Using if-then planning in independently delivered and self-help interventions to promote physical and mental health.

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Declaration

I declare that this work has not been submitted for any other degree at the University of Sheffield or any other institution. This thesis is my own original work and all other sources have been referenced accordingly.

Structure and Word Counts

Section One: Literature Review

Excluding references	6,259
Including references	8,482
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Section Two: Research Report

Excluding references	10,416
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Overall Abstract

The first part of this thesis consists of a systematic literature review of the effectiveness of independently delivered interventions incorporating implementation intentions on health outcomes. The second part is a research study examining the effectiveness of a self-help intervention aiming to improve social confidence for people with visible skin conditions in a randomised controlled trial.

In the literature review, ten studies examining the effectiveness of independently delivered interventions incorporating implementation intentions on physical or mental health outcomes were systematically reviewed and critically appraised. Effectiveness was measured by extracting data from the studies and undertaking a meta-analysis. The results showed that independently delivered interventions incorporating implementation intentions had a small, but reliable, overall effect ($g+ = 0.16$).

In the research study, 326 participants with a variety of visible skin conditions were randomised to either (i) self-help enhanced with implementation intentions, (ii) standard self-help without implementation intentions or (iii) a wait-list control condition. The results showed that participants exhibited clinically significant levels of social anxiety, ‘mild’ symptoms of generalised anxiety and ‘moderate’ symptoms of depression. There was no evidence that the standard or enhanced self-help interventions reduced fear of negative evaluation, symptoms of anxiety or symptoms of depression in comparison to the wait-list control condition.

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Firstly, I would like to thank the individuals who gave up their time to take part in this study and the skin charities and organisations who helped with the recruitment process. Without your contribution, this project would not have been possible.

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Section One: Literature Review

Using independently delivered interventions incorporating if-then planning: A meta-analysis of randomised controlled trials targeting health outcomes

Abstract

Objectives. Interventions incorporating if-then planning (or implementation intentions) are increasingly used to improve health outcomes. Independently delivered interventions are rising in popularity due to their accessibility and cost-effectiveness. The present review aimed to combine these two areas and investigate the effectiveness of independently delivered interventions incorporating implementation intentions in improving in physical and mental health outcomes.

Methods. A systematic search of PsychInfo and Web of Science was conducted. Studies were required to be randomised controlled trials, include interventions incorporating the explicit use of implementation intentions and be delivered independently. Further, studies were required to use pre and post quantitative measures of health outcomes to examine changes over time, provide sufficient data for calculating effect size and be published in English. Random effects meta-analysis was used to identify the sample-weighted average effect of the interventions on health outcomes.

Results. In total, 10 studies were included in the review (total $N = 20{,}766$). The sample-weighted effect was $g+ = 0.16$ with a 95% confidence interval from 0.08 to 0.24. The findings suggest that interventions incorporating implementation intentions were favoured in comparison to control conditions.

Conclusions. Independently delivered interventions incorporating implementation intentions have a small, but significant, positive impact in improving health outcomes. However, the findings must be interpreted with caution due to the relatively small number of studies included in the review. More randomised controlled trials (RCTs) examining the effect of interventions incorporating implementation intentions delivered independently are needed, especially in the field of mental health.

Practitioner points:

- Independently delivered interventions incorporating implementation intentions have a small, but reliable, effect on improving physical and mental health outcomes.
- Using technology to promote health outcomes appears to have utility.
- It is possible that the effectiveness of interventions incorporating implementation intentions may be increased through therapist contact.
- The present review's results should be interpreted with caution due to the limited number of studies included.
- Only one rater selected and extracted data for the meta-analysis. As these processes were not carried out with a second rater, bias may have influenced decisions in these two areas.

Introduction

Interventions and implementation intentions

In health contexts, a disparity often exists between individuals' *intention* to act and *actual* behavioural enactment, often referred to as the intention-behaviour 'gap' (Orbell & Sheeran, 1998; Rhodes & de Bruijn, 2013a, 2013b; Sheeran, 2002; Sniehotta, Scholz, & Schwarzer, 2005). Forming if-then plans or 'implementation intentions' (Gollwitzer, 1999; Gollwitzer & Sheeran, 2006) has been suggested as a useful method for overcoming this intention-behaviour gap. Implementation intentions (IIs) require individuals to identify when and where they will carry out their intended behaviour following an 'if x, then y!' format e.g. 'I*f* situation x occurs, *then* I will carry out y behaviour*!'* (Gollwitzer, 1999). For example, an individual with anxiety may form the following II: "If I feel under pressure, then I will immediately use my breathing tactic to relax!" (Varley, Webb, & Sheeran, 2011). Individuals aiming to undertake physical activity may form the following II: "If I am tempted to skip exercising, then I will tell myself 'no excuses' and remind myself that I will feel great after exercising" (Cameron et al., 2015).

Forming IIs has been effective in achieving desired outcomes in numerous contexts. Gollwitzer and Sheeran (2006) undertook a meta-analysis of 94 studies examining the effect of implementation intentions on goal achievement and found that IIs were shown to have a medium-large effect size (Cohen's $d = 0.65$). In the context of physical health outcomes, interventions incorporating IIs have shown to be effective for improving breast self-examination (Orbell, Hodgkins, & Sheeran, 1997; Prestwich et al., 2005), physical activity (Prestwich, Lawton, & Conner, 2003), dietary behaviour (Hagger & Montasem, 2009) and alcohol consumption (Murgraff, Abraham, & McDermott, 2007).

In relation to mental health outcomes, interventions incorporating IIs have shown to be effective in studies by Palayiwa, Sheeran, and Thompson (2012), Sheeran, Aubrey, & Kellett, 2007, Varley et al. (2011) and also in a meta-analysis by Toli, Webb, and Hardy (2016).

Palayiwa, Sheeran, and Thompson (2010) investigated the impact of forming IIs on participants' ability to ignore distressing comments regarding their appearance. 145 female staff and students from a University in the United Kingdom completed a test of attention with either no audio input (control), having formed a goal intention to ignore stigmatising comments (goal intention condition), or having formed an II to ignore stigmatising comments (II condition). The results of the study showed that participants who formed IIs (i) improved test performance compared to goal intention participants and (ii) demonstrated equivalent performance as compared to control participants. Further, participants who formed IIs were less distressed by the stigmatising comments compared to participants allocated to the goal intention or control condition, particularly for participants with low body satisfaction.

Sheeran, Aubrey, and Kellet (2007) examined the impact of an II intervention aiming to increase attendance at psychotherapy appointments. Non-attendance for psychotherapy is a significant problem for mental health services (e.g., Garfield, 1994) and can have serious, negative clinical and financial consequences (Sheeran et al., 2007). 476 individuals received a postal questionnaire as part of an invite to a scheduled, initial psychotherapy appointment and were randomly assigned to one of two conditions, an II condition or a control condition. Participants in both conditions completed the questionnaire, however the questionnaire in the experimental condition contained an extra paragraph as follows: "People can sometimes feel concerned about attending their appointment. To help you to manage these concerns, please read the statement below 3 times and repeat it silently to yourself one more time: As soon as I

feel concerned about attending my appointment, I will ignore that feeling and tell myself this is perfectly understandable! Now please tick the box below if you have read the statement 3 times and said it to yourself once (please be honest, do not tick the box until you have read and repeated the statement) [white square].” Intention-to-treat analyses (*n* = 390*)* showed that participants in the II condition were more likely to attend their psychotherapy appointment compared to participants in the control condition (75% compared to 63%), with the effect even stronger among participants who returned the questionnaire (83% compared to 57%). The results of this study suggest that forming IIs can help individuals to cope with negative feelings that might be a barrier to attending initial psychotherapy appointments.

Varley et al. (2011) examined the impact of enhancing self-help materials intended to promote the effective self-management of anxiety symptoms with IIs. Participants were randomised to either standard self-help (*n* = 86), self-help enhanced with IIs (*n* = 90) or control (*n* = 86) conditions. Participants allocated to the enhanced self-help condition were prompted to form an II to use a relaxation exercise detailed in the self-help materials (e.g., “If I feel under pressure, then I will immediately use my breathing tactic to relax”). The findings of this study showed a significant reduction in anxiety in the enhanced condition in comparison to both the standard self-help and control conditions. Varley and colleagues suggested that the results of their study indicated that implementation intentions may have the potential to be a beneficial supplement to self-help materials in improving outcomes.

A recent meta-analysis conducted by Toli, Webb, and Hardy (2016) investigated the effect of if-then planning on goal attainment among participants with a clinical diagnosis or scores above clinical cut-offs as specified by clinical measures. Even when excluding one very large effect, forming IIs had a large-sized effect on achieving goals (*d* = 0.99, *k* = 28, *N* = 1,636). The results from this meta-analysis indicate that forming

IIs was effective in promoting goal achievement across a range of mental health difficulties and goals.

However, not all research has shown the efficacy of IIs, for example studies such as Powers, Koestner, and Topciu (2005) and Shah, Hunt, Webb, and Thompson (2014). Powers and colleagues posed the question "Does the development of IIs act uniformly across individuals or is the effect of implementation intentions significantly moderated by stable personality characteristics?". Powers et al. (2005) aimed to investigate if perfectionism moderated the impact of IIs on goal achievement and conducted two studies. The first study (n = 50) examined the effects of an II condition in interaction with perfectionism on the progress of New Year's resolutions. The second study (n = 133) added a repeated II condition and monitored affect and monthly goal achievement. In both studies, the results showed that there was a significant 'back-fire' effect of IIs for participants with higher socially prescribed perfectionism traits. Participants with higher socially prescribed perfectionism traits in the II condition reported doing significantly worse than participants in the control condition. The study by Powers et al. (2005) was one of the first to suggest that IIs could be contra-indicated in some individuals, specifically those with a trait of socially prescribed perfectionism.

A study by Shah, Hunt, Webb and Thompson (2014) aimed to examine if participants allocated to receive self-help enhanced with IIs had significant improvements in social anxiety in comparison to participants allocated either to receive self-help without IIs or a control group. The self-help was based on cognitive behavioural therapy (CBT) principles and included psycho-education, relaxation and attentional refocusing for individuals with Vitiligo. Despite participants in the enhanced self-help condition showing *reliable* and *clinically significant* changes in social anxiety, no statistically significant difference was found between conditions.

In conclusion, although there is a significant body of literature promoting the use of interventions incorporating IIs, there are also studies which suggest that these interventions are not always effective, or have adverse effects.

Using technology to deliver interventions

Despite research demonstrating the effectiveness of interventions in improving health outcomes, these interventions are often expensive and resource intensive. Thus, there is a drive to provide effective but accessible and low cost interventions. In an attempt to provide this, there has been an introduction of stepped-care models into mental health services. The premise of stepped care models is to provide pathways where individuals are offered the most accessible and least restrictive treatment and 'stepped-up' to more intensive interventions as required, resulting in the most efficient use of resources (Bower & Gilbody, 2005). The first step usually involves education, advice and monitoring. The second step involves pure or guided self-help or psychoeducation groups. The third step involves medication (e.g. selective serotonin reuptake inhibitor [SSRI]) or CBT or applied relaxation. The fourth step involves specialist treatment. Stepped-care models are the recommended pathway for the management of a variety of mental health difficulties including generalised anxiety disorder (GAD) and panic disorder (PD) (e.g. National Institute for Health and Care Excellence, 2011a, 2011b).

An increasingly popular strategy to improve accessibility to psycho-education and psychological intervention (i.e. steps one, two and three of the stepped care model) is the use of technology to deliver information or provide interventions. Technology can be used to deliver interventions independently to individuals, or may involve therapist involvement or feedback, such as guided self-help or therapy delivered over Skype. Examples of independently delivered interventions include, but are not limited to,

websites, e-newsletters, forums, downloads of self-help workbooks, mobile phone applications and video-games. An example of a successful intervention delivered online is that of Bessell et al. (2012). Bessell and colleagues (2012) examined the effectiveness of a computer based intervention based on CBT principles in reducing anxiety and appearance related distress in individuals with visible difference. Participants were randomised to one of three conditions, (i) the computer based intervention, (ii) face-to-face CBT or (iii) the no intervention control group. The results of the study showed that participants allocated to the computer based and face-to-face intervention conditions reported a significant decrease in anxiety and appearance related distress. The findings suggest that computer based CBT offers the potential to provide easy, cost-effective psychological interventions to adults with visible difference. In relation to physical health, studies have shown that web-based interventions represent a highly accessible, low-cost method of promoting physical activity in large segments of the population, as examined in a meta-analysis by Davies, Spence, Vandelanotte, Caperchione and Mummery (2012).

The benefits of using technology to deliver interventions include popularity (meaning that interventions can be delivered to a large number of people – potentially at a low cost thus increasing economies of scale) and mobility (meaning interventions are convenient and easy to access) (Free et al., 2013). Interventions delivered using technology have been shown to increase access, engagement, and availability of resources for individuals with depression and anxiety (Ahmedani, Crotty, Abdulhak, & Ondersma, 2015; Clarke & Yarborough, 2013). However, despite, the increase in the use of technology to deliver interventions aiming to improve health outcomes, there is a paucity of research examining the effectiveness of commonly used platforms or delivery methods (Ahmedani, Belville-Robertson, Hirsch, & Jurayj, 2016).

The present review

The aim of the present review was to incorporate the two areas of interest discussed (i) interventions incorporating IIs and (ii) the use of technology to provide independently delivered interventions. By doing so, it was hoped that the present review would also add to the literature base regarding the effectiveness of IIs on physical or mental health outcomes, due to the existing conflicting results. The present review aimed to examine the effectiveness of interventions delivered *independently*, in line with current drivers to provide accessible, low-cost interventions to improve health outcomes. As a result, the present review hoped to add to the currently limited literature regarding the effectiveness of technology platforms (Ahmedani, Belville-Robertson, Hirsch, & Jurayj, 2016). Finally, the present review aimed to include an appraisal of the quality of included studies and use meta-analysis to quantify the sample-weighted average effect of such interventions on outcomes. The primary hypothesis was that, in line with the findings of a meta-analysis by Gollwitzer and Sheeran (2006), independently delivered interventions incorporating implementation intentions would be effective in improving health outcomes.

Method

Search strategy

Electronic databases (those indexed by Web of Science and PsychInfo) were searched for relevant studies. Three sets of search terms (or 'filters') were used and combined with the Boolean operator 'AND' as follows: (i) "implementation intention" OR "if then plan", (ii) "health" OR "mental health" OR "anxiety' OR "depression" OR "physical health" OR "physical activity" OR "exercise", (iii) "online" OR "internet" OR "text message" or "SMS".

Inclusion criteria

Studies were required to fulfil eight inclusion criteria:

1) Studies were required to be published in English.
2) Studies were required to be available online from inception to December 2016.
3) Studies were required to utilise a randomised controlled trial (RCT) design with a minimum of one intervention group and one comparison control group.
4) Studies were required to involve independently delivered interventions with no contact with investigators (e.g., studies where participants received an intervention in a laboratory setting, for example, were excluded).
5) The intervention group was required to aim to influence 'health' which was broadly considered in this review as mental health (e.g., symptoms of anxiety) or physical health (e.g., physical activity, alcohol consumption).
6) The intervention was required to involve participants explicitly forming IIs or 'if-then' plans.
7) Studies were required to report a quantitative measure of pre and post intervention change to enable examination of change over time. Measures could include changes in behaviour (e.g., levels of physical activity, amount of alcohol consumed) or outcomes (e.g., levels of anxiety).
8) Studies were required to report sufficient data for extracting and calculating effect size (e.g., the mean and standard deviation for the relevant outcome by condition).

Screening

In total, 506 records which were potentially eligible for inclusion were screened for relevance (i.e., by looking at the title and abstract). The full texts of 23 studies were

evaluated in detail and 13 were rejected. One study was rejected as it did not have a control condition (Keller, Knoll, Gellert, Schneider, & Ernsting, 2016). One study was rejected as the intervention did not relate to physical or mental health: Bell, Toth, Little, & Smith (2015) examined the effectiveness of an online intervention aiming to change energy-saving behaviour in adolescents. Two studies were rejected as they did not measure pre-post intervention change (Craciun, 2012; Delgadillo, Moreea, Murphy, Ali, & Swift, 2015). Four studies were rejected as they involved contact with investigators and thus were not deemed to be 'independently delivered' (Gibson et al., 2012; Prestwich, Perugini, & Hurling, 2009, 2010; Tapper, Jiga-Boy, Maio, Haddock, & Lewis, 2014). Finally, five studies did not provide adequate data for extracting and calculating effect size. Authors of the studies were contacted but did not provide the requested data and as such were not included in the analysis (Bolman et al., 2015; Budden & Sagarin, 2007; Soureti, Murray, Cobain, van Mechelen, & Hurling, 2011b; Soureti et al., 2011a; de Nooijer, de Vet, Brug, & de Vries, 2006). In total, ten studies met the criteria of the systematic review. Figure 1 shows the flow of papers through the review using a PRISMA diagram (Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2009).

