Do you enjoy the relationships that you have with other residents on your ward/ unit?
13. Are you appreciated by the ward staff?	Do you feel valued by the daily ward staff? Meaning daily care staff like nurses and support workers, but not meaning other staff members like psychiatrists, psychologists, therapists, kitchen staff.
14. Are there enough people you can turn to when you are having a bad time?	Do you have enough people around you who you can get support from if you are having a bad time? Meaning anyone who is supportive, for example staff, other residents, family members etc.
15. Are you satisfied with the degree to which you are able to move freely in the hospital? (For example supervised or unsupervised)	Are you satisfied with the amount of autonomy you have to move freely in the hospital?
16. Are you satisfied with the degree to which you are able to make your own decisions in here?	Are you satisfied with the amount you can make your own decisions in here?

Ellen Vorstenbosch
And do they try to find a solution for sexual needs patients might have. For example are there facilities/arrangements to meet in private with their partner. Maybe in the UK this is not the case (as far as I remember it is quite a controversial theme) but in other countries there are facilities for patients. They have e.g. special rooms where (after thorough screening, and many supervised visits etc.) they can stay overnight with their partner. Or a working group that is looking into special arrangements that could be made with sex workers.

17. Are you of the opinion that you have tried to do your utmost?	Do you think you are working towards achieving your maximum potential or the best that you can? Meaning working towards recovery or discharge.
18. Are you able to discuss questions around life, death and religion with a chaplain?	Is the option to talk to a Chaplain available to you?
19. Have you accepted that you will be living on a secure unit for some time?	Have you accepted that you will be living on a secure unit for some time yet? Meaning either here or in another unit. 'Some time' meaning a reasonably long or medium amount of time.
20. How would you rate your life in general over the past three months?	How has your overall quality of life been in the last 3 months?

Appendix 14.

Illustrative Example of Analysis Using Conrad and Blair's (1996) Respondent Problem Matrix

	RESPONSE STAGE		
PROBLEM TYPE	Understanding	Task Performance	Response Formatting
Lexical	Q1.6: Participant 2 appears to misunderstand the central meaning of the word 'gender' and instead answer in respect of their sexuality/ sexual orientation, "Well, that would be bisexual" Q10: Participant 2 appears does not appear to understand the combination of words, 'opportunities you receive with regards to your sexuality' in the question, "I don't know really. Um. Yeah, I don't really understand it."		
Temporal			
Logical		Q14: The pre-supposition in the question is that the respondent has had 'a bad time'. The pre-supposition appears to be false for Participant 2, "I guess so, I've just, I haven't, haven't had that much of a bad time that I've had to turn to anyone." Whilst performing the primary task, Participant 2 considers times when they have turned to staff for an answer, "Obviously, when I've got problems that I need answers to, there's people that I can turn to" (which is different to a bad time) as well as support received from their previous ward, "…some on the staff on there were quite perceptive…they got me through a bad time" Participant 2 seems to answer prospectively, rather than based on their experience, " I think, if I was having a bad time, there would be people I could turn to" Q16: Participant 2 appears to have correctly understood the unstated directive, however finds performing the task difficult due to the logic of the question/ tension between decision making and being subject to prison order restrictions in hospital, "I don't know really, 'cause at the end of the day, like, apart from it being a hospital, I'm a prisoner here as well"	
Computational		Q1.4a: Participant 2 appears to encounter difficulty recalling events from autobiographical memory/ factual information necessary to perform the task and give an accurate exact answer, "So, it's just, sort of, like my memory. I might be slightly out by one, you know, 'cause people come and go, but I'm pretty sure it's about fourteen or fifteen" Q18: Participant 2 attempts to perform the task as intended but has difficulty executing this. As such, Participant 2 provides a guess, which may not be accurate, "I haven't seen a chaplain since I've been here. But, I've been told you can, if you want to. So, I'm guessing you can, but it's a pure guess."	
Omission/ Inclusion	Q3.1: Participant 2 understands the central meaning of the word 'leave', however is unsure whether grounds leave is considered within its scope and seeks clarification before they perform the task, "Not community leave, I have, um, grounds leave. Is that still the same thing?" Q8: Participant 2 appears to exclude psychological/ therapeutic support from their answer and interprets 'treatment' as medical treatment only, "I think, it's more to do with the, uh, drug treatment you get. Um, sort of, like, from your doctor." Q11: Participant 2 appears a little uncertain to whom the question relates to and whether 'family' is within the scope of the question, "Is that, like, my family?"		

