An ACT self-help intervention for adults with a visible difference in appearance: A pilot feasibility and acceptability randomized controlled study

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ABSTRACT

Individuals living with a visible difference in appearance experience high levels of social anxiety, yet self-help interventions for this heterogeneous population are not available. We conducted a pilot trial of a novel Acceptance and Commitment Therapy (ACT) based self-help intervention. Individuals with anxiety about having a visible difference in appearance (n = 284) were randomized to an ACT-based four-week intervention (n = 145) or a waitlist control condition (n = 139). We collected pre and follow-up (four-weeks after the completion of the intervention) data. Primary outcomes included social anxiety and impairments in functioning. Psychological flexibility (PF) was also examined. ANCOVAs, controlling for pre scores, indicated significant improvements in functioning by the intervention group. No significant differences were observed for anxiety and PF between conditions at follow-up. Drop out was 68% for the intervention and 41% for the control group, with no differences in the groups in age, origin, gender, or type of visible difference. Participants in the intervention group found the intervention almost equally, useful (77%) and helpful (73%). An ACT-based self-help intervention can alleviate distress related to visible difference in appearance. More sophisticated designs are needed now, to collect idiographic and longitudinal data and examine personalized changes across time in this population.

1. Introduction

Visible difference in appearance is an term representing multiple conditions that have an impact on appearance and may arise from either congenital cause (e.g., cleft lip and palate, craniofacial abnormalities), or be acquired (e.g., burns, scarring, medical interventions, etc; Rumsey et al., 2014). Studies show that individuals with visible differences may develop a fear of being negatively evaluated and this can be apparent even in childhood (Griffiths, Williamson, Rumsey, 2012; Rumsey & Harcourt, 2012; Thompson & Kent, 2001). Mounting evidence demonstrates that the fear of being negatively evaluated increases the risk of experiencing social anxiety (van Dalen et al., 2020). Consequently, visible difference can have a profound effect on quality of life (Abel, 2016; Chiang, Bundy, Griffiths, Paus, & Harries, 2015; Kakar et al., 2016; Montgomery, White, & Thompson, 2017). For example, a large European survey examining visible difference, found that more than 79% of the referrals from specialists were associated with social anxiety (Harcourt et al., 2018). Furthermore, a recent meta-analysis found that compared to unaffected individuals, adolescents with a visible difference have more symptoms of anxiety, but not depression, and this may vary by condition (van Dalen et al., 2020).

Social anxiety is usually characterized as an intense, persistent fear of being judged negatively by others. Whilst social anxiety is a significant psychological experience that may be associated with visible difference it is important to recognise that people do also receive negative appearance based reactions from others that can also be related to stigmatization (Clarke, Thompson, Jenkinson, Rumsey, & Newell, 2013). Consequently, the fear of negative evaluation associated with visible difference is likely to be phenomenologically different from social anxiety experienced by people without a visible difference (Clarke et al., 2013; Kent & Kehane, 2001; Rumsey & Harcourt, 2012; Thompson & Kent, 2001).

There is likely to be an interplay between the noticeability of a condition or its objective severity and psychological variables in
accounting for individual differences in distress (Thompson, 2012). However, it is now well documented that the severity of the visible difference is not a good sole predictor of psychological distress (Moss, 2005; Robinson, Ramsey, & Partridge, 1996), and the degree to which individuals experience distress is likely to be better predicted by various contextual factors (Rumsey & Harcourt, 2012), such as cultural acceptability of appearance, social comparisons, and stigmatization. This is congruent with the biopsychosocial model of distress that suggests that individual difference and social factors are likely to interact to lead to the development and maintenance of social anxiety (Clarke et al., 2013; Egan et al., 2011; Moss & Rosser, 2012; Thompson & Kent, 2001). Psychological factors, such as the value society and individuals place upon appearance (MacLeod, Shepherd, & Thompson, 2016), optimism (Coneo, Thompson, & Lavda, 2016), cognitive-processing biases (Thompson et al., 2019), and self-evaluation (Clarke, Newell, Thompson, Harcourt, & Lindenmeyer, 2014) can also contribute to the levels of social anxiety individuals with a visible difference may experience (Thompson, 2014). Hence, interventions that can concurrently address the contextual (e.g., stigmatization) and psychological (e.g., how individuals cope with thoughts and emotions) parameters, involved in social anxiety related to appearance, are greatly needed (Egan, Harcourt, Rumsey, & Appearance Research Collaboration, 2011; Kent, 2010; Rumsey, 2002).

There are limited psychological support services available for people living with visible differences (All Party Parliamentary Report on Skin, 2020, Gibson, Ackling, Bisson, Dobbs, & Whitaker, 2018; Gruber, Prinstein, Clark, et al., 2021; Lowry, Shah, Fleming, Taylor, & Bewley, 2014) and the COVID-19 pandemic has also further highlighted the need for self-help resources to be developed (Karyotaki et al., 2018; Viswa et al., 2020). Such interventions lend themselves to being implemented in a scalable way as they can be provided in paper format or delivered online (Mufin & Thompson, 2013; Mufin, Gilbert, & Thompson, 2022; Shah, Hunt, Webb, & Thompson, 2014). These interventions also have other advantages over traditional delivery approaches, as they can be available at any time of the day and be accessible to those where there may be reluctance to seek treatment either due to disability or stigmatization (Cuijpers et al., 2008; Karekla et al., 2019).

Self-help interventions for visual differences in appearance should be designed to be transdiagnostic, meaning they can be applied to more than one condition (Pinto et al., 2017), malleable, meaning they can be delivered in different formats (Glester et al., 2017), and dynamic, meaning they should include a series of processes of change linked with defined outcomes (Hofmann, Hayes, & Lorscheid, 2021). Acceptance and Commitment Therapy (ACT: Hayes et al., 2012) is one such approach that meets these criteria.