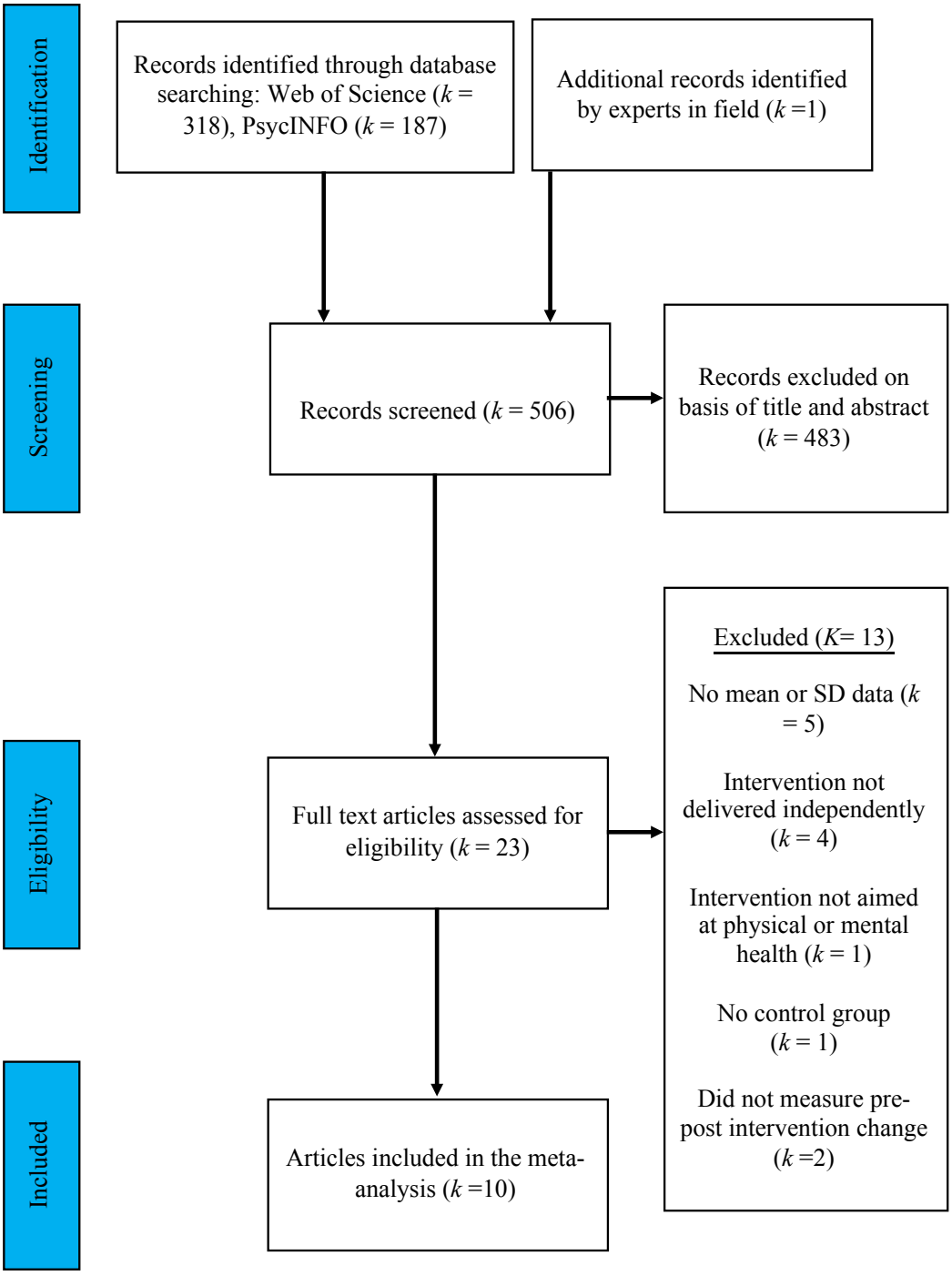

Figure 1. *PRISMA diagram displaying the flow of papers through the review.*

Data extraction and Assessment of Quality

The following information was extracted from each paper: Authors, participant information (i.e. characteristics, sample size, country in which recruited), health outcome examined (i.e. anxiety symptoms, physical activity, fruit and vegetable intake, alcohol consumption, hand-washing), primary outcome measures, method of delivery (i.e. online, download of self-help, mobile phone application, videogame, newsletter, website) and mean and standard deviation statistics. The quality of the studies was assessed using the CONSORT checklist (Schulz, Altman, & Moher, 2010) of information to include when reporting a randomised trial. The CONSORT checklist was selected as it is designed to specifically assess the quality of RCTs, enabling comparison between studies herein. Higher scores on this measure indicate greater methodological quality (Schulz, Altman, & Moher, 2010). An assessment of study quality was conducted to ensure that the studies included in this review were of a sufficient standard. The quality analysis in this review was also conducted to allow for studies of an insufficient quality to be excluded if required. See Appendix A for a copy of the CONSORT quality checklist. See Appendix B for a quality appraisal of the included studies.

Meta-analytic strategy

Effect sizes (Hedges *g*) were computed by extracting mean and standard deviation (SD) data from the studies. Effect sizes were calculated using data analysis and statistical software Stata (Version 12). Hedges *g* may be interpreted using Cohen's (1988) convention where 0.2 is considered a small effect, 0.5 a medium effect and 0.8 a large effect (Cohen, 1988). A random effects model was chosen as the studies were likely to be 'different from one another in ways too complex to capture by a few simple study characteristics' (Cooper, 1986, pp. 526). Where mean and standard deviation data

were reported for more than one time point (e.g. Cameron et al., 2015 measured at both one and six months) the effect size was computed using the longest follow up point. Where studies contained multiple outcome measures (e.g., Cameron et al., 2015 measured fruit and vegetable intake, physical activity and alcohol consumption) the effect sizes within each study (across outcome measures) were meta-analysed in their own right and weighted by sample size prior to being included in the main meta-analysis. An overall effect size was computed for each study (based on all the variables examined). This strategy capitalises on the data available, while maintaining the independence of effect sizes that is central to the validity of meta-analysis. Where studies included more than one comparison condition (e.g. Shah et al., 2014) the most 'active' conditions (as opposed to 'passive' conditions such as wait list controls) were compared with the aim of isolating the effect of IIs where possible. In the case of Shah et al. (2014), outcomes from participants who were randomised to an intervention enhanced with IIs condition were compared against outcomes from participants who were randomised to an intervention without IIs, as opposed to comparing to the wait-list control group. Where it was not possible to separate the data for different interventions conditions, the active conditions were combined and treated as one intervention (e.g., Elbert, Dijkstra, & Oenema (2016) delivered two interventions by audio or text, in comparison to a wait list control). The threshold for statistical significance was an alpha value of 0.05 in line with the majority of published research (Borenstein, Hedges, Higgins, & Rothenstein, 2009). Moderator analysis was also performed. Moderating variables were agreed a-priori in line with the areas of interest of the present review and (i) examined the mode of intervention delivery and (ii) whether the impact of IIs were isolated by condition (i.e. intervention with II compared to active condition, or intervention with II compared to passive control condition).

Reporting bias

To assess for between-study reporting bias, a funnel plot was drawn to provide a visual representation of the relationship between the standard error (SE) of included studies and their effect sizes (Sterne, Egger, & Smith, 2001). Straight lines on the funnel plot indicate where 95% of studies would be expected to fall in the absence of heterogeneity and reporting bias. As purely relying on the visual inspection of a funnel plot has been criticised (Terrin, Schmid, & Lau, 2005), Egger's regression method was calculated to assess publication bias (Egger, Smith, Schneider, & Minder, 1997).

Results

A total of $k = 10$ studies with $N = 20{,}766$ participants were included in the review. Table 1 summarises the characteristics for all ten studies including participant characteristics, target health outcome, outcome measures administered, sample size, whether the effect of IIs was isolated by the study design, method of intervention delivery, overall quality score and effect size (Hedges *g*).

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Table 1. *Characteristics and effect size of the reviewed studies*

Author and Year	Country	Population	Target Health Outcome	NC	NE	Effect of II isolated by condition?	Primary Outcome Measure(s)	Delivery method	Quality Score*	Effect size (*g*)
Cameron et al. (2015)	United Kingdom	Incoming undergraduate students to the University of Sheffield. 55% female.	Healthy lifestyle behaviours (e.g., fruit and vegetable intake, physical activity, alcohol consumption)	799	696	×	i) Number of portions of fruits consumed per day ii) Physical activity in the previous week iii) Alcohol consumption in the previous week iv) Smoking status at six month follow up	Online	26	0.06
Chapman, Campbell, & Wilson (2015)	Australia	South Australian public sector office workers aged 18-60. 31.5% in 40-50 age range. 71% female.	Physical activity	130	124	✓	i) Measure of behavioural intention and self-efficacy (3 item 5 point Likert scale) e.g. My intention to increase my weekly amount of exercise (strongly disagree to strongly agree) ii) Open-ended item for weekly exercise "Over the past week, how many vigorous 20-minute or moderate 30-minute exercise sessions did you do?"	Online	16	0.06
Elbert, Dijkstra, & Oenema (2016)	The Netherlands	Individuals aged 16 years or above, who owned an Android device and did not consume two pieces of fruit and 200 grams of vegetables on a daily basis. 73.3% female. Mean age 41.4 years.	Fruit and Vegetable consumption	58	88	×	i) Food frequency questionnaire (Likert Scale 0 = never or less than 1 day a week – 7 = every day) ii) Number of fruit and vegetables portions consumed per day	Mobile Phone Application	21	0.21

Author and Year	Country	Population	Target Health Outcome	NC	NE	Effect of II isolated by condition?	Primary Outcome Measure(s)	Delivery method	Quality Score*	Effect size (*g*)
Hagger, Lonsdale, & Chatzisarantis (2012)	United Kingdom	Undergraduate students from 19 academic departments at the University of Nottingham. Mean age 20.37 years.	Alcohol consumption	149	238	×	i) Self-reported measure of number of units of alcohol used ii) number of heavy episodic 'binge' drinking occasions in the past four weeks iii) (FAST)	Online	21	0.00
Lange et al. (2013)	Germany	Community population recruited through university internet site. Mean age 37.73 years. 79.0% female. 70.3% had college degree. 64% employed.	Fruit consumption	399	392	✓	i) Fruit intake (open answer – "Please think of your dietary behaviour in the past week: How many servings of fruit did you eat on average per day" ii) 2 item dietary planning (6 point Likert scale) iii) 3 item dietary action (6 point Likert scale)	Online	17	0.20
Little et al. (2015)	United Kingdom	Patients of General Practices In England aged 18 or over. Mean age 56.6 years. 56% female.	Handwashing	8667	8241	×	Number of respiratory track infection at 16 weeks.	Online	28	0.15
Shah, Hunt, Webb, & Thompson (2014)	United Kingdom	Individuals with Vitiligo aged 18 – 65 recruited from the U.K. Vitiligo Society website and newsletter.	Social Anxiety	24	21	✓	12 item BFNE	Download of self-help	22	0.17

Author and Year	Country	Population	Target Health Outcome	NC	NE	Effect of II isolated by condition?	Primary Outcome Measure(s)	Delivery method	Quality Score*	Effect size (*g*)
Skår, Sniehotta, Molloy, Prestwich, & Araújo-Soares (2011)	United Kingdom	University students. Mean age 22.8 years. 63.4% female. Mean Body Mass Index 22.5	Physical activity	188	187	×	Self-report measure of physical activity behaviour ("How often have you participated in physical activities for at least 30 min per session in your free time in the last week?")	Online	21	0.03
Thompson et al. (2015)	USA	Children (9~11 years old) who had a computer and high speed internet access and a parent willing to participate.	Fruit and vegetable consumption	97	97	✓	24 hour dietary recalls (two weekday, one weekend day)	Videogame (child). Electronic Newsletter/ website (parent)	24	0.40
Varley, Webb, & Sheeran (2011)	United Kingdom	University Staff and Students at The University of Sheffield who identified as experiencing anxiety symptoms (but not receiving professional help for anxiety). 68.7% White British. 64.7% students Mean age 29.63 years.	Anxiety Symptoms	81	90	✓	i) 14 item HADS ii) 20 item STAI	Download of self-help	23	0.53

Note: BFNE: Brief Fear of Negative Evaluation Scale (Leary, 1983); FAST: Fast Alcohol Screening Test (Hodgson, Alwyn, John, Thom, & Smith, 2002); HADS: Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983); STAI: State Trait Anxiety Inventory (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983); NC= number of participants in control group; NE = number of participants in experimental group; *Quality score: The higher the score the higher the quality rating given.

There was significant variety in both sample characteristics and study characteristics (e.g. intervention type, delivery method) of the included studies. The studies included interventions targeted at students, children and parent dyads, office workers, people with Vitiligo, patients recruited from GP surgeries, community populations and University staff. Participants were recruited from the United Kingdom (UK), Australia, The Netherlands, Germany and the United States of America (USA). Eight out of ten studies (80%) were focused on physical health outcomes whereas only two studies (20%) were focused on mental health outcomes. There was also a variety of health behaviours targeted by the interventions in the studies including fruit and vegetable intake, alcohol intake, physical activity, handwashing and anxiety symptoms. The technology used to deliver the interventions included online platforms, mobile phone applications, downloads of self-help materials, newsletters and/or video-games. All studies undertook a longitudinal design incorporating only one follow up measurement apart from Cameron et al. (2015) who followed up participants at both one and six month time points.

Quality appraisal

Overall, the majority of studies reviewed were of a reasonable quality as assessed using the CONSORT checklist (Schulz et al., 2010). All studies included in this review were RCTs. RCTs are often regarded as the most scientifically rigorous method of hypothesis testing (Last, 2001) and referred to as the "gold standard" for examining efficacy of interventions (McGovern, 2001). Most studies provided sufficient detail to aid replication, and detailed methods of statistical analyses conducted. Participant flow through the study, including the number of participants analysed and reasons for losses and exclusions was provided by all studies in the present review. However, studies tended to lack detail regarding the method and type of randomisation.

Further, not all studies reported the RCT design in the title of the manuscript, which may result in these studies being missed in literature searches seeking to identify studies with an RCT design. Studies could be improved by detailing more information about participants; information regarding demographics was not always provided or tabulated, and at times the nature of the participants included was vague. Only half of the studies detailed how their sample size was determined and no study reported why their trial ended. Finally, the registration of trials was inconsistent; four studies reported where the trial was registered (Cameron et al., 2015; Elbert et al., 2016; Little et al., 2015; Thompson et al., 2015).

Overall effect of self-help interventions incorporating IIs on health behaviour change

The effect sizes ranged from $g = 0.00$ to 0.53 (see Fig. 2). The sample-weighted effect was $g+ = 0.16$ with a 95% confidence interval from 0.08 to 0.24. These findings indicate that independently delivered interventions incorporating IIs had a small-sized, but reliable, effect on health outcome change according to Cohen's (1988) criteria. The heterogeneity statistic was significant ($p = < 0.01$), suggesting that the effect sizes were variable.

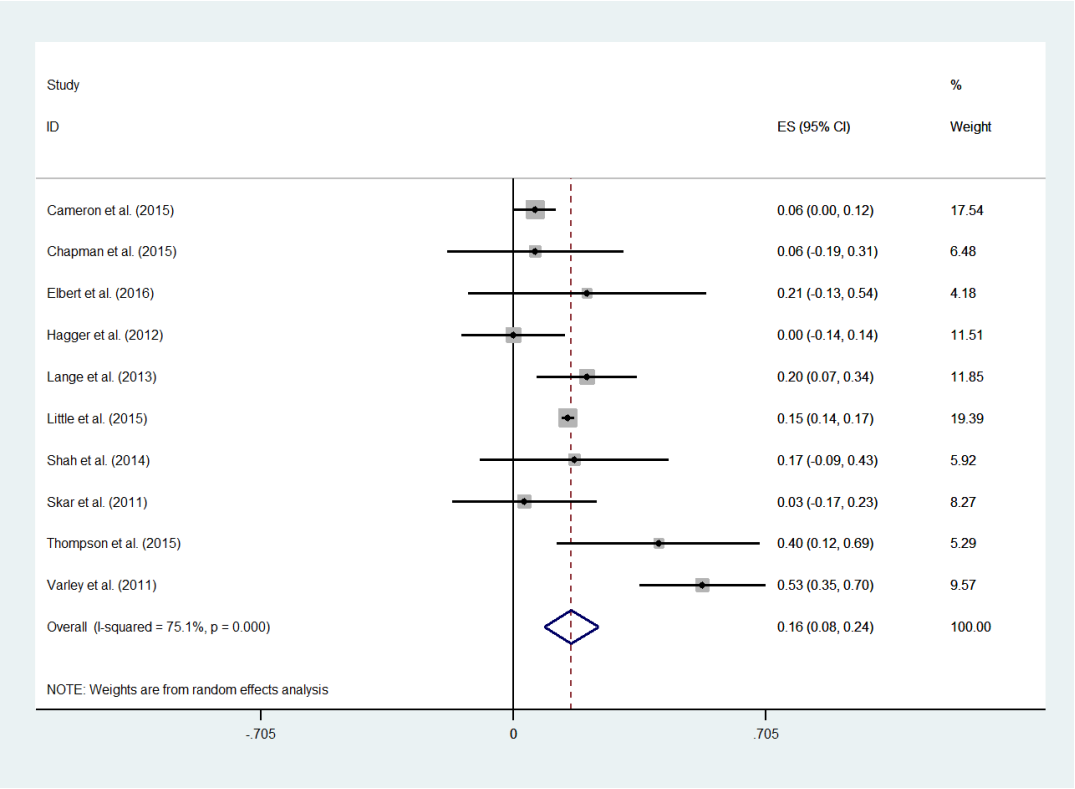

Figure 2. *Effect sizes, standard error, confidence interval, and weighting of studies.*

Reporting Bias

The distribution of the ten studies around the pooled mean effect size is shown as a funnel plot (see Fig. 3). The Egger regression method (Egger et al., 1997) was calculated to assess for publication bias. The Egger regression method did not indicate the presence of significant reporting bias, $p = .83$. Funnel plots were not drawn out for sub-group analyses as it is difficult to detect bias with ≤10 studies (Higgins & Green, 2011).

