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Starting to develop self-help for social anxiety associated with vitiligo: Using clinical significance to measure the potential effectiveness of enhanced psychological self-help

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What's already known about this topic?

- Vitiligo can be associated with psychological distress that influences quality of life.
- CBT has been shown to be potentially effective, however there are currently no self-help interventions available.

What does this study add?

- Evidence that social anxiety is a significant problem in vitiligo.
- The development and test of a self-help intervention based on cognitive behavioural techniques and enhanced with implementation intentions.
- Evidence that enhanced self-help has the potential to reduce social anxiety associated with vitiligo.

Background: Vitiligo can be associated with high levels of distress, yet there are currently no self-help interventions available.

Objectives*:* This study describes the initial development of a psychosocial self-help intervention designed to reduce social anxiety associated with vitiligo. It also examines whether including a planning exercise, aimed at increasing use of the intervention (termed implementation intentions), has the potential to achieve a clinically significant reduction in distress.

Methods: Participants (N=75) were randomised to one of three groups: cognitive behavioural self-help (CBSH), cognitive behavioural self-help augmented with implementation intentions (CBSH+), or no intervention. Participants were assessed at baseline and after eight weeks on measures of social anxiety, anxiety and depression, and appearance related concern. The two intervention groups also completed a questionnaire evaluating their use of, and satisfaction with, the intervention.

Results: High levels of social anxiety and appearance concern were reported. 24% of participants in the CBSH+ group experienced clinically significant change on the measure of social anxiety, compared to 8% in the CBSH group and 0% in the control group. In addition, 58% of the control group deteriorated during the study period. There were no significant differences between the conditions on the other outcome measures. Participants reported that the self-help leaflets were helpful.

Conclusions: The findings demonstrate that augmented CBSH provides a relatively simple and accessible intervention that can result in a clinically significant reduction in social

anxiety. The augmented intervention has potential and might be further developed and evaluated in subsequent trials.

Introduction

Vitiligo is an incurable skin disorder resulting from the destruction of melanin-producing cells leading to visible white patches[1]. The aetiology and course of the condition is unknown, however there is some evidence that stress may play a role[2, 3] and vitiligo has been found to be associated with high levels of psychological distress[4, 5, 6]. Kent and Al'Abadie[7] surveyed over 600 members of the UK Vitiligo Society and reported that 35% of respondents had poor quality of life, and similar findings have been reported from studies conducted in Africa and Asia[8,9]. Qualitative studies provide accounts of actual discrimination and experience of intrusive reactions from others[10, 11, 12.] Despite the clear suggestion that people living with vitiligo might be at risk of developing social anxiety no existing study has attempted to examine methods of reducing such distress.

Recent systematic reviews indicate that relatively few studies have examined the efficacy of psychological interventions for vitiligo[13, 1]. To date there have been just two studies assessing the efficacy of psychological interventions. Papadopoulous et al.[14] conducted a small trial (14 participants) of cognitive behavioural orientated therapy (CBT), finding positive changes in quality of life, self-esteem, and body image. Papadopoulos et al.[15] conducted a further randomised control trial (RCT) with 45 participants randomised to group CBT, group person-centred therapy, or no treatment. This study did not find any evidence for the effectiveness of psychological therapy. Both of the studies have some significant methodological limitations, having small samples sizes, and neither of them targeted social anxiety, which has been thought to be a primary psychological issue associated with living with vitiligo.

The Present Research

The present research reports the development of a self-help intervention designed to reduce social anxiety associated with vitiligo. It also sought to provide an initial examination of the interventions potential to achieve clinically significant change and improve quality of life in vitiligo. The method of developing and testing the self-help intervention was based upon recognised principles for developing behaviour change interventions[16] that emphasise examining theoretical proof of concept and user acceptability before conducting randomised controlled trials. The theoretical basis for the intervention was derived from cognitive behavioural models of social anxiety, which focus on adapting attentional biases[17, 18].

In addition, we sought to investigate the efficacy of augmenting the self-help instructions with specific if-then plans (or implementation intentions[19]). Implementation intentions are plans that specify exactly when, where, and how to act in future situations and have been increasingly used in behaviour change interventions. For example, Gollwitzer and Sheeran[20] conducted a meta-analysis demonstrating that implementation intentions have a medium to large effect (d=0.65) on goal achievement. Recently, Varley, Webb, and Sheeran[21] have shown that adding implementation intentions to simple self-help leaflet significantly increased the use of the techniques, leading to reductions in general anxiety among an undergraduate sample.

