Cognitive behavioural therapy for older adults with generalised anxiety disorder

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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.

Word Count

Literature Review

Excluding references	7948
Including references	10936
Including references and appendices	12186

Research Report

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Total

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Abstract

Cognitive behavioural therapy (CBT) and applied relaxation are the recommended talking treatments for generalised anxiety disorder (GAD) in adults. No specific recommendations are currently available for older adults with GAD due to paucity of evidence. In order to contribute to the GAD older adult evidence base (1) a meta-analysis of clinical trials has been performed and (2) a case series of providing group CBT has been conducted.

The first part of the thesis reports a meta-analytic review of 14 randomized controlled trials of CBT for GAD in older adults. Results showed CBT to be an effective treatment, but did not provide conclusive evidence of superiority of CBT against other evidenced-based psychotherapies. Avenues for the continued methodological development of field are discussed.

The second part of the thesis presents a case series study evaluating group delivery of an existing GAD treatment protocol with older adults. The focus of the study was on feasibility, acceptability and effectiveness. Mixed methods were used across the three main study phases (baseline, intervention and follow-up) with N=23 eligible participants. Participant dropout was low, homework compliance high, and large treatment effects on the primary outcome measure of worry were found. Merged findings suggested the group intervention was an acceptable, feasible, effective, and durable treatment option. The potential of group interventions for late life GAD are discussed. Taken together, the two studies suggest that group format does not reduce the acceptability and effectiveness of treatment, and provide an opportunity for delivery of cost-effective treatment for older adults with GAD.

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Part One: Literature Review

Efficacy of cognitive behavioural therapy for generalised anxiety disorder in older adults: Systematic review, meta-analysis, and meta-regression

Abstract

Objective: To review the gold standard evidence for cognitive behavioural therapy (CBT) for generalised anxiety disorder (GAD) in older adults, for the hallmark symptom of GAD, uncontrolled and excessive worry.

Method: Systematic searches of relevant databases (PsychInfo, Web of Science, and ProQuest Dissertation and Theses) and iterative searches of references from retrieved articles. Studies were required to be a randomised control trial (RCT), to have used the Penn State Worry Questionnaire (PPSWQ/PSWQ-A) as the primary outcome measure, and to have conducted CBT with outpatient older adults. Random-effects meta-analyses and moderator analyses were conducted.

Results: Fourteen RCTs met inclusion criteria (N = 985). At the end of treatment, and 6-month follow-up, significant treatment effects favouring CBT were found when CBT was compared with waitlist or treatment-as-usual (TAU). One in every three older adult patients would be expected to find additional benefit from CBT for their GAD compared to TAU. When CBT was compared with active controls, however, a small overall treatment advantage was found. Treatment effect size was moderated by attrition rates and end of treatment depression effect size.

Conclusions: Findings suggest that CBT is an effective treatment for uncontrolled and excessive worry in older adults with GAD. Whilst comparable level of evidence is not available for other psychotherapeutic approaches, CBT should be routinely offered to older adults presenting to services with GAD. Future trials need to compare the relative efficacy of CBT against other active psychotherapies, using long-term follow-up.

Practitioner Points

- CBT is an effective treatment and should be routinely offered to older adults presenting with GAD.
- Services should explore group CBT as a front line treatment option for older adults with GAD.
- Practitioners should use strategies to reduce attrition from treatment via addressing assumptions around psychotherapy for older people.

Treatment of Generalised Anxiety Disorder (GAD)

Generalised anxiety disorder (GAD) is a chronic and disabling condition (Revicki et al., 2012). It is the most common anxiety condition in older adults (aged 65 and over), with reported prevalence rates ranging from 3.4% to 6.3% (Golden et al., 2011; Wittchen et al., 2011). In older adults, GAD is associated with increased functional impairment (Brenes et al., 2005; Nabi et al., 2010; Porensky et al., 2009), cognitive impairment (Beaudreau & O'Hara, 2008, Mantella et al., 2007), reduced quality of life (Porensky et al., 2009; Wetherell et al., 2004), and increased service use (Porensky et al., 2009; Stanley et al., 2003a). High rates of comorbidity occur, particularly with depression – for which comorbidity rates as high as 60% have been reported (Wolitzky-Taylor, Castriotta, Lenze, Stanley, & Craske, 2010). The National Institute of Clinical Excellence (NICE) currently recommends pharmacotherapy, Cognitive Behavioural Therapy (CBT) or Applied Relaxation to treat GAD in adults (NICE, 2011). No specific recommendations have been made for older adult patients, due to lack of credible evidence. Given that services are frequently presented with older adults with GAD, review and synthesis of the evidence base is indicated (Gum, King-Kallimanis, & Kohn, 2009). This review also provides contemporary guidance to clinicians concerning patient allocation and signposting.