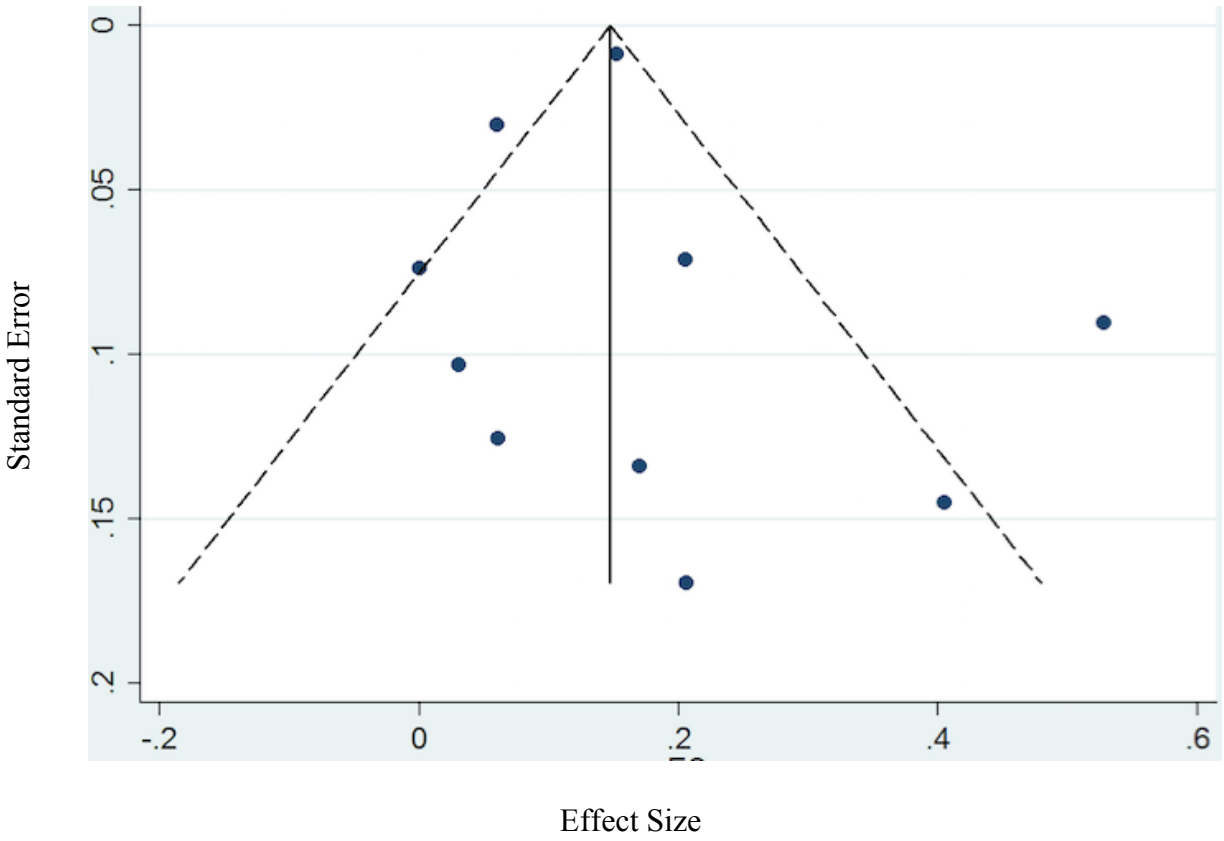

Figure 3. *Funnel plot of effect sizes from the primary studies*.

Moderators of the effect of interventions incorporating IIs on health behaviour change

The impact of two moderators were explored (see Table 2). Firstly, the method of delivery. The method of delivering the intervention had a varied effect where interventions delivered online ($g+ = 0.10$, k = 6), video-game and newsletter ($g+ = 0.40$, k = 1), mobile phone application ($g+ = 0.21$, k = 1) and download of self-help ($g+ = 0.36$, k = 2). I-squared was used to evaluate whether the effect sizes associated with each level were significantly different. For online interventions, I-squared = 66.20%, $p = 0.011$ and for download of self-help interventions I-squared = 79.6%, $p = 0.027$, indicating that the effect sizes within this level were significantly different. It was not possible to compute I-Squared calculations for the mobile phone app and combination categories due to the lack of comparable studies using the same method of delivery. Due to the small amount of studies overall, and also within the download of self-help,

mobile phone application and combination of video-game, newsletter, and website categories the results must be interpreted with significant caution.

Secondly, the effect sizes of studies which isolated the impact of IIs (comparing active interventions with and without IIs) were compared to interventions which did not (comparing interventions with IIs to a passive control such as information provision or a no intervention wait list). Where the effect of IIs was isolated, the overall effect size was $g+ = 0.28$, compared to where overall effect of IIs was not isolated $g+ = 0.09$.

Table 2. *Effect of moderators on effect size*

Moderator	Level	*N*	*k*	95% CI	Effect size (Hedges *g*)
Method of delivery	Online	20,210	6	0.03 - 0.17	0.10
	Download of self-help	216	2	0.01 – 0.71	0.36
	Mobile phone application	146	1	-0.13 – 0.54	0.21
	Videogame, Electronic Newsletters, website	194	1	0.12 – 0.69	0.40
Was the effect of IIs isolated?	Yes	1455	5	0.11 - 0.45	0.28
	No	19,311	5	0.01 – 0.16	0.09

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Discussion

The present review is the first to systematically evaluate the effectiveness of independently delivered interventions incorporating IIs on physical and mental health outcomes. The findings indicate that independently delivered interventions incorporating IIs have a reliable, positive effect on health behaviour change. However, the overall sample-weighted effect size found in the present review was smaller than the medium to large effect size reported in a previous meta-analysis by Gollwitzer and Sheeran (2006). When examining the moderating variables, there was a small effect of interventions incorporating IIs in comparison to active comparison conditions. Interestingly, this effect was larger than the effect of II interventions in comparison to passive controls (e.g. wait list control) highlighting the possible benefits of incorporating IIs into interventions. However, due to the small number of studies included to calculate both overall and moderator effect sizes, the results of the present review must be interpreted with caution. Possible explanations for the findings of the present review, clinical implications and directions for future research are explored below. Moderator analyses results are not explored further due to the small number of studies included and the increased possibility of unfounded inferences being drawn.

Inclusion of independently delivered interventions. Only studies with independently delivered interventions were included in the study. It is possible that the overall effect size calculated for the present review is smaller than existing literature due to the nature of *how* the intervention is delivered. As reported previously, a large meta-analysis by Gollwitzer and Sheeran (2006), calculated a medium to large effect of interventions incorporating IIs. However, Gollwitzer and Sheeran's (2006) review included a wide variety of interventions including those with research and therapist contact. Research shows that interventions involving therapist contact have a larger effect than independently delivered interventions. For example, several reviews indicate

that contact from a therapist or a para-professional increases the efficacy of self-help materials (Hirai & Clum, 2006; Menchola, Arkowitz, & Burke, 2007; van Boeijen et al., 2005). Thus, it is possible that the intensity of interventions included in Gollwitzer and Sheeran's (2006) review inflated the overall effect of IIs on goal attainment. As a result, it is less surprising that the effect sizes from the present review indicate a smaller effect size compared to the existing literature which includes interventions with therapist or researcher contact.

Publication bias. It is possible that some research in this area was not accounted for as studies published in a non-English language and unpublished theses were not considered. However, results of Egger's regression method did not indicate the presence of a significant reporting bias.

Limitations and areas for future research

The present review has several limitations. Only one rater selected and extracted data for the meta-analysis. As these processes were not carried out with a second rater, bias may have influenced decision regarding these two areas. The addition of a second rater would have been beneficial to confirm coding bias and data extraction accuracy.

Although the review aimed to be as inclusive as possible, only ten studies were included in the meta-analysis. Disappointingly, five studies were excluded from analysis as they did not provide adequate data to calculate precise effect sizes. Future research would benefit from providing the data required to allow the precise computation of effect sizes in meta-analyses, such as mean and standard deviation data. Due to the relatively small number of studies included in the present review, it is possible that certain study or sample characteristics could significantly skew the results of the analysis. Although sample-weighted effect sizes were calculated to overcome the differing sample sizes across studies, the small number of studies is a limitation and

results must be interpreted with caution. Indeed, the heterogeneity within the studies broadly (e.g. population, target health behaviour), within the overall effect sizes and within the moderator effect sizes raises questions regarding inferences that can be drawn from the present review's findings. Further, the lack of studies resulted in limited exploration taking place of moderating variables. The moderator analyses indicated overlapping confidence intervals, and as such the results must be interpreted with caution. Future research should aim to undertake a meta-analysis when more studies examining the effectiveness of independently delivered interventions incorporating IIs are available. An increase in the number of studies included in the meta-analysis would allow for more reliable and generalisable conclusions to be drawn. Further, the majority of existing literature focuses on physical health outcomes, as opposed to mental health outcomes. Future research focusing on mental health outcomes would be beneficial to add to the literature base. In the present review, all but one study (excluding Cameron et al., 2015) measured follow up at one time-point only. It would also be beneficial if future studies examined outcomes at multiple time points to allow inferences to be made regarding the longevity of any effects found.

However, where the present review may lack in study quantity, it provides in study quality. Studies were required to have a randomised controlled trial (RCT) design. RCTs are often regarded as the most scientifically rigorous method of hypothesis testing (Last, 2001) and referred to as the "gold standard" for examining efficacy of interventions (McGovern, 2001). Indeed, Cochrane recommendations for systematic reviews report randomisation as a key criterion of high level evidence (Higgin & Green, 2008).

Clinical Implications

The findings of the present review suggest that independently delivered interventions incorporating IIs have a small, but reliable, effect in comparison to control

conditions and thus have utility in improving mental and physical health outcomes. Further, as the effect size increased when the impact of IIs in comparison to active comparisons, the use of IIs per se may have particular utility. It is possible that the effectiveness of independently delivered interventions based on IIs could be increased through therapist contact as research suggests that guided interventions can be more effective than pure self-help (Hirai & Clum, 2006; Menchola, Arkowitz, & Burke, 2007; van Boeijen et al., 2005). Further, the results of the study suggest that the use of technology to deliver interventions appears beneficial.

Conclusions

The main aim of this review was to investigate whether interventions incorporating IIs were effective when delivered independently (i.e. without therapist or researcher contact). The driver behind this aim is the need to provide accessible, low-cost interventions to improve health outcomes and add to the currently limited literature regarding the use of technology as a delivery platform (Ahmedani, Belville-Robertson, Hirsch, & Jurayj, 2016).

The results of this review suggest that independently delivered interventions incorporating IIs have a small, but significant, positive effect on health outcomes and thus show promise both clinically and theoretically. However, this review is limited by the relatively small number of studies eligible for inclusion and further research is required. There is a need for more RCTs examining the effect of interventions incorporating IIs delivered independently, as the effect size is lower in comparison to previous reviews that incorporate therapist or researcher delivered interventions. Further, this review has highlighted the lack of research regarding the efficacy of independently delivered interventions incorporating IIs on mental health outcomes in comparison to physical health outcomes. More research in the field of mental health

outcomes would be beneficial in adding to the literature base. As part of future research, there is also a need for researchers to carry out multiple follow up periods so that treatment effects can be explored further. Unfortunately, not all studies that were suitable for this review provided sufficient data to enable effect sizes to be calculated. Thus, there is a call for these data to be reported when studies are published.

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An asterisk precedes studies that were included in the meta-analysis.

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Appendix A: Quality Checklist (CONSORT Statement: Schulz, Altman, & Moher, 2010).

CONSORT 2010 checklist of information to include when reporting a randomised trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

Appendix B: Quality appraisal of the included studies

	1a	1b	2a	2b	3a	3b	4a	4b	5	6a	6b	7a	7b	8a	8b	9	10	11a	11b	12a	12b	13a	13b	14a	14b	15	16	17a	17b	18	19	20	21	22	23	24	25
Cameron et al. (2015)	✓	✓	✓	✓	×	-	✓	✓	✓	✓	-	✓	-	✓	-	-	✓	-	-	✓	✓	✓	✓	✓	×	✓	✓	✓	-	✓	×	✓	✓	✓	✓	✓	✓
Chapman et al. (2015)	×	✓	✓	✓	L	-	×	L	✓	✓	-	×	-	×	×	×	×	-	-	✓	✓	✓	✓	L	×	×	✓	✓	×	✓	-	✓	✓	✓	×	-	✓
Elbert et al. (2016)	✓	✓	✓	✓	×	-	✓	✓	✓	L	-	✓	-	×	×	-	×	×	-	✓	✓	✓	✓	✓	×	×	✓	✓	-	✓	✓	✓	L	✓	✓	-	✓
Hagger et al. (2012)	×	✓	✓	✓	✓	-	×	✓	✓	✓	-	×	-	✓	✓	-	-	×	-	✓	✓	✓	✓	✓	×	×	✓	✓	-	✓	✓	✓	×	✓	✓	-	✓
Lange et al. (2013)	✓	✓	✓	✓	×	-	×	×	L	L	-	×	-	L	×	-	-	-	✓	✓	✓	✓	✓	✓	×	×	✓	✓	-	✓	-	✓	✓	✓	×	-	✓
Little et al. (2015)	×	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	-	-	×	×	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	✓
Shah et al. (2014)	×	✓	✓	✓	L	-	✓	✓	✓	✓	-	×	-	✓	×	-	-	-	✓	✓	✓	✓	✓	L	×	✓	✓	✓	-	✓	✓	✓	✓	✓	×	-	✓
Skår et al. (2011)	✓	✓	✓	✓	L	-	×	×	×	×	-	✓	-	✓	✓	-	-	✓	✓	✓	✓	✓	✓	✓	×	×	✓	✓	-	✓	✓	✓	✓	✓	×	-	-
Thompson et al. (2015)	✓	✓	✓	×	×	-	✓	L	✓	✓	-	✓	-	✓	✓	-	-	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	L	-	✓	-	✓	✓	✓	✓	-	✓
Varley et al. (2011)	✓	✓	✓	✓	✓	-	L	✓	✓	✓	-	×	-	✓	✓	-	-	-	-	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	×	✓	✓	L	×	×	✓

Note. L = limited information resulting in unclear if study meets criteria

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Section Two: Research Report

Enhancing psychological self-help with implementation intentions for those with visible skin conditions and fear of negative evaluation: A randomised controlled trial

Abstract

Objectives. People with visible skin conditions commonly fear being negatively evaluated during social interactions. Online self-help interventions tailored to this population may be beneficial; however, the effectiveness of such materials can be limited by failure to undertake recommended exercises or deploy learned techniques. The present research examined the effectiveness of a self-help intervention incorporating if-then plans or implementation intentions (IIs) designed to promote the use of the materials.

Methods. $N = 326$ individuals who reported lowered confidence due to their skin condition were recruited online (predominantly through skin charities) and randomly allocated to one of three conditions, (i) self-help, (ii) self-help enhanced with II, (iii) or a waiting list control condition. Participants in the self-help conditions were provided with a PDF of the self-help materials. Outcome measures included fear of negative evaluation and symptoms of anxiety and depression.

Results. Participants scores at baseline gave an indication of clinically significant levels of social anxiety, mild symptoms of generalised anxiety, and moderate symptoms of depression. A series of ANCOVAs controlling for baseline scores indicated no statistically significant differences between the conditions at four week follow-up on any of the outcome measures, despite positive feedback from the participants who received the self-help materials.

Conclusions. In contrast to previous research, the findings suggest (i) the self-help materials were not effective at reducing fear of negative evaluation, anxiety or depression and (ii) IIs did not promote the use of these materials.

Practitioner points

- Routinely assess for psychosocial distress in the visible skin condition population. Consider using measures of social anxiety to aid assessment, such as the Brief Fear of Negative Evaluation Scale II (BFNE-II).
- Offer longer periods of guided self-help or consider referral for psycho-education groups, CBT or applied relaxation as required (based on a stepped-care model).
- The present study is limited by a high level of participant attrition.
- The present study did not objectively measure, and thus control for, changes in skin conditions which may have impacted on results.

Introduction

The Proprietary Association of Great Britain (PAGB) conducted a survey in 2005 which asked 1,500 members of the general public a range of questions regarding their everyday health in the preceding twelve months and the ways in which they responded to various health conditions. The results of the survey showed that in total 818 people (54%) had experienced a skin condition. Self-care was common, however, 14% sought further medical advice, largely from a doctor or nurse in the community (Schofield, Grindlay, & Williams, 2009). Examples of skin conditions include eczema, acne, vitiligo, psoriasis and alopecia. Skin conditions may be present at birth or develop later in life. The degree to which individuals are affected psychologically by skin conditions varies greatly and is *not* well predicted by type, severity or cause of condition. However, the visibility of the condition has been shown to exacerbate distress (All Party Parliamentary Report on Skin, 2013). Individual adjustment to skin conditions is affected by a complex interaction of physical, cultural and social factors (Moss, 1997). Some individuals do not feel their skin difference plays a major role in their life (Rumsey, 2002) or use it to a positive advantage (Partridge, 1990).

Some individuals experience a significant negative psychological impact due to visible difference (Rumsey & Harcourt, 2004, 2005; Thompson & Kent, 2001). Skin conditions and burn injuries can be associated with disability, loss of earnings, and impaired quality of life (All Party Parliamentary Report on Skin, 2013; Schofield et al., 2009). Depression and anxiety are commonly reported by individuals living with a skin condition or scarring; One European cross-sectional study found 17.2% of patients attending dermatology clinics exhibited clinical levels of anxiety, 10.1% exhibited clinical levels of depression and 12.7% reported suicidal ideation (Dalgard et al., 2015). Research suggests that 30% of individuals with a dermatological condition seek a

secondary care referral in connection with clinically significant levels of distress (Fried, 2013; Thompson, 2009, 2012).

The All Party Parliamentary Group on Skin produced a report on the psychological and social impact of skin diseases on people's lives and highlighted the common experience of prejudice and discrimination (All Party Parliamentary Report on Skin, 2013). Individuals with visible conditions often report encountering intrusive and discriminatory reactions from other people (Thompson & Kent, 2001; Rumsey & Harcourt, 2004). Social encounters can be difficult and involve unwelcome attention such as staring, negative comments, bullying and questions (Robinson, 1997). The All Party Parliamentary Group report stated that many individuals withdrew from, or avoided, social activities or situations where they felt uncomfortable (All Party Parliamentary Report on Skin, 2013) and research shows that the most common psychological problems experienced by people with visible differences are related to social interaction (Bull & Rumsey, 1988). Avoidance related coping styles, or avoidance of social interactions completely, can develop because of embarrassment or shame (Green, 2010). For example, individuals with alopecia have reported attempting to conceal their hair loss (Welsh & Guy, 2009).

Psychological interventions for visible skin conditions

Lavda, Webb, and Thompson (2012) undertook a meta-analysis of twenty-two studies examining the effect of psychosocial interventions for adults with skin conditions. The interventions included biofeedback and relaxation, meditation, cognitive-behavioural therapy (CBT), group therapy and emotional disclosure. The results showed that psychological interventions had a medium-sized effect ($g = 0.54$) on skin conditions.