Sensitivity Problems:

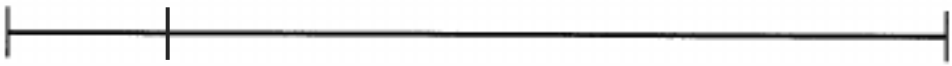
P2 appears to find the Q1.6 difficult to answer due to the sensitive nature of the perceived question, "Pretty difficult question to answer that one, you know?" and, "I don't really like being judged. So, you know, that sort of thing's quite personal to me. So, that's all I've got to say on that really."

Appendix 15.
Suggested Revisions to EFQL-SV Item

ENGLISH VERSION OF THE FORENSIC QUALITY OF LIFE QUESTIONNAIRE - SHORT VERSION
(EFQL-SV)

Name: _____
Date: _____
Ward Name: _____
Name of Staff Member: _____

We hope that this questionnaire will help us to understand more about your everyday life, including your daily routine, your health, and your social life. You are asked to rate your level of satisfaction in each of these areas. You are asked to rate the extent to which you agree or disagree with certain statements. To do this, you are asked to put a small vertical mark on the horizontal line. There are no right or wrong answers.



Not at all Completely

The more you disagree with the statement, the further to the left your mark will go.

Not at all Completely

The more you agree with the statement, the further to the right your mark will go.

You may find some questions quite difficult. If this is the case, you can discuss them with a member of staff. If you are unable or do not wish to complete any of the questions, please let a member of staff know.

Once the questionnaire has been completed, we will keep your information confidential.

PERSONAL DETAILS

1.1. What is your Date of Birth? _____

1.2. What is your ethnic background? (Please circle)

White
- Welsh/ English/ Scottish/ Northern Irish/ British
- Irish
- Gypsy or Irish Traveller
- Any other White background

Mixed/ Multiple ethnic groups
- White and Black Caribbean
- White and Black African
- White and Asian
- Any other Mixed/ Multiple ethnic backgrounds

Asian/ Asian British
- Indian
- Pakistani
- Bangladeshi
- Chinese
- Any other Asian background

Black/ African/ Caribbean/ Black British
- African
- Caribbean
- Any other Black/ African/ Caribbean background

Other ethnic groups
- Arab
- Any other ethnic group

1.2.a. Where were you born? _____

1.2.b. How long have you lived in the UK?

- Since birth
- Other (Please specify) _____

1.3. How many months/ years have you lived in this secure hospital for? _____

1.3.a. Have you come to this secure hospital straight from another secure hospital? (Please circle)

- Yes
- No

If yes, how long have you been in secure hospitals for all together? _____

1.4.a. How many other patients live with you on the ward? _____

1.5. What is the highest level of education you have completed? (Please circle)

- No qualifications
- O levels/ CSEs/ GCSEs (Any grades)
- AS levels, A levels
- College course (Please specify) _____
- University (Please specify) _____
- Other vocational/ work related qualifications
- Other (Please specify) _____

1.6. What is your gender? (Please circle)

- Male
- Female
- Transgender
- Gender Variant/ Non-Confirming
- Other (Please specify) _____
- Prefer not to say

2. In general, do you enjoy your day-to-day activities?
(Please mark the line below)

Not at all Completely

3.1. Do you have leave? (Please circle) Yes/ No

3.2. Are you satisfied with your current leave? (This can be supervised leave, unsupervised leave, or no leave outside the hospital)
(Please mark the line below)

