Can a pre-therapeutic intervention improve recovery rates? An RCT

Chris Worfolk, Chris Osborne

Correspondence to: Chris Worfolk, Leeds Beckett University, Leeds, LS1 3HE, United Kingdom, chris.worfolk@anxietyleeds.org.uk

Abstract

Objective: we compared a peer-led in-person pre-therapeutic intervention to the home study intervention currently offered by Leeds IAPT to see if it improved engagement with therapy.

Design: unblinded parallel RCT using matched pairs.

Methods: participants with self-reported anxiety were recruited and randomly allocated to either an in-person intervention or home study control group. Participants completed a attitudes towards seeking professional help inventory pre and post-intervention.

Results: 23 participants were allocated to each group. Eight participants were included in the analysis. Primary outcome.

Conclusions: Peer-lead pre-therapeutic interventions may be efficacious, but high dropout rates exist across both interventions. Larger trials are required to establish a broader evidence base.

Background

Over the five years that Anxiety Leeds has been running, many of our service users have disclosed that they have had bad experiences with cognitive behavioural therapy (CBT), or that they have had to go through it several times.

This flies in the face of evidence and practice as many studies have supported the effectiveness of CBT for treating generalised anxiety disorder (GAD, Otte, 2011, Hofmann et al., 2012) and it is the primary intervention recommended by the National Institute of Health and Care Excellence (Kendrick & Pilling, 2012).

The current state of affairs is best summed up by Springer, Levy, & Tolin (2018) in their meta-analysis of remission rates following CBT for anxiety disorders. They put the figure at 48-56%, concluding that CBT is effective, but there is significant room for improvement.

One possibility for this gap is that patients are not sufficiently prepared for CBT when they begin their treatment. They don't understand what CBT is, they're not prepared to do the homework, and they are not emotionally prepared to

put themselves through the discomfort required to complete the exposure components.

In response to this, Leeds IAPT (Improving Access to Psychology Therapies, an NHS initiative to provide more psychological services) developed a set of online videos and workbooks to help prepare people for therapy (Groom, 2013).

While these resources may be helpful, we believe that an in-person peer-led approach could help bridge the divide between patients and medical professionals and thus provide a more effective introduction to CBT.

To test this, we developed an intervention we call "pre-counselling" based on the techniques used in our existing support group model. We hypothesise that participants who engage in the new intervention will be more likely to engage positively with therapy than participants who are sent the existing home-study resources.

Method

Design: An unblinded parallel RCT using a matched-pairs design based on participants ATSPH-SF scores (see *materials* for full details). Parallel groups were used with equal allocation to both groups.

The study methodology was reviewed in accordance with the Consolidated Standards of Reporting Trials (CONSORT) and is being reported in accordance with the 2010 checklist (Schulz, Altman, & Moher, 2010).

Sample: Participants were recruited using volunteer sampling. To be eligible, participants were required to have a self-reported anxiety disorder (including OCD), with or without a formal diagnosis.

We used social media, predominantly Facebook advertising, our website and flyers to direct people to a web page where they could register. To avoid any systematic bias from attendees of our support group, the research was not advertised directly to them, although they were free to participate if they saw an advert independently.

Sample size was based on the maximum number of participants we could include in a single workshop, based on our existing group framework.

46 participants were recruited (38 female, 8 male). When registering, each completed an ATSPH-SF inventory (M = 22.44, range = 12-30) and this was used to create a matched-pair design with participants allocated to either the pre-counselling intervention group or the home study control group.

Participants were randomly allocated using Excel's random number function.

Materials: The following self-report inventories were used:

Attitudes Toward Seeking Professional Help - Short Form (ATSPH-SF, Fischer and Farina, 1995). A ten-item inventory with responses rated on a Likert scale of 0 (disagree) to 3 (agree). It has good internal consistency (α = .86) and its test-retest reliability is also acceptable (r = .73–.89).

Generalized Anxiety Disorder Scale (GAD-7, Spitzer, Kroenke, Williams & Löwe, 2006). A seven-item inventory with responses rated on a scale of 0 (not at all) to 3 (nearly every day) with a score of >= 5 representing mild anxiety, >= 10 representing moderate anxiety and >= 15 representing severe anxiety. The GAD-7 has a Cronbach's α = 0.92 (Seo & Park, 2015).