Unfortunately, a recent survey of UK dermatologists indicated that only 8% of patients had access to a Psychologist or Psychotherapist (Lowry, Shah, Fleming, Taylor, & Bewley, 2014). Where patients *do* have access to mainstream mental health services, they are not always deemed acceptable by dermatology patients due to a lack specialist dermatology knowledge (Thompson, 2014a). However, there have been some positive recent developments; The Integrating Mental and Physical Healthcare: Research, training and services (IMPARTS) programme has been implemented in 25 services across South London and aims to address the needs of patients. Patients' needs are identified from questionnaires administered on an electronic tablet. As part of the programme, condition specific self-help has been developed and staff have been trained in basic mental health skills (Lamb et al., 2016).

As a result of limited access to specialist psychological services, the availability of self-help interventions tailored to individuals with skin conditions may be beneficial. Further, in the climate of an over-stretched National Health Service (NHS), there is a need for efficacious interventions that are easily reached by individuals in a cost-effective way. Self-help may be offered before, or as an alternative to, traditional one-to-one psychological intervention, often referred to as a stepped-care model. A stepped-care model is the recommended pathway for the management of mental health difficulties and is part of treatment guidelines for generalised anxiety disorder (GAD) and panic disorder (PD) (e.g. National Institute for Health and Care Excellence, 2011a, 2011b). When employing a stepped-care model, individuals are offered the most accessible and least restrictive treatment and "stepped-up" to more intensive interventions as required, resulting in the most efficient use of resources (Bower & Gilbody, 2005). The first step usually involves education, advice and monitoring. The second step involves pure or guided self-help or psychoeducation groups. The third step involves medication (e.g. selective serotonin reuptake inhibitor [SSRI]) or CBT or

applied relaxation. Finally, the fourth step involves specialist treatment. There is no formally agreed definition of 'self-help', however, the phrases 'self-help', 'self-management', or 'self-care' are often used interchangeably to portray interventions where an individual has minimal or no contact with an 'expert' or 'professional' (Richards, 2004). Research demonstrates the efficacy of self-help interventions for individuals with health difficulties; including for adults with depression, anxiety and chronic conditions (Beatty & Lambert, 2013; Gellatly et al., 2007). Indeed, the National Institute for Health and Clinical Excellence (NICE, 2009) recommend CBT-based self-help as an effective intervention for people with mild-moderate depression and long-term conditions. In the United Kingdom, Improving Access to Psychological Therapies (IAPT) services are expanding to provide psychological therapies for people with long term conditions as set out in the "Implementing the five year forward view for mental health" (NHS England, 2016).

Unfortunately, there is little research into psychological self-help specifically for individuals with skin conditions (Thompson, 2014b). However, a review by Muftin and Thompson (2013) indicated that self-help is viewed as acceptable by individuals with disfigurement. This review also found limited, but promising, evidence that self-help was effective in reducing stress and appearance concerns. Pasterfield (2014) designed a CBT-based self-help intervention leaflet entitled "Building confidence in social situations: A guide for people living with a skin condition, including scars" and aimed to gain feedback from skin camouflage users and practitioners. The CBT intervention was based on a theoretical model of social anxiety by Clark and Wells (1995) and included components such as psycho-education, cognitive restructuring and graded exposure (Cujipers & Schuurmans, 2007). Pasterfield (2014) gathered feedback on the intervention's acceptability and usability from six camouflage users and three skin-camouflage practitioners using a "think aloud" method (Fonteyn, Kuipers, & Grobe,

1993). Thematic analysis was undertaken and the three emerging superordinate themes were (i) positive comments about the intervention leaflet, (ii) comments about how the intervention leaflet might be used and (iii) suggested changes and improvements. Although the study may be limited by a small sample size, participants were diverse and IPA analysis allowed for a detailed focus on the participant's experience.

A study by Shah, Hunt, Webb, and Thompson (2014) evaluated a CBT-based self-help intervention including psycho-education, relaxation and attentional refocusing for individuals with Vitiligo. Participants were randomised to receive either standard self-help, self-help enhanced with 'implementation intentions' (a planning exercise; Gollwitzer, 1999), or to a waitlist control condition. Despite no significant difference being found between conditions, participants in the enhanced self-help condition showed reliable and clinically significant changes in social anxiety. However, it is important to note that this study did have a small sample size (n = 45) and thus results should be interpreted with caution.

Overall, the research suggests that the use of self-help interventions tailored to individuals with visible skin conditions holds promise, although the literature is limited and further research is required.

Self-help interventions and implementation intentions

The effectiveness of self-help materials can be limited by the failure to undertake recommended exercises or deploy learned techniques at crucial moments. A number of studies have enhanced self-help with 'implementation intentions' to overcome the gap between individuals intending to carry out a behaviour and *actually* carrying it out. Implementation intentions (IIs; Gollwitzer, 1999) are 'if-then' plans that connect opportunities to act *with* cognitive or behavioural responses that are effective in achieving one's goals. Whereas goal intentions specify *what* an individual wants to

achieve, IIs specify *both* the behaviour to be performed *and* the situational context in which this will occur. To form an II, the individual must (i) identify the response that that will promote goal attainment and, (ii) anticipate an appropriate occasion in which to initiate that response (Gollwitzer, 1999). IIs have been increasingly used in behaviour change interventions targeting health behaviours such as smoking cessation (Armitage, 2008), alcohol intake (Armitage, 2009) and healthy eating (Verplanken & Faes, 1999). In a meta-analysis of 94 studies involving a wide variety of behavioural domains, IIs had a medium-to-large effect ($d = 0.65$) on the achievement of intended goals (Gollwitzer & Sheeran, 2006).

A randomised controlled trial by Varley, Webb and Sheeran (2011) investigated the efficacy of self-help materials promoting the effective management of anxiety symptoms enhanced with IIs. The results indicated that there was a statistically significant decrease in anxiety in the condition that received the self-help enhanced with IIs compared to both the standard self-help and control conditions. These findings indicate that IIs are a valued addition to self-help materials.

The present study

This study aimed to expand on the work of Pasterfield (2014) by (i) enhancing the existing self-help intervention with IIs and (ii) examining the effectiveness of both the standard and enhanced self-help interventions in reducing fear of negative evaluation, anxiety and depression among people with visible skin conditions.

Hypotheses

1) Participants receiving either the enhanced or standard self-help intervention will demonstrate a statistically significant decrease in:

a) fear of negative evaluation (primary outcome measure) as measured by the Brief Fear of Negative Evaluation scale (BFNE-II; Carleton, Collimore, & Asmundson, 2007) and;

b) symptoms of anxiety (measured by the Generalised Anxiety Disorder 7 scale (GAD-7); Spitzer, Kroenke, Williams, & Löwe, 2006) and depression (measured by the Patient Health Questionnaire-9 (PHQ-9); Kroenke, Spitzer, & Williams, 2001) (secondary outcome measures) in comparison to the control condition.

2) Participants receiving the enhanced self-help intervention will demonstrate a statistically significant decrease in comparison to the standard self-help intervention in:

a) fear of negative evaluation as measured by the BFNE-II and;

b) symptoms of anxiety (measured by the GAD-7) and depression (PHQ-9).

Method

Ethical approval

Ethical approval was provided by an independent ethics committee from the Department of Psychology, University of Sheffield on 9th May 2016. See Appendix K for letter confirming ethical approval.

Design

A randomised controlled trial with a parallel condition design was conducted in accordance with CONSORT guidelines (Schulz, Altman, & Moher, 2010) to examine the effectiveness of two forms – standard and enhanced – of a self-help intervention for people with visible skin conditions. As the intervention was in the early stages of its development, a waiting list control condition was required to investigate the efficacy of

the intervention relative to no intervention. Participants were randomised to condition using a balanced allocation ratio by the online survey provider Qualtrics (www.qualtrics.com).

The study had two independent variables, one 'between-subjects' variable with three levels; treatment condition (standard self-help intervention, enhanced self-help intervention, and waiting list control condition) and one 'within-subjects' variable with two levels (time point: baseline vs. follow-up). The primary outcome variable was fear of negative evaluation and the secondary outcome measures were symptoms of anxiety and depression.

Intervention

The self-help intervention (see Appendix A) was developed by Dr. Madeline Pasterfield and Dr. Andrew Thompson as part of a Doctoral thesis (Pasterfield, 2014) and was originally called 'Building confidence in social situations: A guide for people living with a visible skin conditions, including scars'. For the purpose of the current study, the intervention was re-named 'Building confidence in social situations: A guide for people with a visible skin difference' in order to be more inclusive of skin conditions. The intervention was based on a theoretical model of social anxiety by Clark and Wells (1995) and included a number of components such as psycho-education, cognitive restructuring, and graded exposure (Cujipers & Schuurmans, 2007). The intervention had an introduction and five sections: 1 - 'Understanding why people worry about their appearance and how loss of social confidence develops'; 2 - 'Beginning to change unhelpful thoughts'; 3 - 'Breathing and relaxation'; 4 - 'Tackling avoidance'; and 5 - 'Dealing with comments and negative reactions from others'. The intervention was developed with feedback from providers of skin camouflage from the British Association of Skin Camouflage, as well as experts by experience in the form of

users of skin camouflage services and people with lived experience of visible skin conditions. It is available on The British Association of Dermatologists patient support website (http://skinsupport.org.uk/sites/default/files/Social%20Confidence%20Self-help%20Leaflet_0.pdf).

As part of the present research, the 'standard' intervention was developed further to create an 'enhanced' intervention by drawing on the work of both Varley et al. (2011) and Shah et al. (2015) and adding instructions to form IIs. The IIs were designed to help participants plan to carry out the specific self-help activities recommended in the guide. Instructions to form IIs were applied to each section of the intervention. An example of how 'Section 3: Breathing and Relaxation' was enhanced with IIs is shown in Figure 1.

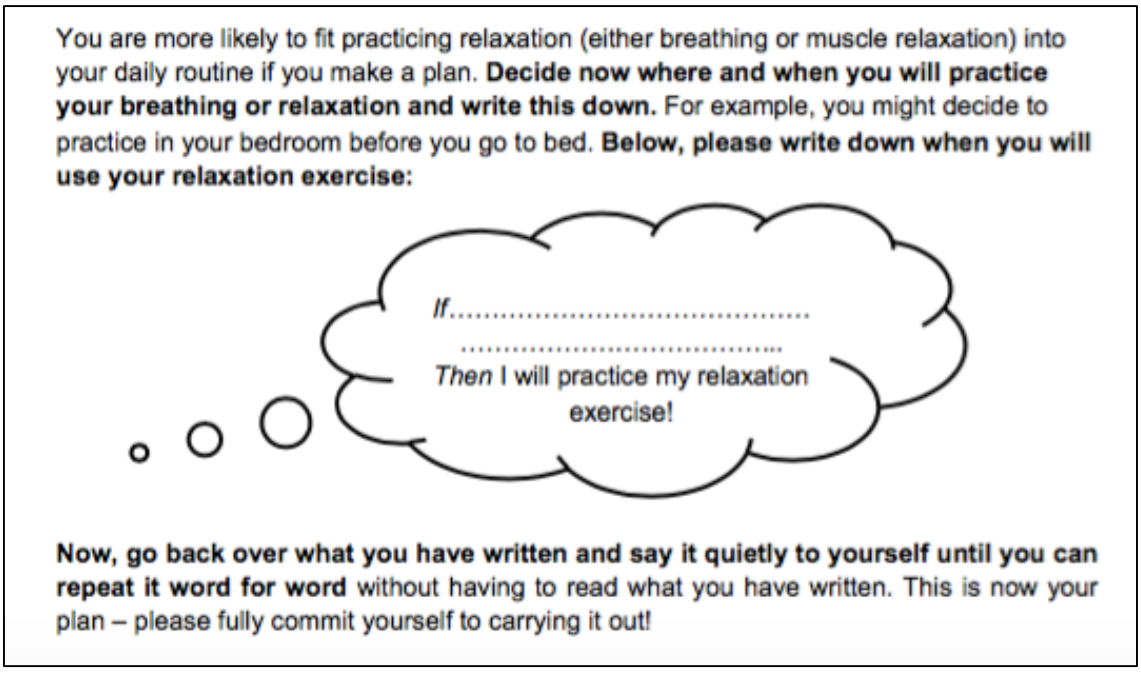

Figure 1. *II instruction in Section 3 'Breathing and Relaxation' of the enhanced self-help intervention.*

Participants

Participants were recruited online between 6th January and 10th February 2017. The inclusion criteria specified that participants were required to be aged 18 years or over, fluent in the English Language and define themselves as having a visible skin

condition which affects their confidence. Visible skin condition included, but was not limited to, vitiligo, psoriasis, ichthyosis, alopecia, acne, scarring, birthmarks and eczema. Participants were excluded from the study if they were currently receiving psychotherapy. Participants were asked questions designed to assess their eligibility before commencing the study and were not able to continue if they did not meet the inclusion criteria. Participants were advised to contact their GP if they were not eligible to take part, but felt they required psychological support.

International and UK organisations and charities associated with visible skin conditions were approached and asked to advertise the study on their websites, social media, newsletters, and forums. An example advert for the study was provided to aid organisations with wording the advert (see Appendix B). Participants were also recruited via an email sent to the University of Sheffield's Staff and Students' volunteers mailing list. The Primary Researcher and Supervisors also advertised the study through social media and by email. The following charities and organisations agreed to advertise the study: Vitiligo Support and Awareness Foundation (VITSAF: Nigeria), the Psoriasis Association (UK), the Psoriasis and Psoriatic Arthritis Alliance (PAPAA: UK), Dan's Fund for Burns (UK), Alopecia UK, the National Alopecia Areata Foundation (USA) and Bald Girls do Lunch inc. (USA).

A power analysis was conducted using G*Power version 3.1.5 (Faul, Erdfelder, Lang & Buchner, 2007). The analysis was based on two time points, three conditions, an alpha of 0.05 and a medium-sized effect size (i.e., $f = 0.25$). The calculation indicated that a sample size of 120 participants (i.e., 40 per condition) would provide 80% power to detect an effect of the specified magnitude. Allowing for an attrition rate of 20%, we aimed to recruit 144 participants (48 per condition). To aid participant retention, participants were informed that they would be entered into a prize draw to win a £50 Amazon voucher if they completed the questions at follow up.

Procedure

The intervention was hosted online through Qualtrics (www.qualtrics.com) and potential participants were provided with a hyperlink to access the study. Participants viewed information about the study (see Appendix C), answered questions designed to assess their eligibility to take part, provided consent (see Appendix D) and completed the Brief Fear of Negative Evaluation Scale (Brief FNE-II: Carleton et al., 2007), the Generalised Anxiety Disorder Scale-7 (GAD-7: Spitzer et al., 2006), and the Patient Health Questionnaire-9 (PHQ-9: Kroenke et al., 2001). Next, participants were randomised to one of three conditions: (i) standard self-help, (ii) enhanced self-help or (iii) no intervention waiting list control. Participants were made aware from the information provided about the study that they would be allocated to receive the intervention either immediately or after a waiting period. Participants were blinded to whether they received the standard or enhanced intervention. Participants were then asked demographic questions including their age, gender, ethnicity, marital status and employment status. Participants were also asked to provide details of their visible skin condition. Figure 2 provides a visual representation of the survey at baseline.

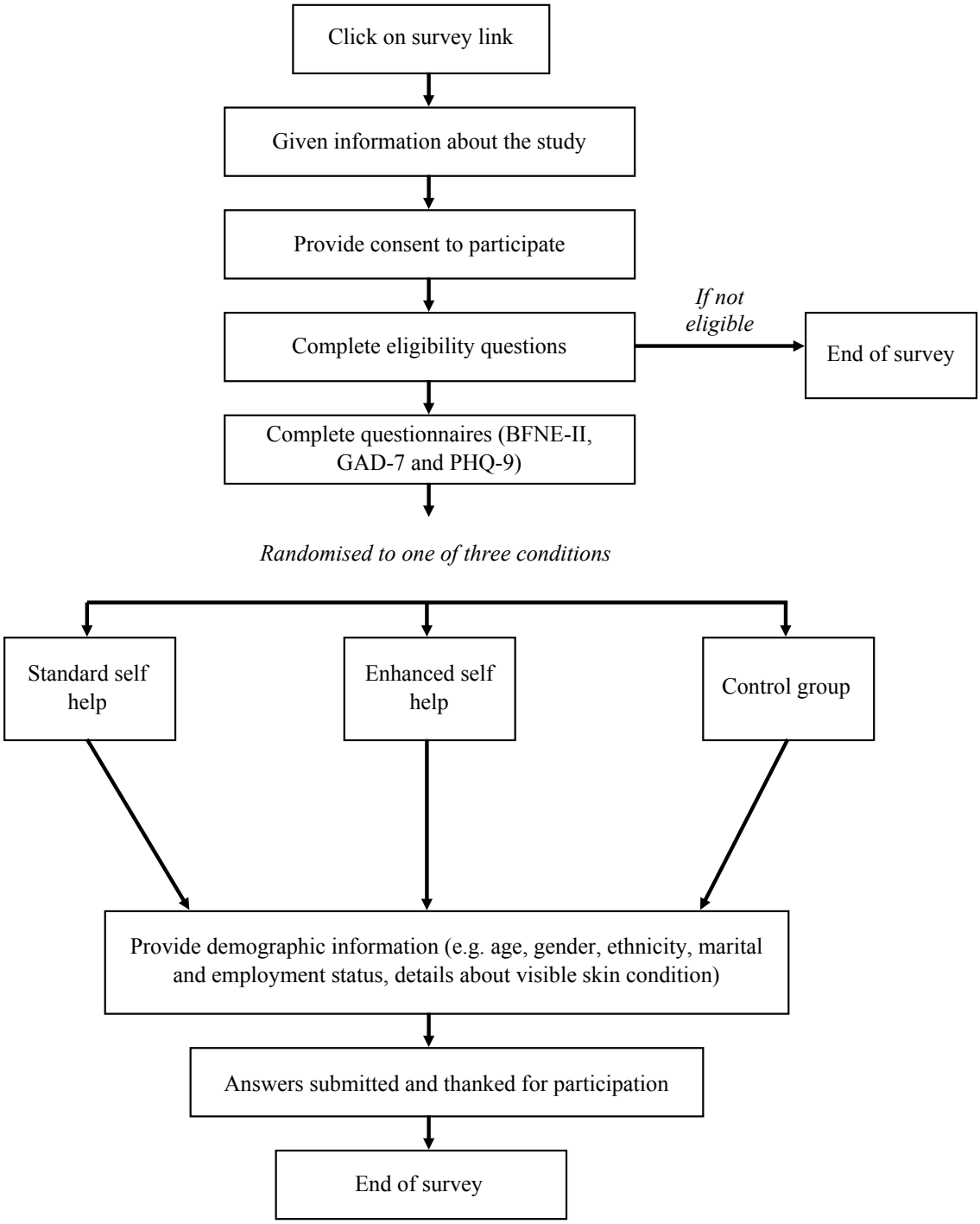

Figure 2. *Flow of participants through the survey at baseline.*

A small number of participants contacted the researcher to report that they had missed clicking the link provided within the online survey to download the self-help materials. This difficulty was overcome by adding a feature from the survey software

which automatically sent each participant in the intervention conditions an email with a link to download the applicable self-help materials (either standard or enhanced as allocated). Crucially, the survey software enabled the participants to remain blind to intervention condition. Further, a small number of participants reported that their University of Sheffield computers were not allowing the PDF download of the self-help materials. This difficulty was overcome by contacting the University of Sheffield computer department who reported that there had been a historical block on the website, which was promptly removed. Both of these changes was made early in the recruitment period, so was unlikely to affect a significant number of participants.