ACT focuses on changing one’s relationship with unwanted internal experiences by promoting flexible and adaptive coping with these experiences. It uses a series of trainable skills, such as acceptance and mindfulness that can be delivered through different modes of treatment (e.g., in-person, group-based, digital; Dindo, Van Liew, & Arch, 2017), targeting functional outcomes (e.g., reducing social avoidance and impairment of daily functioning). ACT stems from the psychological flexibility model, or the ability to consciously engage meaningfully with values whilst being in contact with painful experiences (Rashdan & Rottenberg, 2010). Evidence demonstrates that overall psychological flexibility processes promote more advantageous outcomes in functioning and quality of life than focusing on reducing symptomatology that might not be easily changed (Herbert et al., 2022; McCracken, Yu, & Vowles, 2022). ACT’s mechanism of action seems very compatible with the needs of individuals with visible differences and there is some evidence that these factors are implicated in adjustment in this population (Shepherd, Reynolds, Turner, O’Boyle, & Thompson, 2019; Vasiiliou et al., 2023). For example, one of the ACT processes, called cognitive defusion, targets helping individuals see the difference between a thought (e.g., I’m ugly) and the impulse to act based on the content of this thought (e.g., avoid going to a social event).

ACT has been found to be effective in several populations with body-focused conditions, including body image dissatisfaction (Griffiths, Williamson, Zucchelli, Paraskeva, & Moss, 2018; Zucchelli et al., 2022), trichotillomania (Lee et al., 2020), and adjustment with pain problems such as chronic neuropathic pain (Veehof, Trompeter, Bohlmeijer, & Schreurs, 2016), fibromyalgia (Simister et al., 2018; Wicksell et al., 2013), and headaches (Vasiiliou, Karademas, Christou, Papacostas, & Karekla, 2021). Studies also suggest ACT’s self-help intervention is effective with emotional problems which are highly prevalent among people with a visible difference, including depression (Lappalainen, Langrial, Oinas-Kukkonen, Tolvanen, & Lappalainen, 2015), anxiety (Ritz et al., 2016), and long-term medical health conditions (Graham, Gouck, Krahe, & Gillanders, 2016; Trompeter, Bohlmeijer, Veehof, & Schreurs, 2015). Yet at present there is a huge variations in the availability of support individuals with visible differences can receive, worldwide (Harcourt, Hamlet, & Forage, 2018), and limited data about the use of self-help interventions, especially ACT, to target social anxiety and impairment in functioning relevant to appearance. Our previous pilot feasibility study with three cases indicated that ACT may be a useful psychological therapy for appearance anxiety (Shepherd et al., 2020). Following this line of preliminary findings, we decided to run a more robust evaluation of an ACT intervention.

Therefore, in this study, we used a wait-list randomized controlled trial (RCT) to investigate an ACT-based self-help intervention in comparison to a wait list control. The self-help tested in a workbook format that targeted at reducing social anxiety, improving functioning, and increasing psychological flexibility in adults with a visible difference. We hypothesized that, relative to participants randomized to the waitlist control group, individuals in the ACT-based self-help intervention group would demonstrate (a) significant decreases in social anxiety, (b) reductions in visible difference-related impairments, and (c) increases in psychological flexible responses to the body-focused problem and its associated distress, at follow-up four weeks after the intervention was completed.

2. Methods

2.1. Design

For this RCT, we followed the CONSORT guidelines (Schulz, Altman, & Moher, 2010) to examine the pilot feasibility, acceptability, and preliminary efficacy of an ACT-based self-help intervention workbook. Ethical approval was granted by the School of Psychology University of Sheffield ethics committee (Ref number: #012266) and registration of the trial to ‘Clinical Trials.gov’ (ID: NCT03205839) was achieved. The study was conducted in accordance with the declaration of Helsinki suggestions.

2.2. Participants

As Fig. 1 illustrates, 473 individuals expressed an interest to participate in a study that was advertised as “Surviving to Thriving: An ACT intervention for living well with a visible difference in appearance”. Recruitment occurred online via collaborations with international (e.g. Australia Alopecia Areata Foundation Inc, British Skin Foundation), UK-based charities (e.g., The Katie Piper Foundation”), and other organisations (e.g., Vitiligo Support and Awareness Foundation (VITSAF: Nigeria, Vitiligo Research Foundation, US), supporting people with visible differences in appearance (see supplementary workbook SI for a complete list of charities and organizations agreed to advertise the study through their websites and social media pages). Additionally, advertisement in relevant social media groups with administrative permission was used, to aid recruitment. We attempted to examine the benefit of our self-help delivered intervention in an international sample, to evaluate its potential pilot acceptability and feasibility to a heterogeneous
sample. Thus, English-speaking individuals could enter the study regardless of their location.

Inclusion criteria required: (a) participants identified themselves as people having a visible difference in appearance (as assessed with an open-text input, requesting participants state their condition before their enrolment, e.g., psoriasis, vitiligo); (b) a self-report experience of social anxiety (as measured with scores above the mean in the Brief Fear of Negative Evaluation scale II (BFNE-II; Carleton, Collimore, & Asmundson, 2007); (c) being 18 years of age or older, and (d) being fluent in the English language. Participants were excluded if they were receiving psychological support at the time of the study or if their open text input about the nature of their visible difference was not clear.

Fig. 1. Study CONSORT flow diagram.
2.3. Randomization

Prior to entering the study, and before enrolment and randomization, participants: (a) received the information sheet which informed them about the study procedures (e.g., randomization to one of the two groups and the time of the self-help intervention workbook delivery and completion); (b) answered questions about their eligibility via email (e.g., information about participants’ visible difference, completion of social anxiety scale, etc.); and (c) provided consent. Eligible participants were enrolled in the study and then randomized by the online survey provider Qualtrics, at a ratio of 1:1 to either a waitlist control (n = 139) or the ACT-based self-help condition (n = 145). The survey software randomly allocated participants to condition at the point immediately following their informed consent. Following this, participants provided demographic information, including their visible difference, country of residence, age, and skin colour. Participants were not informed of the condition they had been assigned to until completion of the pre (pre-treatment) survey at time 1.