Not at all Completely

4. Do you feel physically and emotionally safe on the ward? (For example, safe from being physically attacked and safe from bullying and being pressured)
(Please mark the line below)

Not at all Completely

5. Are you satisfied with the ward atmosphere and the ward environment?
(Please mark the line below)

Not at all Completely

6. Are you satisfied with the quality of the food?
(Please mark the line below)

Not at all Completely

7. Are you satisfied with your opportunities to keep yourself and your clothes clean?
(Please mark the line below)

Not at all Completely

8. Are you satisfied with the therapeutic and other forms of treatment you receive for your mental health symptoms?
(Please mark the line below)

Not at all Completely

9. Do you rate yourself as physically fit and healthy?
(Please mark the line below)

Not at all Completely

10.a. Do staff try and support you with any sexual needs you might have? (Please circle)

- Yes
- No
- Not applicable

10.b. Are you satisfied with the amount that staff try and support you with any sexual needs you might have?
(Please mark the line below)

Not at all Completely

11.a. Are you satisfied with your relationships with family?
(Please mark the line below)

Not at all Completely

11.b. Are you satisfied with your relationships with friends?
(Please mark the line below)

Not at all Completely

11.c. Are you satisfied with your relationships with professionals outside of the hospital?
(Please mark the line below)

Not at all Completely

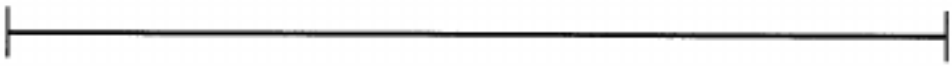
12. Are you satisfied with your relationships with other patients on the ward?
(Please mark the line below)

Not at all Completely

13. Do you feel valued by the nurses and support workers on the ward?
(Please mark the line below)

Not at all Completely

14. Are there enough people to help and support you if you are having a bad time?
(Please mark the line below)

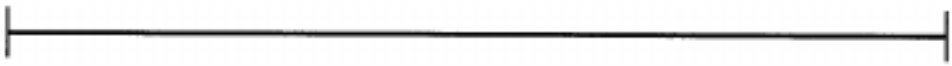


Not at all Completely

15. Are you satisfied with the freedom you have to move around the ward and inside the hospital?
(Please mark the line below)

Not at all Completely

16. Are you satisfied with the degree to which you are able to make your own decisions in here?
(Please mark the line below)



Not at all Completely

17. Have you done all you can to move on from hospital?
(Please mark the line below)

Not at all Completely

18. Is a chaplain available to discuss questions around life, death and religion?
(Please mark the line below)

Not at all Completely

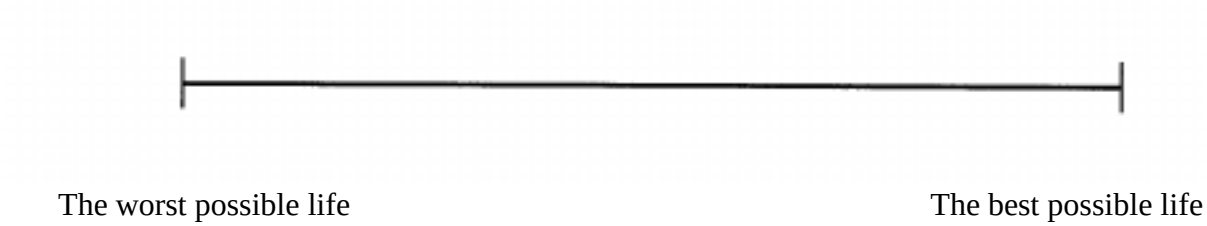
19.a. Do you think you will be living in a secure hospital for some time? (Please circle)

- Yes
- No

19.b. If yes, have you come to terms with this?
(Please mark the line below)

Not at all Completely

20. How would you rate your life in general over the past three months?
(Please mark the line below)



The worst possible life The best possible life