Four weeks after participants completed the baseline questionnaire and received the intervention (if applicable), an email was sent to invite participants to complete the follow up questions. The same measures were used at follow up as at baseline (i.e., the BFNE-II, GAD-7 and PHQ-9). Participants allocated to the intervention conditions were also asked "Which sections of the self-help did you read? (please select all that apply)" and could chose Section 1: 'Understanding why people worry about their appearance and how loss of social confidence develops', Section 2: 'Beginning to change unhelpful thoughts', Section 3: 'Breathing and Relaxation', Section 4: 'Tackling avoidance', and / or Section 5: 'Dealing with comments and negative reactions from others'. Finally, participants were able to write comments about their experience of the self-help intervention in a free-text box. Participants who wished to enter the prize draw to win a £50 Amazon voucher were also asked to provide their email address. Finally, all participants were thanked for their participation. Figure 3 provides a visual representation of the follow-up survey.

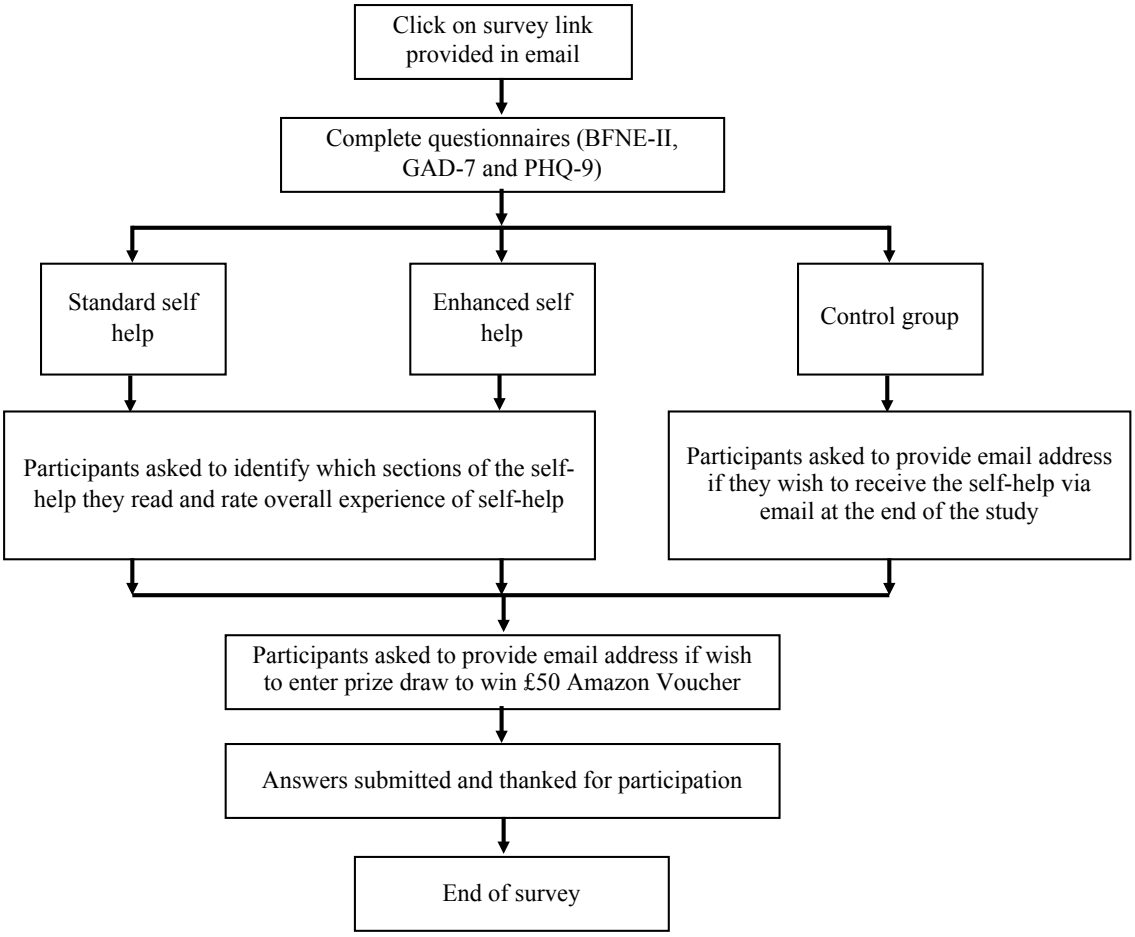

Figure 3. *Participant flow through the survey at follow up.*

Primary and secondary outcome measures

Three established self-report measures were used to examine the effectiveness of the psychological self-help intervention. The primary outcome measure was change in levels of fear of negative evaluation (measured with the BFNE-II, see below). The secondary outcome measures were anxiety and depression (measured with the GAD-7 and PHQ-9, see below). Copies of these three measures can be found in Appendix E-G.

The Brief Fear of Negative Evaluation scale (II) **(**BFNE-II; Carleton et al., 2007) is a 12-item revised version of the Brief Fear of Negative Evaluation scale (BFNE; Leary, 1983) and is used to measure fear of negative evaluation (e.g. “I am afraid that

others will not approve of me"). Items are rated on a 5-point Likert scale ranging from 0 (not at all characteristic of me) to 4 (extremely characteristic of me). For the current study, a reliability analysis was carried out on the baseline and follow up scores of the BFNE-II. Cronbach's alpha showed the BFNE-II to have excellent internal consistency at baseline and follow up (α = .97). The BFNE-II also correlates highly with the BFNE, and factor analyses have supported a unitary solution (Carleton et al., 2007; Carleton, McCreary, Norton & Asmundson, 2006). A cut-off score of 25 may be indicative of clinically significant social anxiety (Carleton, Collimore, McCabe & Anthony, 2011).

The Generalised Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006) consists of seven items measuring anxiety-related symptoms. Individuals are asked "Over the last two weeks, how often have you been bothered by the following problems?" such as "Feeling nervous, anxious or on edge", "Worrying too much about different things" and "Becoming easily annoyed or irritable". Individuals are asked to choose one of four responses including "not at all", "several days", "more than half the days" or "nearly every day" which are scored 0–3 points per item. Scores are summed and interpreted as indicating either no anxiety (0-4), mild anxiety (5-9), moderate anxiety (10-14), or severe anxiety (15+). Original psychometric evaluation of the GAD-7 was conducted in a sample of 2,739 patients from 15 primary care sites (Spitzer et al., 2006). Scores on the GAD-7 have demonstrated good internal consistency (α = .92) and test-retest reliability (intraclass correlation = 0.83) (Spitzer et al., 2006). For the current study, reliability analysis was carried out on the baseline and follow up scores of the GAD-7. Cronbach's alpha showed the GAD-7 to have good internal reliability at baseline α = .87 and follow up α = 0.89.

The Patient Health Questionnaire 9 (PHQ–9; Kroenke et al., 2001) consists of seven items designed to correspond to the nine diagnostic criteria for major depressive disorder as described by the Diagnostic and Statistical Manual of Mental Disorders

(DSM–IV; American Psychiatric Association, 1994). Individuals are asked "Over the last two weeks, how often have you been bothered by the following problems?" such as "Little interest or pleasure doing things", "Feeling down, depressed or hopeless" or "Feeling bad about yourself – or that you are a failure or have let yourself or your family down". Individuals are asked to choose one of four responses including "not at all", "several days", "more than half the days" or "nearly every day". Scores are summed and interpreted as indicating either no depression (0-4), mild depression (5-9), moderate depression (10-14), moderately severe depression (15-19), or severe depression (20-27). Research suggests that the measure has sound psychometric properties and high internal consistency (Kroenke et al., 2001). A reliability analysis was carried out on the baseline and follow up scores of the PHQ-9. Cronbach's alpha showed the PHQ-9 to have $\alpha = .86$ at baseline and $\alpha = .89$ at follow up, which suggests good internal reliability.

Data security and management

All data provided by participants was kept confidential and stored on password protected computers. User ID's (created to enable matching of data between baseline and follow up) were kept separately from participant responses.

Data analyses

There were no missing data on the outcome measures as the survey software required participants to complete all questions to enable submission. Descriptive statistics were calculated for baseline data including demographic variables and the three outcome measures (BFNE-II, GAD-7, PHQ-9,). The outcome measures at baseline were tested for normality and homogeneity of variance to fulfill the assumptions for statistical analyses. Levene's test for homogeneity of variance was non-significant for all three outcome measures ($p>0.05$). The Shapiro-Wilk test for

normality was significant ($p = <0.05$) for all three outcome measures indicating the data were not normally distributed. When data is not normally distributed, there may be an increased chance of producing a Type I error (a 'false positive') when using inferential tests that assume normal distribution. However, on inspection of the Q-Q plots and histogram outputs, the deviation from normality appeared minimal (see Appendix H-J for Q-Q plots and histograms on the BFNE-II, GAD-7 and PHQ-9 respectively). Further, simulation studies using a number of non-normal distributions have shown that the occurrence of Type I errors are not particularly affected by violation in normal distribution assumption (Glass, Peckham & Sanders, 1972).

In the Intention to Treat (ITT) analyses, ANCOVA was used to test for differences between the control and intervention conditions at follow up on the BFNE-II, GAD-7, and PHQ-9 using a last observation (baseline score) carried forward method of imputation. The ANCOVA analyses were then repeated for the complete-case analysis. ANCOVA has been found to yield optimum statistical power when evaluating randomised controlled trials (Blance, Tu, Baelum, & Gilthorpe, 2007). Variables that were theoretically expected to influence the outcomes (e.g. baseline scores on the BFNE-II, GAD-7 and PHQ-9) were statistically controlled for in the analyses. All statistical analyses were undertaken using Statistical Package for Social Sciences (SPSS) version 24.0. All analyses are reported with a two-tailed level of significance at an alpha level of .05.

Registering as trial

The study was registered on the website 'Clinical Trials' with the identifier NCT03004027 (see https://clinicaltrials.gov/ct2/show/NCT03004027).

Results

Demographic characteristics

A total of 472 individuals provided informed consent and were assessed for eligibility. 58 individuals did not meet the eligibility criteria and 43 did not fully complete the eligibility criteria questions. A further 45 participants did not complete all of the questions at baseline. As a result, a remaining 326 individuals were eligible for the study and were randomised to condition (107 individuals were allocated to the waiting list control, 111 individuals to the standard intervention and 108 individuals to the enhanced intervention). The flow of participants through the study based on the CONSORT guidelines for reporting parallel condition randomised trials can be found in Figure 4 (adapted from Schulz et al., 2010). The demographic characteristics of participants in the study are shown in Table 1.

Table 1. *Baseline demographic characteristics of participants.*

Variable	Total (*n* = 326)	Control (*n* = 107)	Standard (*n* =111)	Enhanced (*n* = 108)
Age, *M (SD)*	35.32 (12.29)	35.22 (11.72)	34.68 (12.20)	36.08 (12.99)
Gender, *n* (%)				
Female	261 (80.06)	82 (76.64)	90 (81.08)	89 (82.41)
Male	64 (19.63)	25 (23.26)	20 (18.02)	19 (17.59)
Prefer not to say	1 (0.31)	-	1 (0.90)	-
White British, *n* (%)	199 (61.04)	63 (58.88)	68 (61.3)	68 (62.96)
Single, *n* (%)	142 (43.56)	46 (42.99)	46 (41.44)	50 (46.30)
Employed Full Time, *n* (%)	158 (48.47)	50 (46.73)	54 (48.65)	54 (50.00)
Skin Condition, *n* (%)				
Alopecia	81 (24.85)	23 (21.50)	26 (23.42)	32 (29.63)
Psoriasis	48 (14.72)	19 (17.76)	20 (18.02)	9 (8.33)
Vitiligo	34 (10.43)	10 (9.35)	11 (9.91)	13 (12.04)
Eczema	45 (13.80)	19 (17.76)	14 (12.61)	12 (11.11)
Scarring	8 (2.45)	4 (3.74)	7 (6.31)	6 (5.56)
Acne	17 (5.21)	4 (3.74)	7 (6.31)	6 (5.56)
Birth mark	10 (3.07)	1 (0.93)	4 (3.60)	5 (4.63)
Rosacea	3 (0.92)	-	1 (0.90)	2 (1.85)
Ichthyosis	3 (0.92)	1 (0.93)	2 (1.80)	-
Two or more	60 (18.40)	19 (17.76)	20 (18.02)	21 (19.44)
Other	17 (5.21)	7 (6.54)	3 (2.70)	7 (6.48)

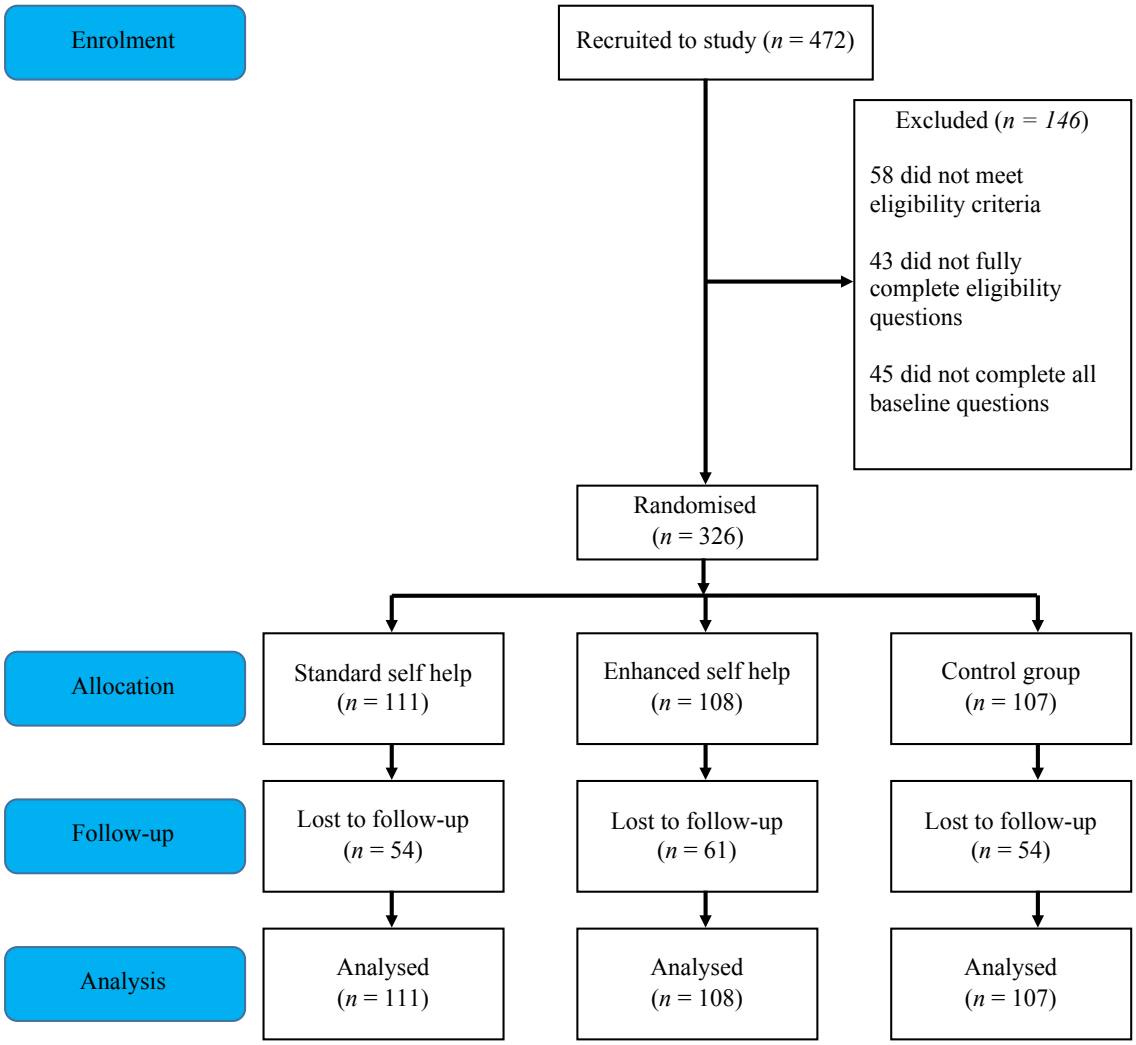

Figure 4. *Flow of participants through the study (based on CONSORT guidelines, Schulz et al., 2010).*

Randomisation checks

A series of Chi-squared tests and an independent samples ANOVA were conducted to establish if there were any differences between the conditions on the demographic variables at baseline (see Table 1).