2.4. Procedures

After randomization and enrolment procedures, as Fig. 1 illustrates, participants in both groups were invited via email to complete the questionnaires embedded in an online Qualtrics survey. The survey was provided to participants at two time points: pre-treatment (time 1 questionnaires: prior to the intervention) and four weeks following the completion of the intervention (time 2 questionnaires). There was no completion of the measures at post-intervention, but only at 4-weeks assessment. Participants were informed at the completion of the questionnaires that due to randomization, they would receive the self-help workbook immediately (treatment group), or after four weeks (control group). Following the completion of time-1 questionnaires, those who were randomized to the intervention condition, received the self-help workbook via email. Then, they immediately had access to the self-help intervention and were recommended with written guidance to work through the self-help workbook over a four-week period. Participants in the wait-list control group were instructed to wait until the intervention group completed the intervention. When the intervention group completed the intervention, they self-reported the completion of it and completed the time 2 questionnaires. At this time (time 2 questionnaires), those in the wait-list control group received the self-help workbook and were invited to complete the time 2 questionnaires. All participants in the wait-list control received the self-help workbook via email regardless of whether they had completed or not the time 2 questionnaires.

2.5. Measures

During the screening phase, we examined the study selection criteria by collecting a series of demographic information, including age (numeric value), gender (male, female or other), ethnicity (Caucasian or non-Caucasian), their country of residency (open text), and the exact type of visible difference they had. At pre-treatment, all participants completed a 10-item distress questionnaire (pre-treatment measure), to assess the level of distress. Finally, at time-1 and time-2, all participants completed three self-report measures. To reduce participant burden, this study focussed on two primary outcome variables measuring social anxiety, and impact on work and social functioning. In addition, the study measured one process variable - psychological flexibility.

2.5.1. Pre-treatment measure

The CORE-10 (Barkham et al., 2013) was used prior to randomization to ascertain that the participants met the inclusion and exclusion criteria. The CORE-10 (Barkham et al., 2013) is a 10-item measure of general distress, rated on a 5-point Likert scale. Scores range from 0 to 40, with higher scores indicating greater distress. It has high internal reliability (α = .90), correlates highly with the 34-item CORE-OM (r = .94), and is considered feasible and acceptable.

2.5.2. Primary outcome measures

The 12-item Brief Fear of Negative Evaluation scale II (BFNE-II; Carleton et al., 2007) was used as one of the two primary outcome measures. BFNE-II assesses fear of negative evaluation, using a five-point Likert scale, ranging from 0 to 4. Scores range from 0 to 48 with higher scores indicating greater fear of negative evaluation. As an indicator of social anxiety for this study, a mean score of 25 or above was used, and not the cut off scores, suggested by the authors, as this has been shown to be indicative of clinically significant social anxiety (Carleton, Collimore, McCabe, & Antony, 2011). The scale shows excellent internal consistency (α = .95) and the internal consistency for this study was α = .84.

The Work and Social Adjustment Scale (WSAS; Marks, 1986) is a five-item measure that examines impairments in work, social leisure, private leisure, home management, and close relationships. It is scored on a Likert scale from 0 to 8, with higher scores indicating greater impairments in functioning and quality of life. It has good reliability with an internal consistency of α = .84, test-retest reliability of α = .84, and for this study the reliability was α = .84. The WSAS focuses on a specific functional outcome, such as visible difference in this study.

2.5.3. Other outcome variable

The 23-item Comprehensive Assessment of Acceptance and Commitment Therapy processes (CompACT; Francis, Dawson, Golijani-Moghaddam, 2016) measure was used so as to assess changes from time 1 (pre) to time 2 (4-weeks assessment) questionnaires intervention in this key ACT-related variable. The CompACT assesses psychological flexibility in a seven-point Likert scale and has three sub-factors: "behavioral awareness," "openness to experience," and "valued action." Scores from the three sub-factors provide an overall psychological flexibility score ranging from 0 to 138. The CompACT has good internal consistency (α = .91) and also in our study (α = .87).

2.5.4. Assessing feasibility

To assess feasibility, we attempted to primarily understand how participants perceived the content and usefulness of the intervention. Engagement (adherence to the intervention) was quantitatively examined. We used Qualtrics to track whether participants completed the intervention. We asked participants who completed the intervention to self-rate their adherence, using the following categorization: (a) High = I read all the booklet and completed all of the self-help exercises following the recommended timescale; (b) Moderate = I read most of the booklet and completed some of the self-help exercises; and (c) Low = I read some of the self-help and completed a few of the self-help exercises. As part of the feasibility assessment, we conducted a preliminary evaluation of planned outcome measures’ sensitivity, to explore whether the defined measures appear to be sensitive to the effects of the intervention, comparing completers versus non-completers. We calculated their change scores from time 1 (pre) to time 2 (4 weeks assessment) questionnaires for all three outcome measures, running three-way ANOVAs.

2.5.5. Assessing acceptability

To assess acceptability, we examined participants’ perspectives on the intervention’s content, context, and quality, which are key parameters in acceptability (Sekhon, Cartwright, & Francis, 2017). Participants were asked to provide textual-based feedback to three questions: what was most helpful about the workbook? What was least helpful about the workbook? and then a free text box for additional comments about the usefulness and understanding of the workbook, the audio, and the video workbook. Specifically, we collected retrospectively some qualitative data from participants to understand the self-help intervention’s appropriateness in addressing common challenges.
experienced by individuals with visible differences in appearance, such as social anxiety and functioning (perceived effectiveness). We used textual data to capture completers’ subjective evaluations of the self-help intervention’s delivery. Finally, participants in the intervention condition also rated, on a five-point Likert scale (e.g., 1 = not helpful to 5 = extremely helpful), how ‘helpful’ they had found the intervention.