In the present research, participants were randomly allocated to receive a self-help leaflet, the same leaflet enhanced with implementation intentions, or no intervention. Given the current limited availability of psychosocial services within dermatology, a pdf leaflet has the potential to be a highly accessible and low cost medium for delivering psychosocial interventions. Levels of distress and quality of life were measured at baseline and at eight

weeks. It was predicted that participants who received self-help (standard or enhanced) would be more likely to show a clinically significant reduction in distress in comparison to participants who received treatment as usual (contact with UK Vitiligo Society). However, as the success of self-help requires practice and implementation, it was predicted that participants in the group receiving the leaflet enhanced with the implementation intention would be more likely to achieve clinically significant changes than participants in the leaflet only group. As the intervention was novel, information on usability and acceptability was collected.

Method

An independent repeated measures design was conducted to explore whether standard and augmented self-help interventions could reduce psychological distress associated with vitiligo. Participants in the intervention groups were emailed self-help leaflets after completing measures at time 1. Eight weeks later, follow-up measures were sent. At the end of the intervention period the control group were also given access to the intervention. Ethical approval was gained from Cardiff University.

Intervention

The intervention was based on a cognitive behavioural model of social anxiety[17, 18] and incorporates CBT techniques presented in a leaflet form. The leaflet included psychoeducation, relaxation[22] and attentional refocusing[23]. The first three authors developed the intervention, a copy of which is available from the corresponding author. Representatives from the UK Vitiligo Society helped to ensure that the interventions were likely to be acceptable to a patient population. The cognitive behavioural self-help intervention (CBSH) had three parts: (i) psycho-education, including a description of how social anxiety is likely to be maintained in vitiligo; (ii) symptom monitoring with an

emphasis on the recognition of self-focused attention and triggers of anxiety; and (iii) guided imagery based relaxation and techniques for switching attention.

In the enhanced cognitive behavioural self-help condition (CBSH+) guidance was also provided on forming specific if-then plans aimed at increasing the use of the interventions. For example, 'If I feel anxious at a party, then I will improve my confidence by thinking of a beach scene' or 'If I feel anxious when shopping, then I will improve my confidence by focusing on external objects or noises around me'. Participants in the control group did not receive the intervention (CBSH+) until after completion of the study. Once the participants had completed the baseline questionnaires, they were directed to download the leaflet (or have the option for it to be sent in the post). They were asked to read and use the leaflet as frequently as possible over the next eight weeks.

Participants

The study was advertised via the UK Vitiligo Society's website and newsletter. Inclusion criteria included self-certification as being diagnosed by a physician as having vitiligo, being able to read English, and being aged between 18-65 years. Five participants were excluded because they identified themselves as having a significant neurological or psychiatric condition (such as brain injury or psychosis), or were currently receiving psychological or psychiatric intervention. Participants were allocated by random number generation to one of the three groups. A total of 81 participants completed a consent form and questionnaire recording demographic information. Seventy-five participants completed the baseline measures using an online survey tool and all of these participants completed follow-up measures.

Measures

The primary outcome measure was the Brief Fear of Negative Evaluation Scale (Brief FNE[24]), which is commonly used to measure cognitive aspects of social anxiety. The Hospital Anxiety and Depression Scale (HADS[25]) was used to measure depression and anxiety, The brief Derriford Appearance Scale (DAS-24[26]) was used to measure appearance concern, and the Dermatology Life Quality Index (DLQI[27]) was used to measure skin specific quality of life.

Results

Four participants were removed from the analysis as they reported that they did not use the leaflet (no reason was given), leaving 71 remaining participants. An intention-to-treat analysis was conducted and the same clinical findings held. Baseline data from the outcome measures is shown in Table 1.

Insert Table 1 here

Analysis of baseline data revealed that randomisation was successful. A one-way between groups analysis of variance (ANOVA) found no significant differences between the three treatment groups on the demographic variables (all F-tests were $p>0.05$). Participants tended to have high levels of social anxiety (FNE) and appearance related concerns (DAS-24). The participants' scores also fell in the clinical range for anxiety (HADS score $\geq$ 11), they ranged between the borderline (HADS score $\geq$ 8) to clinical (HADS score $\geq$ 11) range for depression and reported that their vitiligo had a moderate effect on their quality of life (DLQI).