Chi-squared tests were conducted for the categorical variables. When conducting Chi-squared tests, expected frequencies should be greater than 5 to avoid failing to detect a genuine effect. The demographic variables incorporated a number of categories which resulted in some categories having frequencies of less than 5. To overcome this,

categories were collapsed to run Chi-Squared tests. There were no significant differences in gender (Male, Female) between conditions ($\chi2 = 1.37$, $p = .504$), marital status (Single, Co-habiting, Married, Other, $\chi2 = 1.63$, $p = .950$), ethnicity (White British/Irish, Other, $\chi2 = 0.11$, $p = .946$), employment status (Employed, Unemployed, Student, Other, $\chi2 = 5.78$, $p = .448$), or nature of the skin condition (alopecia, vitiligo, psoriasis, eczema, acne, other, two or more, $\chi2 = 9.41$, $p = .667$).

A series of independent samples ANOVAs were conducted to establish if there were any differences between conditions in age or in scores on the outcome measures at baseline. There was no statistically significant difference in age ($F(2,323) = .359$, $p = .699$) or scores on the BFNE-II ($F(2,323) = .715$, $p = .490$), GAD-7 ($F(2,323) = 1.035$, $p = .356$) or PHQ-9 ($F(2,323) = .395$, $p = .674$) at baseline.

Overall, there were no statistically significant differences between groups on the variables analysed, suggesting that the randomisation process was successful.

Scores on outcome measures at baseline

Participants' scores at baseline gave an indication of levels of distress in the sample. See Table 2 for the mean scores on outcome measures administered at baseline. For reporting reasons, average scores on the outcome measures have been rounded up or down as appropriate to enable meaningful reporting of clinical categories. For fear of negative evaluation (as measured by the BFNE-II), the mean score was 28. A score of 25 or more may indicate clinically significant levels of social anxiety (Carleton et al., 2011). Thus, participants in the current study reported clinically significant level of social anxiety. In relation to generalised anxiety, the mean score on the GAD-7 of 9 was in the top of the 'mild' symptoms of anxiety category (5-9), approaching the moderate category (10-14). When an individual scores a '10' on the GAD-7 further assessment of a formal Anxiety Disorder is recommended. In relation to depression, the mean score on

the PHQ-9 was 10, falling into the 'moderate' symptoms of depression category (10-14).

Table 2. *Mean scores on outcome measures at baseline.*

Outcome Measure	*Mean (SD) (n* = 326)
BFNE-II	28.49 (12.28)
GAD-7	8.96 (4.89)
PHQ-9	9.55 (5.74)

Impact of the self-help intervention on outcomes

Intention to Treat (ITT) analyses. A series of three one-way, between conditions ANCOVAs were conducted to compare outcomes between the standard, enhanced and control conditions among all participants who completed the baseline measures. ITT analyses were conducted using the last observation carried forward (LOCF) method where the LOCF was the baseline score (i.e. assuming no change). This method of imputing missing values is widely used to handle missing data occurring through attrition in longitudinal trials (Siddiqui & Ali, 1998) and is often considered the only alternative to excluding participants from analysis (Altman, 2009). The independent variable was condition allocation and the dependent variables were scores on the BFNE-II, GAD-7 and PHQ-9. Participant's scores at baseline were used as covariates in the analysis.

The results of the ITT analyses indicated that, after adjusting for baseline scores, there was no significant effect of condition on fear of negative evaluation ($F(2,322) = .29$, $p = .745$), symptoms of anxiety ($F(2,322) = .35$, $p = .706$) or depression ($F(2,322) = .09$, $p = .912$). See Table 3 for mean scores by condition at baseline and follow up as and the results of statistical tests.

Table 3. *Outcome measures by time and condition in the ITT analyses.*

Outcome Measure	Condition	Baseline *M (SD)*	Follow up *M (SD)*
BFNE-II	Control	27.48 (12.36)	25.98 (13.26)
	Standard	29.47 (12.27)	27.54 (12.93)
	Enhanced	28.49 (12.28)	26.97 (12.74)
GAD-7	Control	9.03 (5.11)	8.21 (5.28)
	Standard	9.39 (4.86)	8.23 (4.88)
	Enhanced	8.44 (4.70)	7.40 (4.85)
PHQ-9	Control	9.62 (5.82)	9.01 (5.98)
	Standard	9.85 (5.17)	9.05 (5.67)
	Enhanced	9.17 (6.22)	8.46 (6.39)

Attrition analyses. In total, 157 of the 326 participants (48.16%) completed the follow up survey, which was greater than the anticipated drop out rate of 20%. Chi-square analyses and independent *t*-tests were undertaken to examine if there were any differences between completers and non-completers in demographic characteristics or scores on outcome measures at baseline. See Table 4 for the demographic characteristics of completers and non-completers of the follow up.

Chi-squared analyses indicated no significant difference between completers and non-completers in gender (Male vs. Female, $\chi 2 = .48$, $p = .487$) or nature of skin condition (alopecia, vitiligo, psoriasis, eczema, acne, other, two or more, $\chi 2 = 10.44$, $p = .107$). However, Chi-squared analyses did indicate a significant difference between completers and non-completers in marital status (Single vs. Co-habiting vs. Married vs. Other, $\chi 2 = 7.81$, $p = 0.05$), ethnicity (White British/Irish vs. Other, $\chi 2 = 5.94$, $p = .015$)

and employment status (Employed vs. Unemployed vs. Student vs. Other, $\chi 2 = 9.92$ $p = .019$). Further, an independent *t*-test indicated a significant difference between completers and non-completers in age ($t(324) = -3.35$ $p = 0.001$); the mean age of completers was higher than non-completers.

A series of independent *t*-tests indicated no significant difference between completers and non-completers on baseline levels of fear of negative evaluation ($t(324) = -.83$, $p = .405$), anxiety ($t(324) = .21$, $p = .836$) or depression ($t(324) = .70$, $p = .483$).

See Table 5 for scores on the outcome measures at baseline for completers of the follow up and non-completers.

Table 4. *Demographic characteristics of completers and non-completers of the follow up.*

Variable	Completers (n = 160)	Non - completers (n = 166)
Age, *M (SD)*	37.61 (12.77)	33.12 (11.43)
Gender, *n* (%)		
Female	126 (78.75)	135 (81.33)
Male	34 (21.25)	30 (18.07)
Prefer not to say	-	1 (0.60)
Ethnicity, *n* (%)		
White British/Irish,	132 (82.50)	118 (71.08)
Other	28 (17.50)	48 (28.92)
Marital Status, *n* (%)		
Single	61(38.13)	81 (48.80)
Co-habiting	25 (15.63)	24 (14.46)
Married	59 (36.88)	56 (33.73)
Other	15 (9.38)	5 (3.01)
Employment Status, *n* (%)		
Employed	102 (63.75)	110 (66.27)
Student	30 (18.75)	44 (26.51)
Unemployed	16 (10.00)	5 (3.01)
Retired or Disabled	12 (7.50)	7 (4.22)
Skin Condition, *n* (%)		
Alopecia	41(25.63)	40 (24.10)
Psoriasis	30 (18.75)	18 (10.84)
Vitiligo	12 (7.50)	22 (13.25)
Eczema	27 (16.88)	18 (10.84)
Acne	7 (4.38)	10 (6.02)
Other	17 (10.63)	24 (14.46)

Table 5. *Scores on the outcome measures at baseline for completers and non-completers of the follow up.*

Outcome measure	Completers *M (SD)*	Non - Completers *M (SD)*
BFNE-II	29.07 (11.63)	27.93 (12.89)
GAD-7	8.90 (4.86)	9.01 (4.93)
PHQ-9	9.32 (5.46)	9.77 (6.00)

A series of three one-way, between conditions ANCOVAs were conducted to compare outcomes between the standard and enhanced intervention conditions and the

control condition. Only participants who completed the follow up measures were included (i.e., 'complete case analysis'). The independent variable was condition allocation and the dependent variables were scores on the BFNE-II, GAD-7 and PHQ-9. Participants' scores at baseline were used as covariates in the analysis. There was no significant difference found between conditions on the level of fear of negative evaluation ($F(2,153) = .23$, $p = .799$), anxiety ($F(2,153) = 1.15$, $p = .320$) or depression ($F(2,153) = .71$, $p = .492$). The mean scores by condition at baseline and follow up can be found in Table 6.

Table 6. *Outcome measures by time and condition in the completer analyses.*

Outcome Measure	Condition	Baseline *M (SD)*	Follow up *M (SD)*
BFNE-II	Control	27.48 (12.36)	26.21 (13.02)
	Standard	29.47 (12.27)	25.70 (13.36)
	Enhanced	28.49 (12.28)	27.02 (10.71)
GAD-7	Control	9.03 (5.11)	7.79 (5.35)
	Standard	9.39 (4.86)	6.74 (4.36)
	Enhanced	8.44 (4.70)	6.04 (4.78)
PHQ-9	Control	9.62 (5.82)	9.36 (6.32)
	Standard	9.85 (5.17)	7.60 (5.39)
	Enhanced	9.17 (6.22)	6.81 (5.69)

Use of self-help materials

Differences between standard and enhanced conditions.

Rates of adherence were generally good; 84.48% of participants in the standard condition and 89.36% of participants in the enhanced condition reported reading a minimum of one section from the five available in the self-help intervention.

Chi-squared analyses indicated no statistically significant difference in the number of participants reporting whether they had read at least one section of the self-help intervention ('users') or not ('non-users') between the standard and enhanced intervention conditions ($\chi 2 = .56$, $p = .465$).

Chi-squared analyses also indicated no statistically significant differences in the number of participants who read all five sections of the intervention and participants who reported not reading any of the intervention between the standard and enhanced

intervention conditions ($\chi 2 = .244$, $p = .621$). Table 7 reports the number of sections read by participants in the standard and enhanced conditions.

Table 7. *Number of sections of the self-help intervention read by condition.*

Number of sections read	Standard (*N*, % of total)	Enhanced (*N*, % of total)
None	9 (15.52)	5 (10.64)
One	15 (25.86)	13 (27.66)
Two	3 (5.17)	2 (4.26)
Three	2 (3.45)	4 (8.51)
Four	4 (6.90)	4 (8.51)
Five	25 (43.10)	19 (40.43)
Missing	53	61

Differences between users and non-users on outcomes. A series of one-way, between condition ANCOVAs indicated that there were no statistically significant differences found between 'users' and 'non-users' on the outcome measures at follow up: fear of negative evaluation ($F(1, 101) = 2.04$, $p = .156$), symptoms of anxiety ($F(1, 101) = 1.64$, $p = .203$), symptoms of depression ($F(1, 101) = .95$, $p = .331$). The mean scores on measures at follow up between users and non-users can be found in Table 8.

Table 8. *Outcome measures at follow up between readers and non-readers*

Outcome measure	Readers *M (SD)*	Non - Readers *M (SD)*
BFNE-II	27.89 (11.92)	25.57 (12.63)
GAD-7	8.70 (5.39)	6.11 (4.42)
PHQ-9	9.06 (6.60)	7.48 (5.49)

A series of one-way, between conditions ANCOVAs also indicated that there were no statistically significant differences between participants who read all of the intervention (i.e., all 5 sections) and participants who reported not reading any part of the intervention (0) on the outcome measures at follow up: fear of negative evaluation ($F(1, 54) = 2.27$, $p = .137$), symptoms of anxiety ($F(1, 54) = 2.32$, $p = .134$), symptoms of depression ($F(1, 54), = 2.68$, $p = .107$).

Qualitative feedback

Qualitative feedback was sought regarding overall experience of the leaflet using a 'free-text' response box. A total of 40 participants provided feedback. Responses were clustered into subgroups (see Table 9). Inter-rater reliability sought from a supervisory member of the research team. Any disagreements were resolved through discussion.

Table 9. *Feedback from participants on experience of intervention.*

Feedback on self-help	Number of comments
Positive	28 (70.00%)
Negative	9 (22.50%)
Neutral	3 (7.50%)

Overall, feedback regarding the self-help intervention was positive (70.00%) and included comments such as: "*It has been a huge help in allowing me to accept my alopecia diagnosis*". Participants commented on the usability of the intervention (e.g. *"Easy to read and understand", "I liked that it wasn't too long"*), as well as positive comments about specific aspects of the intervention *(e.g. "I really liked the thought diary", "The tips given to deal with negative comments about your skin - like 'oh it's a skin problem, it's not catching' was great and I wish I'd had a few sentences ready years ago to prompt responses"*. In addition, participants commented that the intervention assisted in normalising their experiences: "*The information in the leaflet was reassuring just to know that others experience these feelings as you tend to think you're alone".*

However, there was also some negative feedback on the intervention (20% of respondents). For example, one participant commented: "*A little basic in parts, and condescending",* and another stated: *"Very wordy, less narrative and more bullet points would have been helpful".*

Participants identified factors that may have influenced their results but were not controlled for in the study. One participant reported *"Over the last month my skin condition has deteriorated physically which may account for the nature of my response this time (as opposed to the impact of the leaflet)",* and another stated *"I have an anxiety disorder as well as alopecia so I think this could have affected my results"*

Interestingly, 17.50% participants reported that the four week follow up period was limiting: *"I think a lot of [the intervention] will be useful however it would take longer than 1 month".* Some participants reported that the self-help was just the start of a longer journey (e.g. *"This is the first step for me...I am still aware I have a long way to go").*

Discussion

The present research found no evidence that the standard or the enhanced self-help interventions reduced fear of negative evaluation, symptoms of anxiety or depression in adults with visible skin conditions, relative to no intervention. Further, there was no evidence that the enhanced self-help intervention was more effective than the standard self-help intervention at reducing fear of negative evaluation and symptoms of anxiety or depression. These results suggest that enhancing the intervention with IIs did not improve outcomes. Usage of the self-help materials was similar between the standard and enhanced conditions. Participants exhibited psychological distress as indicated by baseline scores on outcomes measures. Overall, the results show that (i) the self-help techniques were not effective at reducing fear of negative evaluation and symptoms of anxiety or depression, and (ii) if-then planning did not promote the use of the self-help materials.

Why were the self-help techniques not effective at reducing fear of negative evaluation and symptoms of anxiety or depression?

The present research found no evidence that the self-help techniques were effective at reducing fear of negative evaluation and symptoms of anxiety or depression. These findings were in contrast to Shah et al. (2014). A number of factors may influence the efficacy of self-help interventions. Webster, Thompson, Webb, and Sheeran (2014) suggested the following factors: (i) intervention content, (ii) study factors (including the use of self-report measures, level of clinical severity and population characteristics) and (iii) the amount of therapist contact. The discussion below considers the extent to which each of these factors could have influenced the efficacy (or lack thereof) of the self-help interventions delivered in the present research.

Intervention content. Unfortunately, there is a paucity of reviews sufficiently detailing the content of self-help interventions, limiting opportunities for replication and

implementation. At present, no review assessing the impact of content on intervention efficacy exists, and thus there is limited insight into what the 'active ingredients' of self-help are. In the current study, the self-help intervention examined was based on the principles of CBT. There is a plethora of evidence reporting the effectiveness of CBT for social anxiety (e.g., Clark, 2011) and a meta-analysis by Haug, Nordgreen, Öst, and Havik (2012) suggested that self-help interventions are an effective treatment for social anxiety. Further, models of adjustment to visible difference are based upon cognitive-behavioural principles and Kleve, Rumsey, Wyn-Williams, and White (2002) found that cognitive behavioural interventions including assertiveness skills, social skills training, anxiety management and cognitive therapy had a positive effect on social confidence and reducing symptoms of social anxiety for individuals with a visible disfigurement. The contents of Kleve et al.'s (2002) intervention appear largely comparable to the contents of the intervention used in the present study, however Kleve et al. (2002) did not recruit a control condition for comparison, a substantial limitation, and thus the result must be interpreted with caution. Additionally, the presence of a large number of elements in Kleve et al.'s (2002) intervention result in speculation regarding which, if any, ingredients were responsible for improved outcomes.

Another possible explanation for the lack of effect of the self-help intervention on outcomes could be the low behavioural component. Further, the behavioural component of the self-help involved systematic desensitisation rather than graded exposure which may have further tempered results. Gould, Buckminster, Pollack, Oto, and Yap (1997) reviewed 16 studies which examined the efficacy of exposure, exposure plus cognitive restructuring, and cognitive restructuring alone on social anxiety. Within-group effect sizes post treatment were 0.89 for exposure, 0.80 for exposure plus cognitive restructuring, and 0.60 for cognitive restructuring. The results suggest that exposure therapy either alone or in combination with cognitive restructuring was more

effective than cognitive restructuring only. The self-help intervention in the present study may have benefited from an increased behavioural component with a focus on graded exposure rather than systematic desensitisation.

A further possible explanation for the finding that the interventions employed in the present research did not influence outcomes could be the absence of 'multi' formats. Lewis, Pearson, and Bisson (2012) reported that the inclusion of multi-media such as audio, video and internet in self-help interventions improved efficacy. Additionally, Gould and Clum (1993) found that using more than one means format (e.g., both print copy and audio or video) has the potential to almost double the effectiveness of the intervention. The impact of multi-media components within-self-help on outcomes shows promise and further exploration is needed.

Study factors. With respect to whether methodological decisions within the present study may have accounted for the lack of evidence that the intervention influenced outcomes, the use of self-report measures has shown to have mixed results in estimating outcomes. Den Boer, Wiersnia, and van den Bosch (2004) conducted a meta-analysis examining the effectiveness of self-help for depression and anxiety and reported that self-report measures diminished outcomes, whereas a meta-analysis by Hirai and Clum (2006) examining the effectiveness of self-help for anxiety only found the use of self-report enhanced outcomes. Varley et al. (2011) used self-report measures when examining the impact of enhancing self-help materials with IIs and found improved outcomes in the enhanced self-help in comparison with the control condition. Thus, the impact of self-report measures on outcomes warrants further investigation, and providing inferences about the extent to which the present study's use of self-report measures could account for the findings would be unwise.

The levels of participant attrition were higher than anticipated, however, attrition rates were comparable between the three conditions. The high attrition rate could

suggest that some participants found the intervention unacceptable and dropped out of the study as a result. However, it is important to recognise that there was no evidence that the intervention has an adverse effect on outcome measures and no adverse events were reported to the researcher. High attrition rates are common in interventions designed to promote changes in health behaviour (Crutzen, Viechtbauer, Spigt, & Kotz, 2014) and particularly in internet-based health behaviour change interventions (Kohl, Crutzen, & de Vries, 2013). In the present study, participants who were younger, single, students and not of White British or Irish ethnicity were more likely to drop out. It is unclear why these participants were more likely to drop out. Future research would benefit from exploring patient characteristics and how these interact with attrition rates from online self-help studies.