2.6. Content and structure of the ACT Self-help intervention

The four-week self-help intervention: ‘Surviving to Thriving: ACT self-help intervention for living well with a visible difference in appearance’ is an ACT-based program that was developed by the members of the co-authors (LP & AT) of this study and is heavily based on ACT. The self-help intervention included a PDF-made workbook, audio files, and a video testimony where an individual with visible difference talks about her experience, with reference to the ACT approach. The self-help intervention consisted of 46, A4, pages in length (36 audio exercise transcriptions). Two user-by-experience from the community piloted tested the intervention and based on their feedback, an estimation of four weeks completion was noted.

The self-help intervention was divided into three main sections all targeting at (a) increasing awareness of internal sensations, (b) promoting distancing from skin-related thoughts, and (c) helping individuals to identify value-based actions and practical strategies to manage stigmatization. Though value-based action was mostly presented in the later stages of the workbook, in line with earlier research (Gloster, Klotsche, et al., 2017), focus on values was embedded early on in the workbook. Whilst there was no pre-specified homework, the self-help workbook included multiple exercises and encouraged participants to practice.

Common ACT techniques were included throughout the self-help intervention, among others, structured mindfulness exercises (e.g., body image and compassion mindfulness), thought defusion (e.g., “I notice I’m having the thought…”), value identification (e.g., identify and rate your values), and metaphors (e.g., passengers on the bus).

The transcription of the audio exercises (e.g., our tricky brain, body scan mindfulness) were included in the guide via YouTube videos. The self-help also included relevant images and open fields for participants to complete written tasks. Printed copies were not provided, though participants were able to print the self-help, should they want to. There was no therapist or researcher contact as part of the treatment. Prior to recruitment, feedback was sought from a local ACT expert, who reviewed the self-help intervention and confirmed its consistency with the theoretical and practical aspects of the ACT approach.

2.7. Data analyses

G*Power version 3.1.9.2 (Faul, Erdfelder, Lang, & Buchner, 2007) was used to conduct a power analysis for estimating the power of the sample for a series of one-way between group ANCOVAs. To obtain 80% power, with an alpha of 0.05, a medium effect size ($f = 0.25$), a sample size of 128 was required.

The main analytic design of the study consisted of repeated within-between group by time interaction effects. As presented below, we run both $2 \times 2$ ANOVAs and ANCOVAs to examine the same hypotheses. For both analyses, the independent variables (IV) in the study were time and condition. There were two levels for time: pre (time 1 questionnaires) and 4 weeks assessment (time 2 questionnaires). There were also two levels for condition: waitlist or ACT-based self-help. The dependent variables (DV) included the three outcome variables: the 12-item Brief Fear of Negative Evaluation scale (BFNE-II), The Work and Social Adjustment Scale (WSAS), and the 23-item Comprehensive Assessment of Acceptance and Commitment Therapy processes (CompACT).

Firstly, we run a series of $2 \times 2$ ANOVAs to examine our study’s hypotheses, using the intention to treat analysis (ITT) sample only. For the ANOVAs, the IV were the time and condition and the DV the three outcome variables (BFNE-II, WSAS, and CompACT).

Secondly, we run a series of ANCOVAs, controlling for pre scores, to also examine our study’s hypotheses, using the sample from those who completed the intervention. For the ANCOVAs, we conducted a series of between group ANCOVAs, one for each DV, to compare differences between the two groups at time 2 questionnaires (4 weeks assessment), controlling for participants’ pre scores (time 1 questionnaires) on the DVs (BFNE-II, WSAS, and CompACT).

As this study was completed online and the self-help intervention did not include therapist contact, attrition was estimated, based upon previous attrition rates from similar trials (37%: Bundy et al., 2013; 51%: Hudson, 2015; 52%: Lane, 2017), to be around 50%. Therefore, we attempted to recruit $n = 256$ participants (128 per group). In our attempt to minimize attrition, participants were given the option to be entered into a prize draw for one of two £25 vouchers, if they completed the 4 weeks assessment (time 2 questionnaires).

All data were initially screened and analysed to detect possible assumption violations. Whilst complete data was available for the BFNE-II and WSAS at time 2 questionnaires, five responses were not fully completed on the online data gathering software we used. Thus, in the data set, we excluded three responses for the CompACT from the waitlist and two from the intervention conditions.

Item and scale scores were examined for limited variability, non-normality, and multicollinearity. Cronbach’s alpha test score examined internal consistency with values above .70 considered sufficient and .80 considered high (Kline, 2013). Frequency distribution showed no extreme skewed responses (as assessed by z scores: Hahs-Vaughn & Lomax, 2012) or low variability among the examined variables. Participants selected all the possible scale options for the main variable of interest. Little’s missing completely at random analysis was conducted which indicated that data missing was likely to have occurred, randomly. The correlations of the scales’ item were below .30 (Nunnally & Bernstein, 1994), showing no multicollinearity. Multivariate analysis showed non-normality of data (Mardia skewness and kurtosis, $p < .05$; Bentler, 2005). Mahalanobis distance squared values (based on the Bonferroni corrected chi-square test) showed two cases as multivariate outliers ($p < .001$) which we retained.

Levene’s test for homogeneity was non-significant for all outcome measures, however, the Shapiro-Wilk test for normality was significant for the CompACT, BFNE-II, and WSAS. This could be problematic as violations of the normality assumption may increase Type I error rates when using parametric tests. Histograms showed the pattern of data was similar across conditions and time points. However, there is little benefit of using non-parametric analyses as minimal difference exists between using ANCOVA and non-parametric equivalents in terms of a type I error rate and statistical power (Kneif & Forstmeier, 2021), and similar findings are gained from using rank ANCOVAs (Olejkni & Algina, 1985; Vickers, 2005).