Initially, we considered running the intervention and then tracking participants progress through a course of IAPT-provided CBT to see how the outcomes on the GAD-7 and PHQ-9 (Patient Health Questionnaire, Kroenke, Spitzer & Williams, 2001) differed. However, this approach was deemed unfeasible due to the potential lack of privacy for participants and complexity of using NHS population data. Therefore, the ATSPH-SH was selected as a construct for how likely participants were to engage in therapy.

Additionally, we recorded GAD-7 scores so that we could measure whether there was a systematic difference between effectiveness based on different levels of anxiety.

Procedure: Participants in the experimental group were invited to take part in an in-person event that took place over 3 hours on a Friday morning at a conference venue. The content of the workshop was based on the existing resources for preparing for CBT but delivered using peer facilitators and including time for group discussions and peer support.

At the end of the event, participants were asked to complete an ATSPH-SH inventory and a GAD-7 inventory.

The control group were sent a printed version of the "Managing Your Mind" workbook published by Leeds IAPT. They were instructed to study the workbook for one week, before completing included paper versions of the ATSPH-SH and GAD-7 inventories and posting the forms back to us in a pre-paid envelope.

Data analysis: Changes in the inventory scores will be analysed using a multi-factorial ANOVA. The primary measure will be an increase in ATSPH-SF scores.

Results

Participant dropout: The majority of participants did not complete the study. Only eight participants were included in the final analysis. Reasons for dropping out are detailed in Table 1. The study timeline is shown in Figure 1.

Status	Exp	Con
Withdrew after group allocation	4	1
Cancelled on the day of the in-person intervention	5	
Failed to turn up to the in-person intervention	10	
Failed to supply a postal address for the home-study materials		11
Failed to return the forms included in the home-study materials		6
Excluded due to not meeting the criteria for anxiety		1
Completed the study	4	4
Total participants	23	23

Drop-out percentage	82.6%	82.6%

Table 1: Drop out rates and reasons.

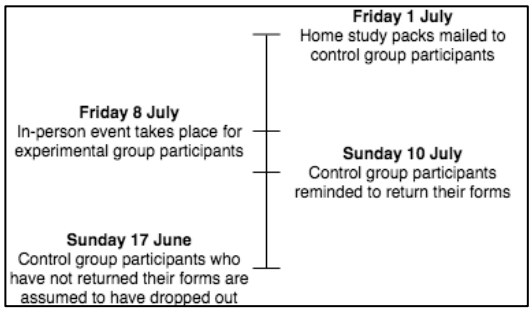

Figure 1: Timeline of study

Clinical outcome measures: A mixed ANOVA revealed a non-significant effect of time (Greenhouse-Geisser's F (1, 6) = 3.60, p = .107) and group (F (1, 6) = 1.84, p = .223). However, there was a significant interaction effect of group and time (F (1, 6) = 6.40, p = .045). Those who received the in-person intervention improved significantly compared to those in the control group. The effect size, n^2 = 0.56, represents a large effect (Cohen, 1988).

Descriptive statistics are shown in Table 2 and Figure 2.

Group	Experimental	Control
Pre-intervention		
Mean	25.25	21.74
SD	1.71	7.01
Post-intervention		
Mean	28.75	21.25
SD	.96	9.01

Table 2: Descriptive statistics

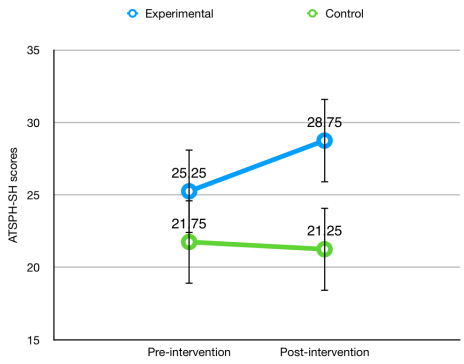

Figure 2: Change in ATSPH-SH scores pre and post-intervention, including Standard Error.