Impact of the Intervention on Outcomes

In order to investigate the impact of the intervention on clinical outcomes, the reliable change index (RCI) was used to estimate the change in outcomes from baseline to follow-up for each participant. The magnitude of change for a given participant was then examined to ascertain whether it was reliable and clinically significant. Finally, we compared the number of participants showing evidence of clinically significant change in each condition. Focusing on the number of participants who achieved clinically significant changes in outcomes overcomes some of the limitations associated with traditional statistical analysis that compares mean changes between conditions. Such tests can obscure variability in responses to treatment, yet information regarding the ability of an intervention to achieve clinically meaningful change is important particularly in early intervention development[28].

RCI and clinical significance were computed using the approach suggested by various authors [28, 29, 30]. Specifically, the percentage of participants who 'improved' (I), 'reliably improved' (RI), showed 'reliable and clinically significant improvement' (RCS), showed no change in the pre and post scores, or 'reliable deterioration' (RD) were identified. Reliability was indicated by the internal consistency of the outcome measures, using the Cronbach's alpha taken from the original papers[24, 25, 26, 27].

The following criteria were used to interpret change (taken from the original papers[28, 29, 30]): If there was a change in score (pre > post score), this was classified as I. If the change in score was more than the reliable change criterion (RCI value), then the change was classified as RI. Finally, if the scores were more than the clinically significant value, then the change was classified as RCS. For example, of 10 participants who improved, 6 may meet the reliable improvement criteria and, of those, 4 classified as showing RCS. If

scores deteriorated more than the reliable change value, then the (negative) change was classified as a RD.

The percentages of participants meeting each criterion for each outcome measure are presented in Figure 1.

Insert Figure 1 here

On the brief-FNE, a higher percentage of participants showed reliable and clinically significant improvement (RCS) in the CBSH+ group (24%) than in the other two groups (8% in the CBSH group and 0% in the control group). In the control group, 58% of participants showed reliable deterioration (RD) over the 8 weeks compared to the intervention groups. Chi-square indicated that there was a significant differences in the proportion of participants who showed RCS change in levels of social anxiety between the time one and time two scores between the three groups, Chi^2 (4, n=71), 19.0, $p = 0.001$.

There was no difference between the groups on anxiety or depression scores or for the appearance related scores; 29% of participants in the CBSH+ group demonstrated RCS improvement in HADS-anxiety scores, 24% on the HADS-depression, and 14% on the DAS-24. However, there was no difference between the percentage of participants that showed RCS improvement in the CBSH+ group, and the percentage of participants that showed RCS improvement in the CBSH and the control groups. In addition, the chi-squared was insignificant between the three groups. According to Jacobson and Truax[28], when calculating the reliable clinical index value, if the mean and standard deviation are similar

with a higher variance this indicates that the results are not reliable, and on this basis the scores were not calculated for the DLQI.

Evaluation questionnaire

Over 71% of participants reported that the leaflets were helpful and only a small percentage of participants (14%) reported that the leaflet was not useful. In addition, 57% of the participants in the CBSH+ group stated that the plan was useful. There was some evidence to suggest that inclusion of the plan in the self-help materials increased the frequency with which participants used the materials. Specifically, participants in the CBSH+ group were more likely to use the leaflet daily than participants in the CBSH group (24% compared to 8% respectively), Chi^2 (1, N=200), 9.52, $p < 0.01$. Also, 91% of the CBSH group used the leaflet weekly compared to 76% of the CBSH+ group, Chi^2 (1, N=200), 8.17, $p < 0.01$.

Discussion

There are very few psychological interventions available for people living with vitiligo, and none that focus on dealing with the social anxiety[14]. Therefore, the present study developed an intervention designed to reduce levels of social anxiety that are associated with this visible skin condition. The intervention was based on cognitive models of social anxiety and techniques derived from theories of behaviour change.

At baseline, participants were found to have clinically significant levels of social anxiety and appearance related concerns, that are comparable to those observed among participants with other skin disorders (e.g., Kent and Keohane[31]). This finding indicates that the predominant psychological issue for those living with a visible difference is managing the perceived reactions of others[32, 33, 34]. However, this is the first study to show that vitiligo

is associated with high levels of social anxiety. The present findings also support existing studies demonstrating that high levels of depression and poor quality of life among people with vitiligo (e.g. Ongenae *et al*[35]).