Given that the pre scores for the CORE-10 were not significantly different across conditions, it was decided to exclude them as a covariate in the analyses. For the sample with the ITT (ANCOVAs analyses), we used the last observation carried forward (LOCF) method, which assumes no change from the pre score of DV (i.e., pre-treatment scores carried forward to time 2 questionnaires). Though often perceived as a conservative method, it is often viewed as the only alternative to excluding participants from analysis (Altman, 2009).

Given the pilot nature of this study, a conservative ITT approach was utilized (Buchner, 1994; Krueger, 2002). All analyses were conducted with SPSS version 23.0 and findings are reported using a significance criterion alpha set at $p < .05$, and all are two-tailed.

Free text was analysed using a simple descriptive version of thematic analysis (TA), as described by Braun and Clarke (2023). For this analysis, patterned responses were derived through two coders who worked independently with the textual inputs. The identified patterns were discussed and confirmed with all the members of the research team and there were no disagreements. Given an initial full consensus observed
between the two coders on the identified candidate patterns of the data, we did not assess for inter-coder reliability coefficient Fleiss’s k.

3. Results

3.1. Demographic characteristics

The sample included residents of the UK (n = 199), countries from North America (n = 52), some from Australasia (n = 11) and other countries across the world (n = 22). Of those who expressed an interest (n = 473), n = 95 individuals were excluded on the grounds of not meeting one of the main criteria and n = 381 met the eligibility criteria and were included in the study. Most participants were female, average 40 years of age (SD = 12.71), with the main visible differences in appearance self-reported problems, including that of alopecia (n = 89; 31%), followed by acquired scarring (n = 31; 11%), and birthmark (n = 23; 8.1%). Table 1 presents additional demographics and other participants’ characteristics. Of the n = 284 individuals who finally completed the pre-treatment data online, n = 145 were randomly allocated to the intervention condition and n = 139 to the control condition.

3.2. Randomisation checks

To assess whether randomization was successful, a series of independent sample t-tests and chi-square analyses were performed on pre data. T-tests were used to examine for differences in age or scores on the four outcome measures. No significant differences were found between groups for any continuous variables; age (t (1283) = 1.057, p = .292), CompACT (t (1283) = 1.667, p = .097), BNE-II (t (1283) = -1.116, p = .265), WSAS (t (1283) = -1.330, p = .185) or CORE-10 (t (1283) = -.792, p = .429). No significant differences were found between the two groups for any continuous variables.

Chi-squared tests were employed to examine differences between groups on categorical variables. As chi-squared tests are most useful when there are five data points within each label (e.g., visible difference type), some labels were merged (e.g., Canada and USA became “North America”). Chi-squared tests revealed no significant differences between groups with regards to visible difference type (χ² = 3.490, p = .991) or country of residence (χ² = 1.424, p = .700). However, there was a significant difference with regards to skin colour (χ² = 5.896, p = .015) with individuals with white skin colour more likely to be assigned to the control group. However, further analyses showed no significant difference in terms of skin colour on any of the outcome measures: BNE-II (t (1283) = .421, p = .517), CompACT (t (1283) = .155, p = .694) and WSAS (t (1283) = 1.551, p = .214), so this was not controlled for in subsequent analyses. Overall, the randomisation process was successful.

Examination of scores at pre-treatment indicates the extent of difficulties experienced within this population. As the CompACT is a recently developed measure, there are no norms available to compare our sample with. The mean score on the BNE-II for the sample was 33.75, Carleton et al. (2011) suggest a score of 25 or above as an indicator of someone with clinically significant social anxiety. Scores of 25 or above were reported by 82% of the sample at pre, indicating that most of the sample could fulfil the criteria for social anxiety disorder. Further, the mean score on the WSAS was n = 13.35 which also is above the clinical threshold, indicating significant impairment (Mundt, Marks, Shear, & Greist, 2002). Finally, the mean score of distress, as measured by the CORE-10 (Cronbach’s alpha for this study :-.78), was indicative of a moderately distress in our population (15–20).

3.3. Intention to treat analyses (ITT): treatment outcome effects

ITT analyses indicated there were no significant time by group interaction effects in the fear of negative evaluation, (BNE-II; F (1283) = 2.449, p > .5). However, a significant time by group interaction effect was observed on impairments in functioning, (WSAS; F (1283) = 16.382, p < .001), with individuals in the ACT group, reporting less impairment at follow up. Further, there was no significant interaction effects of time by group on the process of change measure, psychological flexibility (CompACT; F (1283) = 2.394, p > .5). Table 2 shows the mean scores by group at pre (time 1) and 4 weeks assessment (time 2) in the ITT analyses.

3.4. Attrition analyses

Of the n = 284 participants who completed the outcome measures at pre, n = 128 completed outcome measurement at 4 weeks assessment (time 2 questionnaires), of which n = 82 were from the waitlist condition and n = 46 were from the intervention condition. The overall attrition rate was 54.9%, with 68.3% attrition referring to the intervention condition and 41% attrition to the control condition. Fewer participants completed the CompACT at 4 weeks assessment (time 2 questionnaires; n = 79 from the control condition and n = 44 from the intervention condition). A series of chi-square tests and independent t-tests were conducted to examine for differences between completers and non-completers.

Independent t-tests demonstrated no significant differences between completers and non-completers in age, origin, gender, or type of visible difference. However, significant differences between completers and non-completers were found with regards to the country of residence (χ² = 9.708, p = .021) and group (χ² = 21.315, p = <.001); where individuals were more likely to complete the study at the four weeks assessment (time 2 questionnaires), if they were from the United Kingdom and randomly allocated to the waitlist. Table 3 illustrates the pre outcome scores by completers and non-completers.

3.5. Completers analyses: treatment outcome effects

In addition to the ITT analyses, a series of ANCOVAs were conducted to compare the outcomes between the ACT and the waitlist groups, using only the completers’ data at both time points (time 1: pre and time 2: four weeks assessment). Due to the significantly higher attrition rate in the ACT group, these results should be interpreted with caution, as the equality of variance assumption was not met. Table 4 illustrates the
outcome means by completers.