Older adults are found to prefer psychological therapy over medication for the treatment of anxiety conditions (Lenze et al., 2009; Mohlman, 2012). CBT is the most commonly researched psychotherapeutic treatment approach for GAD in older adults (Cuijpers et al., 2014). CBT for GAD contains aspects of cognitive structuring, exposure, and relaxation training (Barrowclough et al., 2001; Hofman, Asnaani, Vonk, Sawyer, & Fang, 2012). This treatment approach has gained popularity as more recent understanding of GAD has recognised uncontrolled and excessive worry as the key feature (American Psychiatric Association [APA], 2013). A number of reviews of

treatments for GAD in older adults have reported large treatment effects favouring psychotherapy (mainly CBT) in comparison to a passive control (Gonçalves & Byrne, 2012; Gould, Coulson, & Howard, 2012). One review found a significant treatment effect in favour of CBT, when CBT was compared to active comparison groups for the treatment of a range of late-life anxiety disorders (Hendriks, Oude Voshaar, Keijsers, Hoogduin, & Balkom, 2008). However, this finding has not been replicated, and a number of subsequent reviews found no advantage for psychotherapies (mainly CBT) when compared to active comparison groups for the treatment of GAD (Gonçalves & Byrne, 2012; Gould et al., 2012). Studies also suggest that CBT for GAD may be less effective for older adults than it is for younger adults (Ayers, Sorrell, Thorp, & Wetherell, 2007; Covin, Ouimet, Seeds, & Dozois, 2008). Reasons posited include potential cognitive decline due to ageing and higher rates of psychiatric comorbidity (Mohlman, 2008; Wolitzsky-Taylor et al., 2010). There are a number of key weaknesses of this evidence base that warrant attention.

First, existing reviews of CBT for GAD in older adults have tended to cover the range of psychotherapeutic treatment options (Gonçalves & Byrne, 2012), or CBT for the range of late-life anxiety disorders (Gould et al., 2012; Hendriks et al., 2008). The breadth of approaches included in previous reviews may have unwittingly masked apparent differences between specific psychotherapies and late-life anxiety conditions (Mohlman et al., 2004; Siev & Chambless, 2007). Second, previous reviews have predominantly measured effect sizes with respect to the treatment of GAD using a pooled anxiety composite. Unfortunately, this practice may have diluted treatment effects with respect to the hallmark feature of the condition, uncontrolled and excessive worry (APA, 2013). For this reason, in the measurement of GAD treatment effects, researchers are encouraged to use the Penn State Worry Questionnaire (PSWQ; Meyer, Miller, Metzger, & Borkovec, 1990) or its abbreviated version the PSWQ-A (Hopko et

al., 2003). The PSWQ is a 16-item standardised measure of uncontrolled and excessive worry, validated for use in adults of all ages (Brown, Antony, & Barlow, 1992; Brown, Moras, Zinbarg, & Barlow, 1993; Crittendon & Hopko, 2006; Stanley, Novy, Bourland, Beck, & Averill, 2001; Wuthrich, Johnco, & Knight, 2014), as is it's abbreviated version, the 8-item PSWQ-A (Hopko et al., 2003; Wuthrich et al., 2014).

Two published meta-analyses have focused on PSWQ effect sizes in evaluations of the effectiveness of psychological treatments for GAD (Covin et al., 2008; Hanrahan, Field, Jones, & Davey, 2013). Hanrahan et al. (2013) focussed on cognitive therapy (CT) for GAD and excluded all older adult trials. Covin et al. (2008) included any adult, and older adult, trials in a review of CBT for pathological worry in GAD, the effect size for symptoms of pathological worry (as measured by the PSWQ) in the older adult trials was reported to be large (g = 0.82). However, the small number of trials (k = 4) included in the older adult subgroup analysis inflated the risk of positive selection bias. Furthermore, Covin et al. compared treatment effects across studies using a range of controls (i.e. both active and passive); mixing inappropriate groups in meta-analytic comparisons in this way can reduce the generalisability of findings (Wilson & Lipsey, 2001). Thus, there is a need to extend and expand the work of Covin et al. by including a greater number of older adult trials, alongside a number of pre-planned subgroup meta-analyses on the basis of control group subtype.