Despite the high attrition rate, qualitative feedback from the participants on the intervention was largely positive. For example, participants commented on the usability of the intervention, expressed positive comments about specific aspects of the intervention, and the benefits of their experiences being normalised.

The amount of therapist contact. Another possible explanation for the lack of efficacy of the self-help intervention may be the provision of *pure* self-help as opposed to *guided* self-help. A number of reviews indicate that contact from a therapist or a para-professional increases the efficacy of self-help materials (Hirai & Clum, 2006; Menchola, Arkowitz, & Burke, 2007; van Boeijen et al., 2005). However, with the desire to provide cost-effective treatments, creating a feel or sense of contact with a therapist could provide an effective alternative to actual contact. For example, Richardson and Richards (2006) suggested numerous ways in which self-help could be developed to provide a sense of contact, including (but not limited to) using empathetic language, providing goal-setting tasks, including case-studies of self-help successes, giving feedback (where possible) and providing details on how to recommence self-help

in case of drop-out. With increasingly sophisticated technology, responsive systems providing a sense of therapist contact may be more achievable. Although the current study attempted to use empathetic language and, in the case of the enhanced intervention provided goal setting tasks, there was a lack of self-help success stories, feedback and details on how to recommence self-help in case of drop out. It is possible that in the future the intervention could be developed further to create an increased sense of therapist contact or, indeed involve actual therapist contact.

Individual characteristics. The effectiveness of interventions can also be influenced by participant characteristics. For example, Newman (2000) found that therapist directed treatment can be ineffective due to unaddressed co-morbidity, symptoms that are too severe, or a lack of motivation. Therefore, it could be possible that similar factors could influence pure self-help. The current study did not request information regarding the existence of co-morbidities, only excluding participants who were currently receiving psychotherapy. RCTs are often criticised for their exclusion of individuals with co-morbidities and, as such, the current study is potentially more ecologically valid. However, it is also possible that the existence of co-morbidities impacted on the results of the study whereby the self-help was not effective due to multiplicity of mental health difficulties and thus complexity of participants. Indeed, one participant reported in the qualitative feedback that they believed their results may have been impacted by a co-morbid anxiety disorder. It is possible that more intensive psychological interventions would be more effective than self-help for individuals with co-morbidities. The present study could have been improved by collecting data regarding co-morbidities which was then controlled for in the statistical analyses.

It is possible that participants' symptoms were too severe for the present study's self-help to be effective. At baseline, participants exhibited clinically significant levels of social anxiety, mild symptoms of generalised anxiety (approaching cut off for further

assessment of a formal anxiety disorder) and moderate symptoms of depression. In terms of clinical implications, it is recommended that individuals with skin conditions are routinely screened for psychological distress. Using outcome measures which examine difficulties commonly experienced by this population, such as fear of negative evaluation, should be utilised in addition to more commonly used measures of anxiety (GAD-7) and depression (PHQ-9) to ensure that distress common to this population is not missed. Future research may benefit from exploring the effectiveness of the stepped-care model within this population, considering which level of intervention intensity is most effective for differing levels of distress.

MacLeod, Martinez, and Williams (2009) asked therapists which factors they believed predicted the efficacy of self-help interventions. The results suggested that motivation, self-efficacy, beliefs about the credibility of the self-help and level of literacy were important. Unfortunately, the present study only considered fluency of the English Language as an inclusion criteria and other participant characteristics as suggested by Macleod et al. (2009) were not measured as possible variables. It is possible that participants' levels of motivation, self-efficacy, beliefs about the study's credibility and levels of literacy could have influenced whether and how they interacted with the self-help materials and their impact on outcomes. For example, if participants had low motivation or low self-efficacy this could impact negatively on their engagement with the intervention. Further, some participants may have had difficulties with literacy. Despite the inclusion criteria of fluency in the English Language, it is possible that due to the study being open to individuals from all countries, some participants may have struggled with understanding the information or instructions provided in the intervention. Finally, participants in the current study may not have believed that the self-help intervention would benefit them. Despite the majority of participants reading a minimum of one section of the self-help, less than half read all

five sections, possibly indicating participants may not have rated the credibility of the study and thus did not fully adhere to it. Future studies might benefit from measuring motivation, self-efficacy, beliefs about credibility and literacy levels.

There is conflicting evidence regarding the impact of using non-clinical, sub-clinical or clinical populations on outcomes and further research is required to examine the relationship and role of clinical severity on efficacy. In the present study, the population characteristics indicated clinically significant social anxiety and mild symptoms of anxiety and depression (although both in the upper part of the mild range). This could be indicative of a clinical population and one possible explanation regarding the lack of efficacy of the self-help intervention in the population recruited was that their symptoms were too severe to be addressed by an unguided low-intensity intervention. It is possible that a more intensive therapeutic approach, such as increased therapist contact, may have enhanced outcomes in the present study.

Why did if-then planning not promote the use of self-help techniques or influence outcomes?

The results of the present study suggest that the addition of II instructions designed to encourage use of the self-help materials and techniques did not improve outcomes in the visible skin condition population. Overall, these results were unexpected and not in line with the hypotheses. Previous literature has shown the benefit of IIs in influencing behaviour change for a range of health behaviours (Armitage, 2008, 2009; Verplanken & Faes, 1999) and anxiety symptoms (Varley et al., 2011). When considering the visible skin condition population, Shah et al. (2014) recruited individuals with Vitiligo and examined the effectiveness of self-help materials (both with and without IIs) in comparison to control and found reliable and clinically significant improvement in social anxiety in individuals receiving the intervention

enhanced with IIs. Despite this, no statistically significant difference was found between the conditions, in line with the present study's findings.

It is possible that the effectiveness of the enhanced self-help in the present study was influenced by the inclusion of multiple instructions to form IIs. Webb (2006) suggested that the creation of multiple II plans may require higher cognitive load and thus reduce the extent to which each plan is encoded in the planning process. Research has demonstrated mixed findings regarding the efficacy of using single or multiple planning instructions. The majority of research concerning IIs has focused on single planning instructions (e.g. Adriaanse, De Ridder, & de Wit, 2009). However, a number of studies have demonstrated the success of formulating multiple plans (e.g. Armitage, 2004; Achtziger, Gollwitzer & Sheeran, 2008; Koestner, Lekes, Powers & Chicoine, 2002). Unfortunately, there is limited research regarding the effect of multiple IIs compared to creating a single II. Despite two studies suggesting multiple plans were effective in increasing fruit and vegetable intake (Wiedemann, Lippke, & Schwarzer, 2011) and physical activity (Wiedemann, Lippke, Reuter, Ziegelmann, & Schüz, 2010), these results must be interpreted with caution as the studies were correlational, thus casting doubt over causality. A more recent study by Verhoeven, Adriaanse, De Ridder, De Vet, & Fennis (2013) examined the behavioural and cognitive implications of forming multiple IIs and found that formulating multiple IIs was ineffective when changing unwanted behavior. However, it is important to recognise that the present study aimed to introduce new behaviour rather than reduce current behaviour, so these results must be interpreted with caution. Due to mixed findings, future research which aims to examine the efficacy of single vs. multiple IIs further with an interventional, as opposed to correlational, design would be beneficial. In addition, future research examining the impact of single vs. multiple IIs in self-help interventions specifically for individuals with visible skin conditions would be beneficial.

The present study has a number of strengths. Firstly, the study benefits from an inclusive approach to different types of visible skin conditions and recruited participants online, allowing individuals from an unlimited geographical area to participate. The study also attempted to offer a cost-effective means of delivering psychological intervention, in line with a stepped-care model which aims to increase accessibility and best use of limited resources. Another strength is the use of an RCT design. RCTs are often regarded as the most scientifically rigorous method of hypothesis testing (Last, 2001) and referred to as the "gold standard" for examining efficacy of interventions (McGovern, 2001). The design allowed for comparison of intervention conditions to control conditions, enabling the examination of both the intervention itself, which although having previously received qualitative feedback (Pasterfield, 2014), had not received formal experimental testing. In addition, the design also enabled the investigation of the specific impact of adding IIs to the existing materials. Although there is already an existing evidence base supporting the use of IIs for health behaviour change, research examining this method with the visible skin condition population is limited, and the present study benefits in adding to this emerging literature base.

Finally, the present study measured adherence as well as outcomes, which allowed for an increased understanding regarding the mechanisms by which the intervention did not influence outcomes. The results indicated that it wasn't that participants were not reading the materials, but that the materials themselves were not influencing outcomes.

Limitations and areas for future research

The findings of the present research are limited by a high attrition rate, which although seemingly common in internet based studies, is concerning. Future studies might offer participants alternative means of obtaining the materials and examining any

impacts on retention. A further possible limitation of the study was the recruitment strategy which may have introduced sample bias. The study was largely advertised by skin charities and organisations through social media thus potentially creating a barrier for those less technologically able. Further, it is possible that individuals accessing skin charities and organisations may also exhibit higher levels of distress than those not accessing, as suggested by the scores at baseline of fear of negative evaluation, anxiety and depression. It is possible that this level of clinical distress impacted negatively on the extent to which the self-help was effective for this population.

As part of the qualitative feedback, it came to light that some participants did not feel that the intervention period was long enough, and it is possible that providing participants with more time to learn and use the intervention would have improved outcomes. Further, one participant identified that their skin condition has worsened during the intervention period and suspected that this had a negative impact on their outcomes. The present study did not objectively measure, and thus control for, changes in skin conditions which may have impacted on results. Future research should consider allowing for longer periods of intervention use and undertake objective measurements of skin conditions to capture fluctuations.

In relation to future research directions, it would be beneficial to investigate if increasing the level of therapist contact in conjunction with the existing self-help materials improved outcomes. Future research could target populations with lower psychological distress than the participants in this study to establish if the self-help could be effective in less clinical populations. It would also be useful to obtain detailed, rich qualitative feedback from participants to help improve understanding into mechanisms linked to drop out or acceptability of the materials. Finally, there is a need for further investigation into the effectiveness of interventions along the stepped-care

pathway, including psychoeducation groups and one-to-one therapy in the visible skin condition population.

Clinical implications

The results of the present research indicate significant levels of clinical distress amongst individuals with visible skin conditions, as suggested by baseline scores on measures of fear of negative evaluation and symptoms of anxiety and depression. As a result, it is recommended that psychological distress is routinely screened for in clinics. Further, including administering measures of distress commonly experienced by this group in particular, such as social anxiety, is recommended to ensure that distress specific to this population is recognised. The present study suggests that the BFNE-II could be an appropriate tool for screening social anxiety in this population. Conflicting results from the existing research suggest that the efficacy of self-help incorporating IIs remains unclear for the visible skin condition population. Finally, more work is needed to establish the effectiveness of interventions differing in intensity for the visible skin condition population.

Conclusions

The present research evaluated the effectiveness of a self-help intervention enhanced with IIs compared to standard self-help and a control using a randomised-controlled trial design. There was no evidence that either the standard or the enhanced self-help interventions had a different effect on outcomes compared to providing no intervention, suggesting that (i) the self-help techniques were not effective at reducing fear of negative evaluation and symptoms of anxiety or depression, and (ii) that IIs do not promote the use of these techniques. These findings stand in contrast to research, which suggests that psychological interventions can be effective for individuals with

skin conditions (e.g. Lavda et al., 2012), including self-help for anxiety (Shah et al., 2014) and that if-then planning can promote the use of self-help materials (Varley et al., 2011). Future research could benefit from gathering information on participant characteristics such as motivation, self-efficacy, beliefs about the credibility of the self-help and literacy level and examine if these influence outcomes.

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Appendix A: Standard Self-Help materials

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Appendix B: Example of Study Advert

Self-help for visible skin difference in adults

The University Of Sheffield.

We would like to find out whether a self-help intervention is effective for adults with a visible skin difference. The self-help intervention aims to help people build their confidence in social situations.

This study is being conducted by researchers from the Department of Psychology at the University of Sheffield. **If your confidence in social situations is affected by your visible skin difference and you are aged 18 or over and interested in taking part, please click on the link below**. This will take you to the study website, where you can read more information.

The University of Sheffield- study website

If eligible, you can choose to take part, and will be asked to complete a set of questionnaires. These will be repeated once during the course of the study, to see whether the self-help is effective. You will receive the self-help intervention as a PDF document either straight away or after a waiting period. If you know someone else who might be interested in taking part, please feel free to forward this link.

Appendix C: Participant Information Sheet

Department Of Psychology.
Clinical Psychology Unit.

Jessica Lane (Lead Researcher)
Trainee Clinical Psychologist
Department of Psychology
University of Sheffield
Western Bank
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Enhancing psychological self-help with implementation intentions for those with visible difference and fear of negative evaluation: A randomised controlled trial

Participant Information Sheet

You are being invited to take part in a research study. Before you decide on whether or not to take part, it is important for you to understand why the research is being carried out and what it will involve. Please take time to read the following information carefully. You can email the lead researcher (jlane1@sheffield.ac.uk) if you would like more information or have any questions.

What is the purpose of this research?
The purpose of this study is to examine the effectiveness of a psychological self-help intervention.

Why have I been chosen?
You are invited to participate in this study if you are aged 18 or above and identify yourself as having a visible skin difference and a fear of negative evaluation from others. We are recruiting people from a range of charities, online forums and social media.

Do I have to take part?
No, participation in this research is completely voluntary. If you decide to take part, then you are free to withdraw from the study at any time, without giving a reason and without any negative consequences. You can do this by contacting the lead researcher, using the details given above.

What happens if I decide to take part?
You will be asked to complete some demographic questionnaires, which include questions about your age and gender and also questions about your mood, and how you feel in social situations. After completing these questions, you will be randomly allocated to receive either an online intervention now or in four weeks time. When you gain access to the intervention you will have four weeks to read and work through it in

your own time. We have estimated that the intervention will take you approximately four hours to work through. After four weeks, you will be asked to complete the same questionnaires again. The study will then be completed; however you will still be able to access the intervention if you would like to do so.

What are the possible benefits of taking part?
Once you have completed the questionnaires at the end of the four week time period, you will be entered into a prize draw to receive an Amazon voucher worth £50.

What are the possible risks of taking part?
For some people, completing questionnaires and working through the intervention could raise concerns. The researchers are not be able to provide any psychological support to participants, but we recommend that participants contact their GP for support if they are concerned.

Will participation be kept confidential?
Yes, the data you provide will be treated in strict confidence and will not be disclosed beyond the researchers directly involved in the study (see details below). You will be asked to provide your email address, to ensure that you can be contacted to complete the measures again after eight weeks. However, email addresses will be stored securely and separated from any data which you provide. All data will be reported anonymously in any future publication of the results and it will not be possible to identify you in any reports on the findings.

What will happen to the results?
Your responses will be used to see whether the intervention was helpful. The results will be written up as part of the lead researcher's thesis for the Doctorate in Clinical Psychology at the University of Sheffield and we will seek to disseminate the findings through publication in academic journals. A copy of the findings of the research will be available upon request. Your data may also be used in future research.

Who is organising this research?
This study is being run by Jessica Lane, a Trainee Clinical Psychologist at the University of Sheffield. It is being supervised by Dr Andrew Thompson and Dr Thomas Webb at the University of Sheffield.

Who approved this research*?*
This study has been approved by the Ethics Committee in the Department of Psychology at the University of Sheffield. If you have any questions or concerns, please contact Andrew Thompson (a.r.thompson@sheffield.ac.uk) or Thomas Webb (t.webb@sheffield.ac.uk) in the first instance. If you have any further concerns, please contact the University of Sheffield's Office of the Registrar and Secretary at 0114 222 1101.

Appendix D: Participant Consent Form

Department Of Psychology.
Clinical Psychology Unit.

Jessica Lane (Lead Researcher)
Trainee Clinical Psychologist
Department of Psychology
University of Sheffield
Western Bank
Sheffield S10 2TP UK

Telephone: 0114 22 26637
Email: jlane1@sheffield.ac.uk

Enhancing psychological self-help with implementation intentions for those with visible difference and fear of negative evaluation:
A randomised controlled trial

Consent Form

Thank you for your interest in taking part in this study. We aim to explore the effectiveness of a psychological self-help intervention for people with visible skin difference.

To take part, you will need to complete some demographic questions and some brief questionnaires including how your mood and how you feel in social situations.

All answers are confidential. You may withdraw from this study at any point.

By signing this form you agree that you have read the information sheet, you understand it, and you are happy to participate. You are also agreeing to being contacted in the future to complete some further measures. You are also confirming that you are aware that your data may be used in future research.

Signed _____

Date ___/____/___

Email address _____

User ID* _____

(*User ID is the first three letters of your mother's maiden name, followed by the day and month of your birthday. For example,BAR0511. This user ID will allow us to compare responses across time points, if you decide to take part in the follow-up.)

Appendix E: Generalised Anxiety Disorder 7 (GAD-7)

Over the last two weeks, how often have you been bothered by the following problems?

	Not at all	Several Days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge				
Not being able to stop or control worrying				
Worrying too much about different things				
Trouble relaxing				
Being so restless it is hard to sit still				
Becoming easily annoyed or irritable				
Feeling afraid as if something awful might happen				

("✓" to indicate your answer)

Appendix F: Patient Health Questionnaire 9 (PHQ-9)

Over the last two weeks, how often have you been bothered by the following problems?