Completers analyses indicated there was significant effect of group by time for the fear of negative evaluation, \(F(1127) = 7.297, p = .008\) with those in the ACT group, reporting a reduction in fear of negative evaluation, compared to the waitlist condition at the four weeks assessment (time 2 questionnaires). The mean score at four weeks assessment (time 2 questionnaires) was 33.16 for the waitlist group, reporting less impairment at the 4 weeks assessment (time 2 questionnaire). However, there were no significant effects of group by time for the fear of negative evaluation, \(F(1122) = 2.922, p = .090\).

### Table 2
Mean outcome measure scores by time and condition from ITT analyses.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Condition</th>
<th>Pre (Time 1 questionnaires)</th>
<th>4 weeks assessment (time 2 questionnaires)</th>
<th>Interaction effects (Group by Time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological Flexibility (CompACT)</td>
<td>Intervention</td>
<td>M (SD) 66.39 (17.53)</td>
<td>M (SD) 67.28 (17.46)</td>
<td>f (df) 2.93 (1.283) p .123</td>
</tr>
<tr>
<td>Social Anxiety (BFNE-II)</td>
<td>Intervention</td>
<td>M (SD) 34.49 (9.74)</td>
<td>M (SD) 33.83 (9.63)</td>
<td>f (df) 2.39 (1.283) p .119</td>
</tr>
<tr>
<td>Impairment in Functioning (WSAS)</td>
<td>Intervention</td>
<td>M (SD) 12.65 (8.81)</td>
<td>M (SD) 11.26 (8.20)</td>
<td>f (df) 16.38 (1.283) p .001</td>
</tr>
</tbody>
</table>

Note: CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy Processes; BFNE-II: Brief Fear of Negative Evaluation scale II; WSAS: The Work and Social Adjustment Scale.

### Table 3
Pre-Intervention outcome scores by completers and non-completers.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Completers</th>
<th>Non-completers</th>
<th>Comparisons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological Flexibility (CompACT)</td>
<td>M (SD) 65.07 (18.00)</td>
<td>M (SD) 64.29 (18.19)</td>
<td>t .362 p .948</td>
</tr>
<tr>
<td>Social Anxiety (BFNE-II)</td>
<td>M (SD) 34.47 (9.58)</td>
<td>M (SD) 33.16 (10.66)</td>
<td>t 1.077 p .202</td>
</tr>
<tr>
<td>Impairment in Functioning (WSAS)</td>
<td>M (SD) 13.54 (9.11)</td>
<td>M (SD) 13.19 (9.71)</td>
<td>t .308 p .740</td>
</tr>
</tbody>
</table>

Note: CompACT: Comprehensive Assessment of Acceptance and Commitment Therapy Processes; BFNE-II: Brief Fear of Negative Evaluation scale II; WSAS: The Work and Social Adjustment Scale.

#### 3.6. Self-help intervention’s feasibility

Upon completion of the 4 weeks assessment (time 2 questionnaires), those allocated to the ACT group were asked to indicate their adherence. Responses were then categorised into low, moderate, and high adherence. To examine adherence, change scores were calculated from pre (time 1 questionnaires) to the 4 weeks assessment (time 2 questionnaires), for all three outcome measures. Three-way ANOVAs, with adherence as the independent variable and change score as the dependent variable showed no impact of adherence on psychological flexibility (\(F(2,44) = .992, p = .379\)), fear of negative evaluation (\(F(2,44) = 1.033, p = .365\)) or impaired functioning/quality of life (\(F(2,44) = 1.264, p = .293\)).

#### 3.7. Self-help intervention’s acceptability

At the end of the 4 weeks assessment (time 2 questionnaires), participants allocated to the intervention group were given an option to provide qualitative feedback on the self-help intervention. A subsample of \(n = 44\) participants responded to these questions; four (9%) rated self-help as unhelpful, eight (18%) did not feel self-help was unhelpful nor helpful, and 32 (73%) rated self-help as helpful. Four (9%) rated self-help as not useful, six (14%) were unsure whether self-help was useful, and 34 (77%) felt self-help was useful. Two participants did not answer these optional questions, nor did they provide qualitative feedback.

Given the small number of participants which provided qualitative responses, these findings should be treated with caution. Overall, the participants were positively advocated towards the self-help intervention. Specifically, qualitative findings showed that those who completed the 4 weeks assessment (time 2 questionnaires) measures, typically, perceived the self-help intervention as helpful and understandable (e.g., “It just made me feel better about myself and reading it has helped me to focus that bit more which I’m happy about. Also the way it’s written it’s like it understands its readers where others don’t.”). They positively commented on the variability of the exercises included in the workbook.
commenting specifically on the approachability of their delivery via different forms (written and digital), and the comprehensibility of the workbook in the workbook (e.g., I think this workbook is fantastic and it has helped me as I’m sure it will help others”). Notably, several comments referred to the length of the intervention, with different participants characterizing the intervention either as long or a short one (e.g., maybe the amount of time was too short? I felt a little under pressure to finish it and would have maybe liked a bit more time (a couple of months) to process it all’). Yet, the perception of the length of the self-help workbook seems to reflect personalized preferences (please send chasers weekly to remind people to follow this as next week I would have had the time to read the workbook fully). Supplementary Workbook S2 presents further anonymized quotes from textual responses of participants in the intervention group.