Discussion

The most striking result of the study is perhaps the 82.6% non-completion rate for participants. Although mental health trials often experience high dropout rates (Fernandez, Salem, Swift, & Ramtahal, 2015), we encountered more than double what a typical trial would experience.

This problem suggests that if you want to develop an intervention that gets people engaging with therapy, you first have to find a way to engage them in your intervention.

Dropout rates being consistent across the experimental group and control group can be viewed in two ways. On the one hand, you could argue that you would expect to see higher compliance in the experimental group because the intervention was designed to be engaging. On the other hand, you could say that dropout rates being no higher for the experimental group is a success, because it convinced an equal number of people to come to an in-person event which showed a significant benefit to their help-seeking attitude.

The evidence supports the latter view. In terms of efficacy vs effectiveness (Gartlehner et al., 2006), the home-study materials seem to be neither efficacious nor effective. The in-person intervention was at least efficacious in the case of participants engaging with the intervention.

In terms of clinical outcome measures, we can draw two conclusions. First, the current study does not support the use of the home study materials that Leeds IAPT currently provides for patients to use while they are on their waiting list. There was no significant difference between attitudes before and after the intervention.

Second, the results suggest that peer-led model could help improve patent's attitude towards therapy and thereby be more likely to deliver a clinically meaningful outcome to the treatment.

Limitations: The current study was severely limited by the low number of participants who were included in the final analysis. Although a significant result was found ($p = 0.45$), it was only just within the acceptable range. This limitation could be resolved by replicating the study with a larger sample.

Second, as previously discussed, ATSPH could be a poor construct for how people engage with therapy in the real world. Although it is a well-validated inventory, It would be preferable to track participants throughout a course of therapy after having received one of the interventions.

Third, there was no follow-up after the post-invention inventories were administered. The study could be improved by participants repeating the ATSPH-SH at a three or six-month interval to see if the improvement in scores is maintained.

Disclosure statement

Chris Worfolk and Chris Osborne are trustees of Anxiety Leeds. Funding was provided by Leeds SOUP.

References

Cohen, J. (1988). Statistical power analysis for the behavioral sciences 2nd edn.

Fernandez, E., Salem, D., Swift, J. K., & Ramtahal, N. (2015). Meta-analysis of dropout from cognitive behavioral therapy: Magnitude, timing, and moderators. *Journal of consulting and clinical psychology*, *83*(6), 1108.

Fischer, E. H., & Farina, A. (1995). Attitudes toward seeking professional psychologial help: A shortened form and considerations for research. *Journal of College Student Development*.

Gartlehner, G., Hansen, R. A., Nissman, D., Lohr, K. N., & Carey, T. S. Criteria for distinguishing effectiveness from efficacy trials in systematic reviews. 2006. *Rockville, MD: Agency for Healthcare Research and Quality Google Scholar*.

Groom, M., (2013). *Helping to prepare for Cognitive Behavioural Therapy (CBT)*. Retrieved from https://www.leedscommunityhealthcare.nhs.uk/iapt/resources/

Hofmann, S. G., Asnaani, A., Vonk, I. J., Sawyer, A. T., & Fang, A. (2012). The efficacy of cognitive behavioral therapy: A review of meta-analyses.

Cognitive therapy and research, *36*(5), 427-440.

Kendrick, T., & Pilling, S. (2012). Common mental health disorders—identification and pathways to care: NICE clinical guideline. *Br J Gen Pract*, *62*(594), 47-49.

Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The phq-9. *Journal of general internal medicine*, *16*(9), 606-613.

Otte, C. (2011). Cognitive behavioral therapy in anxiety disorders: current state of the evidence. *Dialogues in clinical neuroscience*, *13*(4), 413.

Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC medicine*, *8*(1), 18.

Seo, J. G., & Park, S. P. (2015). Validation of the Generalized Anxiety Disorder-7 (GAD-7) and GAD-2 in patients with migraine. *The journal of headache and pain*, *16*(1), 97.

Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of internal medicine*, *166*(10), 1092-1097.

Springer, K. S., Levy, H. C., & Tolin, D. F. (2018). Remission in CBT for adult anxiety disorders: A meta-analysis. *Clinical psychology review*.