	Not at all	Several Days	More than half the days	Nearly every day
Little interest or pleasure doing things				
Feeling down, depressed, or hopeless				
Trouble falling or staying asleep, or sleeping too much				
Feeling tired or having little interest				
Poor appetite or overeating				
Feeling bad about yourself – or that you are a failure or have let yourself or your family down				
Trouble concentrating on things, such as reading the newspaper or watching television				
Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual				
Thoughts that you would be better off dead or of hurting yourself in some way				

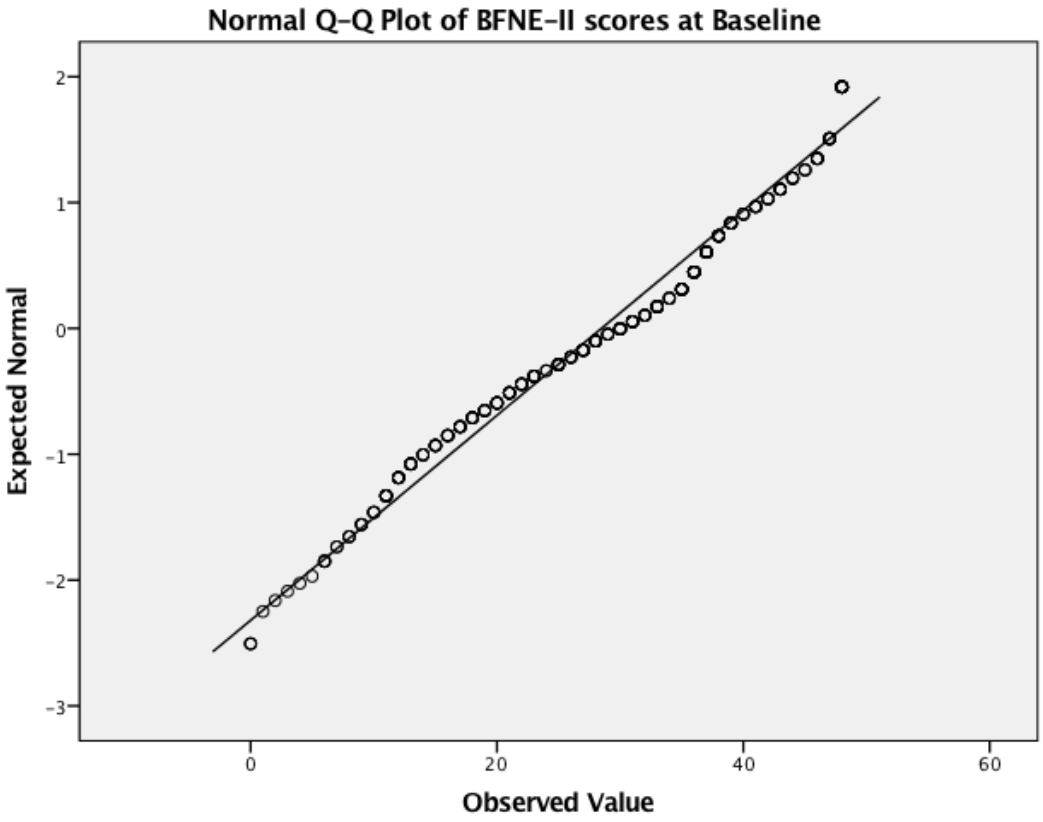
("✓" to indicate your answer)

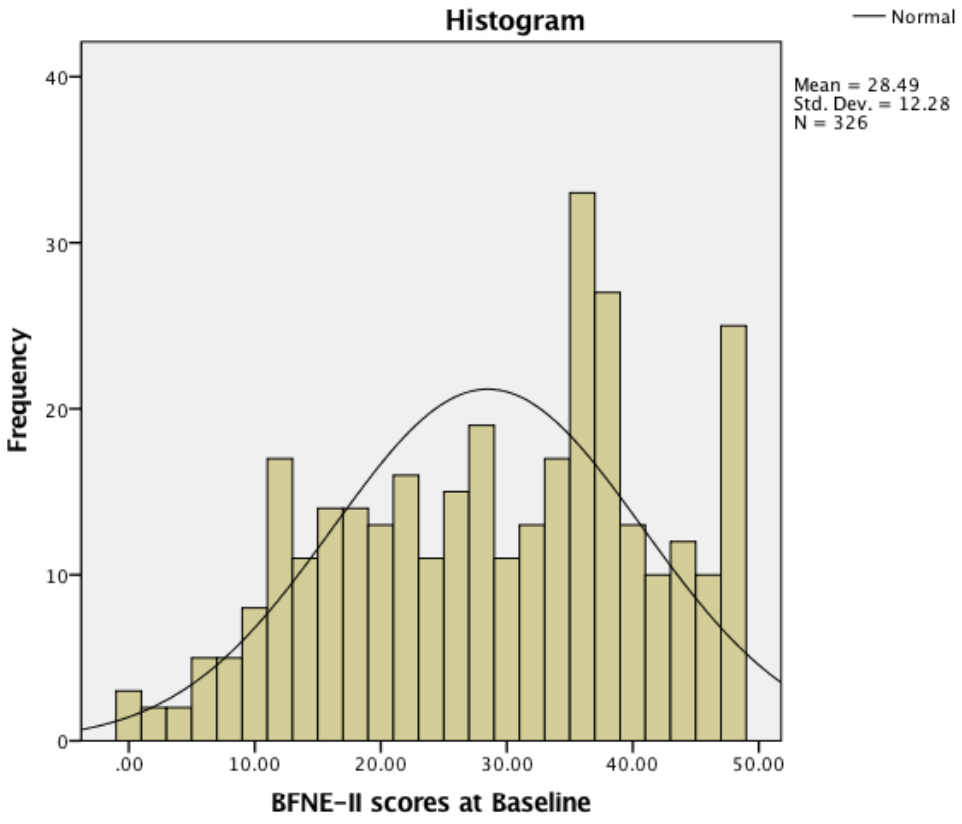
Appendix G: Brief Fear of Negative Evaluation-II (BFNE-II)

Please circle the number that best corresponds to how much you agree with each item.

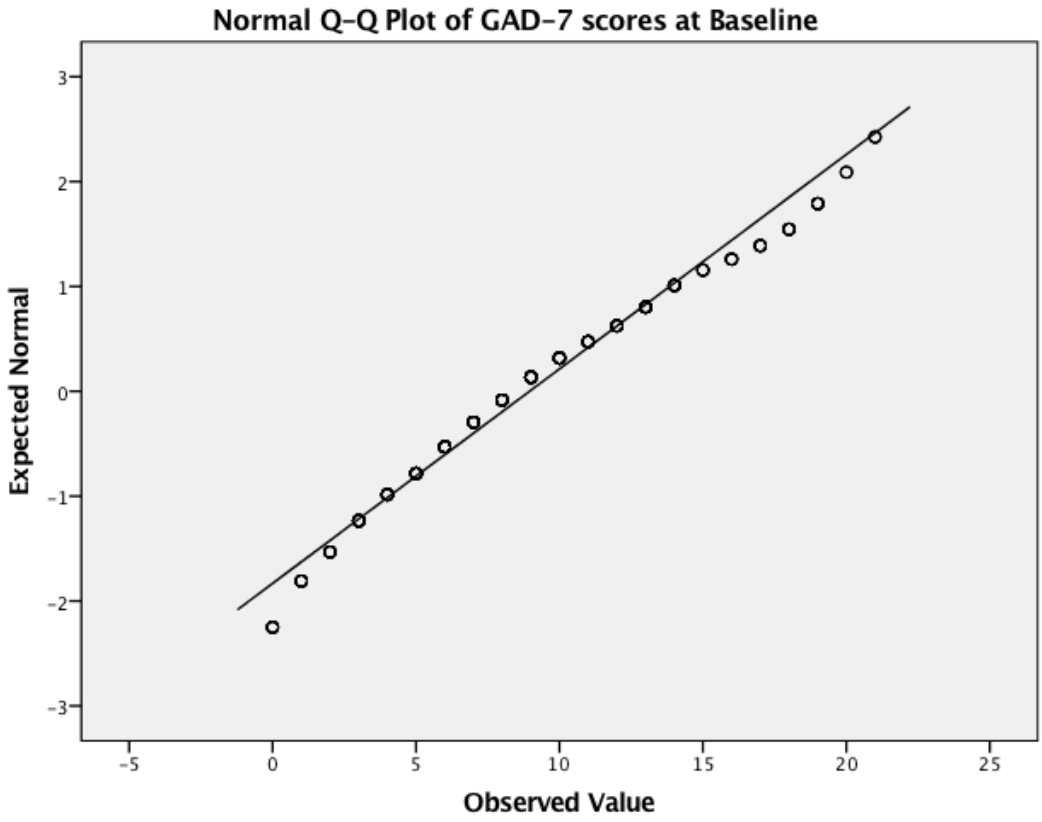
	Not at all characteristic of me	A little characteristic of me	Somewhat characteristic of me	Very characteristic of me	Entirely characteristic of me
1. I worry about what other people will think of me even when I know it doesn't make any difference.	1	2	3	4	5
2. It bothers me when people form an unfavourable impression of me.	1	2	3	4	5
3. I am frequently afraid of other people noticing my shortcomings.	1	2	3	4	5
4. I worry about what kind of impression I make on people.	1	2	3	4	5
5. I am afraid that others will not approve of me.	1	2	3	4	5
6. I am afraid that other people will find fault with me.	1	2	3	4	5
7. I am concerned about other people's opinions of me.	1	2	3	4	5
8. When I am talking to someone, I worry about what they may be thinking about me.	1	2	3	4	5
9. I am usually worried about what kind of impression I make.	1	2	3	4	5
10. If I know someone is judging me, it tends to bother me.	1	2	3	4	5
11. Sometimes I think I am too concerned with what other people think of me.	1	2	3	4	5
12. I often worry that I will say or do wrong things.	1	2	3	4	5

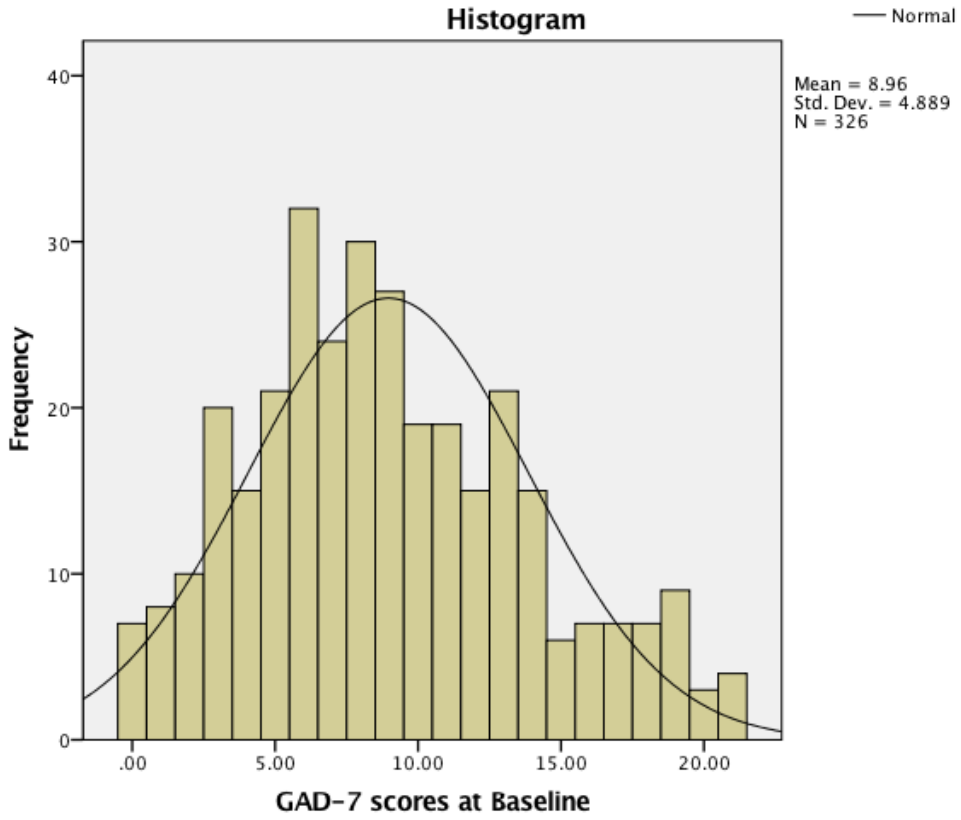
Appendix H: Q-Q plot and Histogram of BFNE-II scores at Baseline



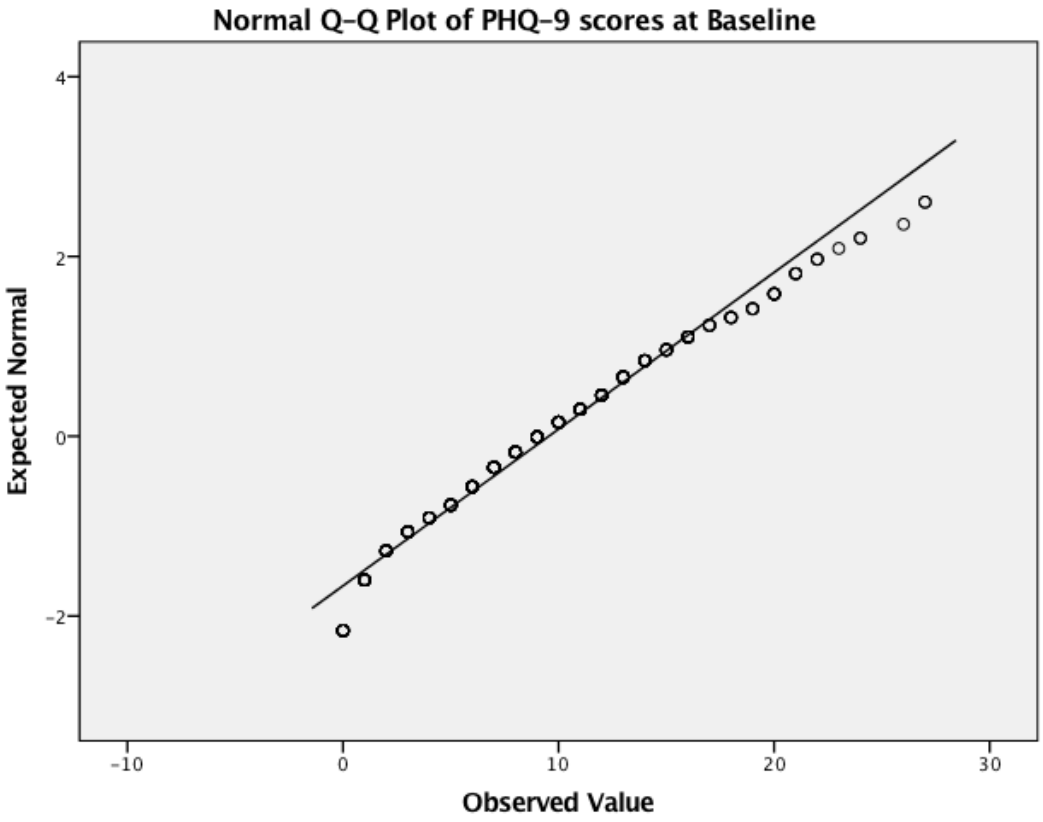


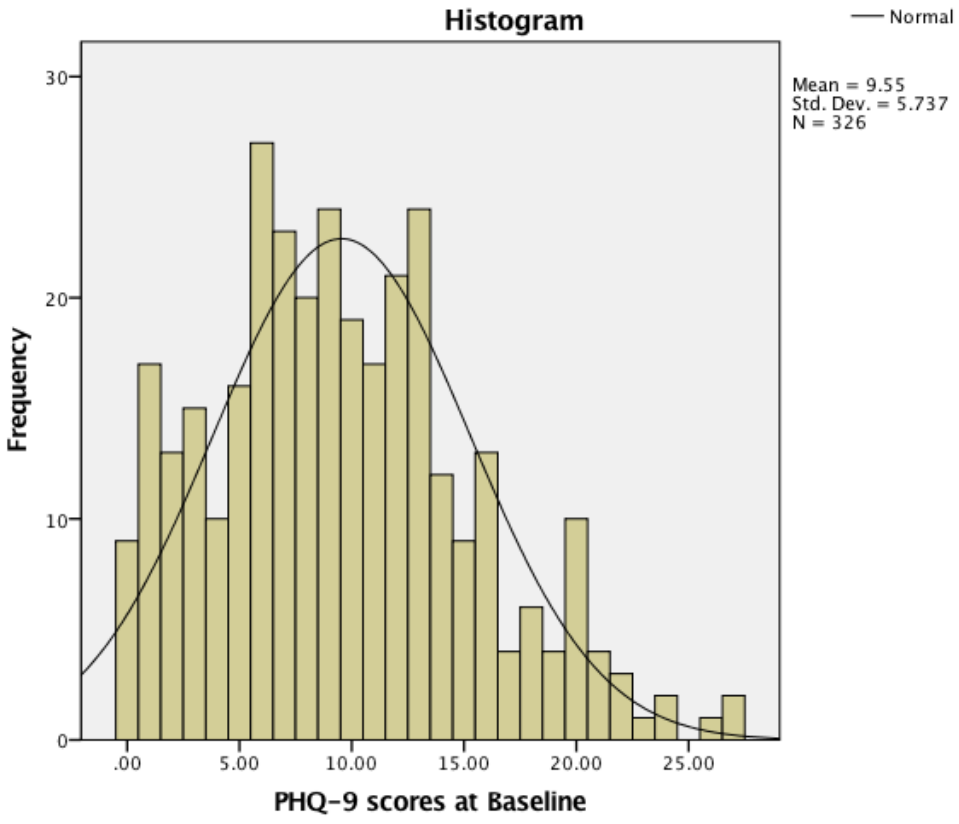
Appendix I: Q-Q plot and Histogram of GAD-7 scores at Baseline





Appendix J: Q-Q plot and Histogram of PHQ-9 scores at Baseline





Appendix K: Ethical Approval

Approved: 09/05/2016

Jessica Lane Registration number: 140109218

Psychology Programme: Doctorate in Clinical Psychology

Dear Jessica

PROJECT TITLE: Enhancing psychological self-help for those with visible skin difference and fear of negative evaluation: A randomised controlled trial **APPLICATION:** Reference Number 008254

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 09/05/2016 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

University research ethics application form 008254 (dated 31/03/2016). Participant information sheet 1016824 version 1 (31/03/2016). Participant consent form 1016825 version 1 (31/03/2016).

The following optional amendments were suggested:

In the information sheet/consent form, please: i) be clear on the time commitment expected from participants when completing the intervention, ii) explain that the data might be used in future research as well as in the current research, iii) state up until when, and how, participants can withdraw their data.

If during the course of the project you need to deviate significantly from the above-approved documentation please inform me since written approval will be required.

Yours sincerely

Thomas Webb

Ethics Administrator Psychology