The novel and brief intervention was developed in consultation with the U.K. Vitiligo Society. For some of the participants, the intervention was enhanced with an implementation intention exercise designed to encourage use of the self-help materials. Our findings indicated that participants using enhanced self-help were more likely to achieve clinically significant changes in levels of social anxiety, than were participants in the other two conditions, although some of those receiving the self-help alone also showed clinically significant improvement. However, there were no differences between the conditions in levels of depression, general anxiety, and appearance concern. The beneficial effects of augmented self-help support those of Varley et al.[21] where the addition of an implementation intention to self-help materials was found to increase the use of the intervention and improve outcomes in a non-clinical sample. The findings here extend those of Varley et al. [21] to provide preliminary evidence of the efficacy of augmented self-help in a clinical sample.

The findings also provide support to the idea that interventions incorporating relaxation[22] and attentional focusing (e.g., Bogels et al.[23]) may be beneficial for people with vitiligo, perhaps due to the connection between social anxiety, stress, and vitiligo[7]. However, the finding that only the enhanced self-help condition showed clinically significant changes in social anxiety points to the importance of ensuring that self-help materials are used. Having said this, a high percentage of participants reported finding the leaflet useful and all participants completed follow-up measures suggesting that the intervention, even in standard form, was acceptable to participants. Nonetheless, a small number did not report finding the intervention useful and this warrants further examination.

The study has a number of limitations. As participants were recruited from the community it was not possible to control for all of the treatment factors that might have influenced the outcomes. Indeed, a number of participants in the no intervention condition improved and declined during the course of the study, suggesting that a number of factors, other than the intervention, can influence outcomes. Nonetheless, the primary aim of the study was to examine the potential usability and ability to achieve clinically significant change of an accessible self-help intervention, and the findings support further testing.

Conclusion

This is the first study to demonstrate that providing a self-help intervention that incorporates planning materials in the form of implementation intentions can lead to a clinically significant reduction in social anxiety associated with vitiligo. Given that self-help delivered in the form of a leaflet is accessible, the approach has the potential to be cost efficient and to reach large numbers of patients. Further studies are clearly needed to examine the efficacy of the intervention further.

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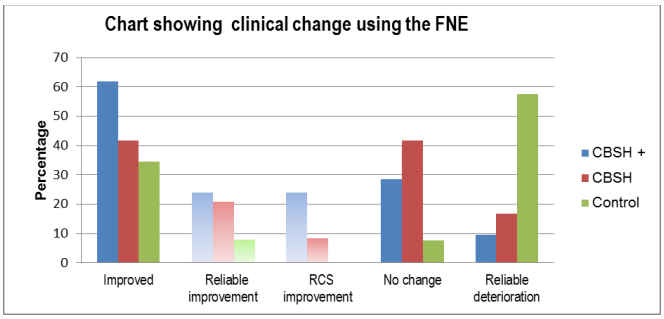
Table 1: Baseline data

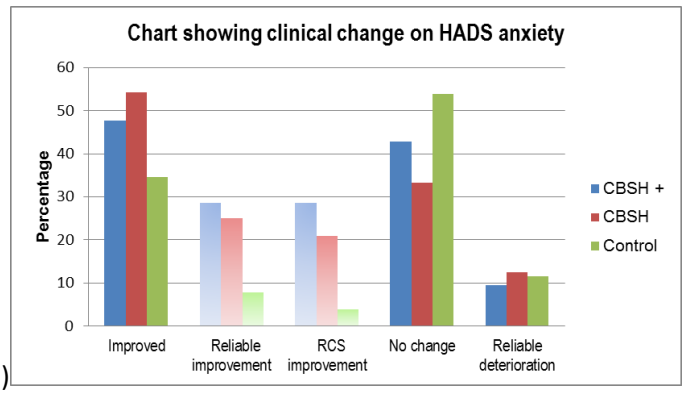
			Condition	
		CBSH +	**CBSH**	**Control**
		n = 24	n =25	n = 26
	Cut-off used to determine clinical significance	Mean (SD)	Mean (SD)	Mean (SD)
FNE	<30	30.89 (10.28)	31.08 (11.56)	31.35 (7.42)
HADS anxiety	<7	12.14 (5.08)	13.17 (6.30)	13.81 (4.75)
HADS depression	<7	9.05 (3.97)	11.42 (5.34)	11.31 (4.26)
DAS-24	<45	48.57 (15.58)	47.33 (17.51)	50.62 (18.57)
DLQI	<5	5.43 (6.17)	6.75 (5.31)	6.73 (5.98)