The present study has therefore been prompted by identified methodological weaknesses of the existing evidence base for psychotherapeutic treatments for GAD in older adults. To enhance the quality of the evidence base, the present review included a greater number of older adult trials, did not report anxiety composite outcomes, performed pre-planned subgroup meta-analyses on the basis of control group subtype, and included a numbers-needed-to-treat (for one patient to expect additional benefit) analysis (NNTB). In order to assess treatment effects with respect to the hallmark

symptom of GAD, uncontrolled and excessive worry, PSWQ/PSWQ-A outcomes were the focus of the meta-analysis. The main aim of the current meta-analysis was therefore to provide a robust examination of the efficacy of CBT for uncontrolled and excessive worry in older adults with GAD.

Method

Preferred reporting items for meta-analyses systematic reviews and meta-analyses (PRISMA) have been included as advised (Moher, Liberati, Tetzlaff, & Altman, 2009).

Search Strategy

Three electronic databases (PsychInfo, Web of Science, and ProQuest Dissertation and Theses) were searched from 01 Jan 1987 to 01 Nov 2015. The date that the DSM-III-R was published (1987) was the start date, as this was the first diagnostic manual to recognise GAD as a distinct disorder, characterised by excessive worrying (APA, 1987). The following title search string was used based on search terms used in related reviews (Gould et al., 2012; Gonçalves & Byrne, 2012): (GAD OR generalized anxiety disorder OR generalised anxiety disorder OR generalized anxiety disorder OR anxious OR anxiety OR worry) AND (older OR elder* OR geriat* OR late life OR late-life) AND (CBT OR cognitive behavioural therapy OR cognitive behavioral therapy OR treatment OR therapy). Reference lists of retrieved articles and prior reviews on the psychological treatment of late-life anxiety published in the last 10 years were also searched manually to identify potentially eligible studies.

Eligibility Criteria

Studies included were required to meet the following criteria. First, participants were required to have been at least 55 years, with a mean age of $\geq$65 years, and a principal or co-principal diagnosis of GAD. In mixed anxiety studies, 75% of

participants were required to have a principal or co-principal diagnosis of GAD, as per the Gonçalves and Byrne (2012) review of interventions for GAD in older adults.

Next, studies were required to have used a randomised controlled trial (RCT) design. One study arm was required to have included a psychological intervention that involved all three core components of CBT for GAD: psycho-education, cognitive restructuring, and exposure to anxiety-provoking situations (Borkovec, Newman, Pincus, & Lytle, 2002). Studies were required to have included comparison group data for participants that did not immediately receive CBT for GAD.

Studies were also required to have used the PSWQ or the PSWQ-A as an outcome measure. In studies in which a composite anxiety score was reported, PSWQ/PSWQ-A outcome data needed to be available from the authors on request. In the case of multiple articles reporting on the same data set, the study with the largest sample size, or that was most relevant to the aims of this review, was selected.

All studies were also required to have been published in English.

Data Extraction

An a priori data extraction coding frame was developed. Studies were coded for a number of trial and practice factors including control group subtype (waitlist control group [WCG], treatment-as-usual [TAU], or active treatment [AT]) and treatment mode (individual or group). Clinical variables extracted included mean baseline PSWQ/PSWQ-A and depressive symptomology scores. These were converted to standardised z-scores, due to the different measures used for each variable across studies (Gallagher, Nies, & Thompson, 1982; Segal, Coolidge, Cahill & Riley, 2008; Wuthrich et al., 2014). Dropout rate was calculated for CBT as: (CBT dropouts from point of randomisation to the end treatment/total number of participants randomised to CBT) x 100. This was repeated for control conditions. Overall attrition rate for each trial was calculated: [(dropouts prior to randomisation + CBT dropouts at the end of

treatment + control dropouts at the end of treatment)/total number of eligible participants prior to randomisation] x 100. Treatment response data was extracted from articles in which it was provided. The percentage of treatment responders was calculated using an intention-to-treat analysis (ITT), and those that dropped out were classified as non-responders (Hollis & Campbell, 1999). Percentage of treatment responders was therefore calculated as follows: (number of treatment responders reported/total number of participants randomised to each study arm) x 100.