4. Discussion

This study examined whether a newly developed ACT-based self-help intervention is effective at decreasing fear of negative evaluation, impairments in functioning, and increasing psychological flexibility, compared to a waitlist control condition in adults living with a visible difference. ACT is a contextual behavioral intervention that has demonstrated its efficacy across conditions, including anxiety, psychological distress, and functional impairment, as indicated by multiple empirical evidence (Brinkborg, Michanek, Hesser, Berglund, 2011; Gloster, Walder, Levin et al., 2020; Flaxman, & Bond, 2010; Dahl, Wilson, Nilsson, 2004; Vasilio, Karademas, Christou, Papacostas, & Karekla, 2022). Its transdiagnostic effects make it suitable for an intervention for individuals with chronic physical problems (Konstantinou, Ioannou, Melanthiou et al., 2023; Hayes et al., 2022; Herbert, Ciarrochi, Hofmann, Chin, Sahdra, 2022), including individuals with visible differences in appearance. Yet, despite the recognition of the significant contribution that tailored, digitally delivered, transdiagnostic, and malleable psychological interventions can play, in improving individuals’ mental health and wellbeing (All-Party Parliamentary Group on Skin, 2020), there is a dearth of studies examining the potential benefits of ACT, delivered via different modes (e.g., group, digital, self-help), for individuals with visible differences in appearance. The present study aimed to address this gap. Therefore, we examined the preliminary acceptability, feasibility, and efficacy of an ACT self-help intervention in an international heterogeneous sample of individuals with visible differences in appearance.

Findings from the ITT analyses showed that there were statistically significant results for the primary outcome of daily functioning only, and not for social anxiety, or changes in the putative process of change variable (psychological flexibility). The statistically significant findings of the primary outcomes lend initial support for the ACT’s efficacy in heterogeneous individuals with visible differences, yet, further research is warranted. Participants in the ACT-self-help group significantly reduced functional impairment, compared to the waitlist control group, at the 4 weeks assessment (time 2 questionnaires). This finding was corroborated by different statistical analytic approaches (LCOF and completers). Finally, preliminary findings showed that the ACT self-help workbook was deemed acceptable for our heterogeneous internationally recruited sample, indicating its potentially broad applicability, yet, any further applications of it should be tested in a larger scale efficacious study.

Both the ITT and completers analyses found no differences between groups in psychological flexibility. This unexpected finding may be attributed to the complete absence of therapist contact during the delivery of the ACT self-help intervention. Qualitative findings from the present study indicate that certain individuals might need more synchronous approaches to engage with the intervention’s content, such as having the availability and guidance of a therapist that could potentially provide support, and motivate individuals to engage with the intervention’s content, especially the psychological flexibility exercises (e.g., […] I honestly did not get as far through the booklet as I meant to). This is in line with previous research that suggests the use of synchronous support, such as weekly check-ins with a therapist or group support sessions as being beneficial for engaging individuals in self-guided interventions (Baumeister, Reichler, Munzinger, & Lin 2014; Ebert et al., 2016). In another study, conducted by Bricker et al., (2014) the support of therapists reduced psychological distress, but it had no significant impact on psychological flexibility. Another study by Flederus et al. (2012) found that a self-guided ACT intervention was effective in improving psychological flexibility but only when paired with weekly therapist support. However, another more recent meta-analysis, conducted by Klimeczak, San Miguel, Mukasa, Twegian, & Levin, 2023, showed improved changes in psychological flexibility in self-help digital intervention, though, it is less clear if and when digital ACT is more efficacious than other digital interventions. It seems that by implicating service users via participatory-qualitative and other user-centered design methods, researchers and clinicians can get more informed decisions about the intervention’s deliverable preference (e.g., synchronous or therapists’ contact; APPG, 2020), and about psychological flexibility skills to be included in the intervention. Research shows that this practice can have a positive impact on the interventions’ delivery (Bartels et al., 2023) and on leveraging the mechanism via which psychological flexibility can drive treatment outcomes, such as well-being (Brown, Glendenning, Hoon, & John, 2016; Karekla et al., 2022; Vasilio et al., 2022) and functioning (van de Graaf, Trompetter, Smeets, & Mols, 2021; Herbert et al., 2022). Future self-help intervention should a priori consider the use of guidance to increase efficacy, but this requires examination in a research context.

A final explanation for the non-significant results of psychological flexibility may be explained by the mechanism via which psychological flexibility drives treatment outcomes. Psychological flexibility consists of a set of trainable skills that lead to healthy behaviours (Zhang, Leeming, Smith, et al., 2018). Yet improvements in psychological flexibility skills may take time- mostly seen after three to six months beyond the completion of intervention- and may not be immediately noticeable (Kemani, Hesser, Olsson, Lekander, & Wicksell, 2016; Lin, Klatt, McCracken, Baumeister, 2018; McCracken & Gutierrez-Martinez, 2011; Vowles, Witkiewitz, Levell, Sowden, Ashworth, 2017; Vasilio et al., 2022). In our study, changes were assessed at the 4 weeks assessment (time 2 questionnaires), which may not have been sufficient time for sensitive changes to occur. While we acknowledge this as a limitation, booster follow-up sessions and longitudinal assessments may be necessary for more long-term changes. On a similar note, we believe that clinicians and researchers should not solely focus on the level of psychological flexibility individuals may reach (from low to high), but on how individuals employ the new skills when facing challenging situations (e.g., moments of distress; Hayes et al., 2019; Hayes & Hoffman, 2020). This can be tracked with idiographic assessment methods or single-case and time-series analyses that can show how individual employ psychological flexibility skills in challenging situations (e.g., when people staring at their visible altered appearance or unsolicited questioning about their appearance), however, this has not been examined in the context of visible differences in appearance and ACT interventions.

Further findings from our trial indicated a high attrition rate, reaching almost 55% overall and 68% on the intervention group. High attrition rates are common in internet-based health behaviour change interventions (Kohl, Cronken, & Riemersma, 2013), but in our case, some qualitative feedback indicated, the high attrition rate may be due to the design in the intervention. For example, some participants reported feeling overwhelmed by the amount of workbook presented (e.g., Length of booklet at times proved overwhelming until noted that it could be read in sections) and struggled with the self-directed nature of the intervention (e.g., the length- I couldn’t read it all: I have low energy/motivation due to a number of reasons…). Additionally, others expressed a desire for more personalized guidance or support from a healthcare professional (e.g.,
evaluate whether participants retain key content and how it might apply. Findings should be treated with some caution. The data analyses indicated that 44 participants responding to them. Consequently, the qualitative acceptability may be limited by the small pool of prompts for textual area of a visible difference and body image, then researchers and clinicians ought to consider individuals’ experiences across the spectrum of appearance and in the context of individuals’ life (Thompson, 2014).