Figure 1: Charts showing the change in outcomes and clinical significance in the three groups. Panel (a) shows the change in FNE; panel (b) the change in HADS anxiety; panel (c) the change in HADS depression; panel (d) the change in DAS-24; and panel (e) the change in DLQI scores. [NB: The three main groups are 'improved', 'no change' and 'deterioration'; hence the 'reliably improvement' and 'RCS improvement' scores (faded bars) are part of 'improved' group].

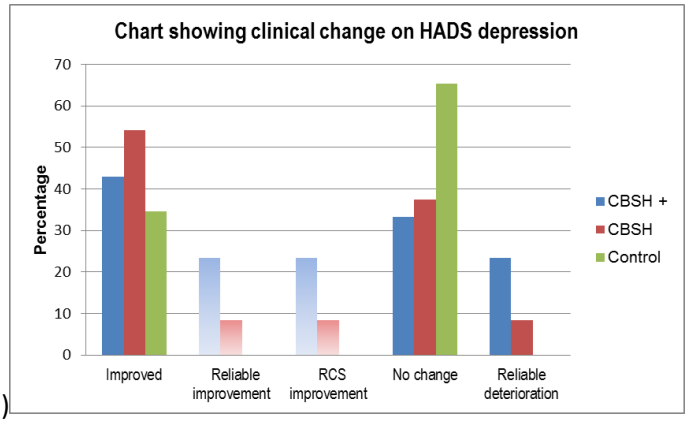
(a)



(b)



(c)



(d)

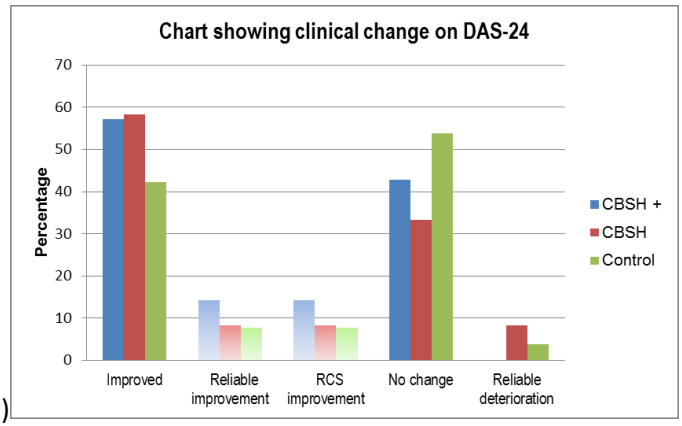


Chart showing clinical change on DAS-24
Percentage
70
60
50
40
30
20
10
0
Improved
Reliable improvement
RCS improvement
No change
Reliable deterioration
CBSH +
CBSH
Control

(e)

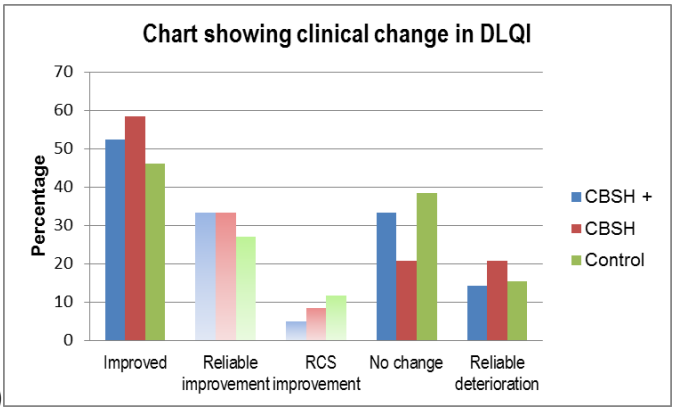


Chart showing clinical change in DLQI
Percentage
70
60
50
40
30
20
10
0
Improved
Reliable improvement
RCS improvement
No change
Reliable deterioration
CBSH +
CBSH
Control