Secondly, another study limitation is the selection of the process of change variable, psychological flexibility, which was measured using the CompACT. While the CompACT is a well-validated measure, it is limited by its reliance on self-report, which may not always accurately reflect the individual’s psychological flexibility. Future research examining process-based therapies for heterogeneous populations should consider adopting high temporal density measurement, such as the process-based assessment tool; PBAT; Ciarrrochi, Sahandra, Hofmann et al., (2022) which capture changes at the level of the person and links this data with clinically relevant outcomes of stress, anxiety, and functioning.

Thirdly, given the absence of more objective measures of adherence, such as accessing audio files or accessing the content in the workbook, future research should include some type of quiz for participants, to evaluate whether participants retain key content and how it might apply to their own life experiences. Likewise, the methods of evaluation of acceptability may be limited by the small pool of prompts for textual responses at the 4 weeks assessment (time 2 questionnaire), with only 44 participants responding to them. Consequently, the qualitative findings should be treated with some caution. The data analyses indicated some negative comments that warrant further investigation. Future research should assess feasibility using methods, such as EMA or N-of-1, to track idiographic characteristics of participants’ behaviours (e.g., how they respond to different interventions’ components, sessions, and other material; Ormsmond & Cohn, 2015).

Further, the recruitment strategy may have introduced bias. The study was advertised primarily through the internet, charities, and organizations, which may have excluded a specific pool of the population that has limited access to computers or low digital literacy. It is also possible individuals who request information via charities and organizations, may exhibit different profile characteristics from those who do not. For example, those who seek information via supporting organizations may have more noticeable visible differences and need psychological support. Finally, although the CONSORT 2015 statement advocates against the testing and controlling of pre scores after randomization to groups (Boer et al., 2015), we did control for the pre scores, and we acknowledge this as a limitation. Likewise, we used the CORE-10 (Barkham et al., 2013) to ensure randomization was successful in terms of distress, at pre. Whilst additional symptom measurements may have been useful, as they are common within this population, no additional measures were used. The purpose of this was to reduce the burden of outcome measurement and aiming to increase the frequency of outcome completion.

Apart from the above limitations, the present findings provide significant theoretical and clinical implications. Theoretically, whilst studies have previously examined ACT-based interventions for body image concerns and weight stigma (Griffiths et al., 2018), this is the first study to show that a scalable ACT-based self-help intervention, delivered digitally, is efficacious for heterogeneous adults with visible differences. Then, this study attempted to address previous methodological drawbacks (Norman & Moss, 2015) by using a randomized design with a control group, and examining participants’ viewpoints, collecting qualitative data. Clinically, findings provide initial support for the use of ACT approach and highlight its potential implementation which can be far outweigh the limited current dermatological support resources (Kazdin & Blase, 2011; APGG, 2020). It may be suggested that for those with high motivation, moderate distress, or long-waiting list for psychological support, may be benefited for this type and delivery of ACT (Norman & Moss, 2015).

Future research should replicate and extend these findings. It is now important to examine, issues of feasibility, acceptability, and efficacy of similar self-help programs, including therapists’ involvement, as this may lower intervention attrition rates and enhance efficacy (Hirai & Clum, 2006). Additionally, studies should target recruiting participants through health settings, such as dermatological clinics, to increase generalizability and explore whether self-help interventions could fit within a stepped care model delivery approach. Likewise, future studies could benefit from examining the potential impact of incentives on participant retention and attrition rates, especially in cases where the incentives are conditional on completing specific study-related task. Further, future studies should a priori set a plan to reduce attrition by following suggested guidelines and examples, using persuasive technology frameworks (Kasinopoulos, Vasiliou, & Karekla, 2023; Karekla et al., 2019). Also, future research should examine whether providing incentives impact attrition rates. In our case, while we acknowledge that offering an incentive to participants may have influenced their decision to remain in the study, we do not believe that it had a significant impact on the estimation of the attrition rate. Our incentive was not conditional on completing the study or any specific study-related task, but rather on simply choosing to participate in the prize draw. Therefore, participants who dropped out of the study were still eligible for the prize draw and their decision to withdraw from the study would not have been influenced by the incentive. Finally, studies should examine the role of psychological flexibility by collecting more aggregated idiographic and longitudinally data, using methodologies (e.g., Ecological Momentary Assessments or N-of-1) that might investigate personalization and individualization of self-help programmes (Vasiliou et al., 2023).

Collectively, adults living with a visible difference present with significant levels of distress, fear of negative evaluation, and functional impairments. Thus, routine screening in relevant clinics may be a necessary action in the provision of a step-care approach. The present study findings indicated that an ACT-based self-help intervention could be integrated into a step-care approach, targeting improving functioning impairment related to visible differences. The lack of observed changes in psychological flexibility indicates the need for research that goes beyond nomothetic approaches and towards idiographic assessment methods that can highlight which process-based components can alleviate suffering in people with visible differences in appearance.**
Author statement file

All authors conceived the manuscript. LDP recruited participants, conducted the analyses, and participated in the writing of the manuscript. VSV edited the writing of the manuscript and revised it. AT edited the manuscript and provided overall supervision of the project. Also, AT was the primary supervisor of the first author during his dissertation thesis. All authors read and approved the final manuscript.

Funding

This study was conducted as part of completing a UK Doctorate in Clinical Psychology (D.Clin.Psy) which was funded by Health Education England.

Declaration of Competing Interest

There are no declarations of interest.

Data Availability

Data will be made available on request.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.bodim.2023.101657.

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L.D. Powell et al. Body Image 47 (2023) 101637