Within-Study Quality and Risk of Bias

The methodological quality assessment tool used (Appendix A) was designed by the Cochrane Common Mental Disorders Anxiety and Neurosis Group (CCDAN; Moncrieff, Churchill, Drummond, & McGuire, 2001). The CCDAN was selected as it has been used in the extant literature, enabling comparison with results obtained herein (Gonçalves & Byrne, 2012). Higher scores on this 23-item measure indicate studies of greater methodological quality (scores range from 0 to 46). The quality of each study was rated independently by three raters (two qualified clinical psychologists, and one trainee clinical psychologist). Two of the three raters were blind to study author(s), year of publication, and journal. Fleiss' kappa was used to assess interrater reliability, as there were more than two raters and ratings were categorical (Fleiss, 1971).

The sole use of quality rating scales has been criticised by the Cochrane group because summary scores necessarily involve arbitrarily weighting items (Higgins & Green, 2011a). For this reason, the Cochrane Risk of Bias Tool was also used in the present review to facilitate the assessment of within-study bias (see Appendix B; Higgins et al., 2011b). For each area of the seven areas of potential bias, studies were assessed as being at high, low, or inconclusive risk (Higgins et al., 2011b).

Between-Group Effect Sizes

Effect sizes corresponded to the standardised difference between the CBT treatment group and control group (Dobson, 1989). Between-group treatment effect sizes at end of treatment were calculated as follows: (CBT group end of treatment score – control group end of treatment score)/pooled SD (Borenstein, Hedges, Higgins, & Rothstein, 2009). Effect sizes were based on completers-only data, as this was the data that was available in 8/14 of the studies included. As a number of trials had small samples, effect sizes were corrected using an adjustment, J , to convert effect sizes to Hedges' g (Hedges, 1981). A formula for calculating an approximation of J described by Borenstein et al. (2009) was applied, $J = 1 - (3/4df - 1)$.

Meta-analyses assume each study is independent, so it was important that each study contributed no more than one between-groups effect size to each analysis (Brewin, Kleiner, Vasterling, & Field, 2007). Thus, in studies in which multiple treatment arms received CBT, where treatment was comparable, data was collapsed to form a combined CBT group (Mohlman & Gorman, 2005; Stanley et al., 2014). In the Wetherell et al. (2013) trial treatments received by the two CBT groups were not considered comparable, therefore data from the CBT group most relevant to this review was extracted (CBT plus escitalopram). In the Mohlman (2008) study, the waitlist data (8-week) from the group that received augmented CBT was used as the control, and compared against the 8-week CBT data from the other treatment arm. For studies in which there were multiple comparison groups that did not receive CBT, data from the control group that had received the most active comparison condition was extracted (Wetherell, Craske, & Gatz, 2003; Wetherell et al., 2013). This enabled a more conservative estimate of population effect size, given that passive controls often result in larger effect sizes than active controls (Gonçalves & Byrne, 2012; Hanrahan et al., 2013).

Meta-Analysis

SPSS macros developed by Wilson (2005) were used to compute random-effects meta-analyses; there were a number of advantages to this. First, random-effects models prevent strong assumptions about the population thus providing a more realistic estimate of the pooled mean effect size (Borenstein et al., 2009). Second, between-study heterogeneity was anticipated (Gonçalves & Bryne, 2012), and random-effects models increase the generalisability of findings in which a degree of between-study heterogeneity is observed (Borenstein et al., 2009).

In the random-effects meta-analysis model used, weighted average effect sizes (*g*) were calculated from the sum of the inverse within-study variance ($W= 1/V_g$) and the between-study variance (Jackson, Bowden, & Baker, 2010). First, the within-study variance of *g* was computed for each study in turn (V_g), using the formula described by Borenstein et al. (2009). Inverse within-study variance was used in order that studies with increased levels of variability (and thus lower precision) were given less weighting in the overall effect size estimate computed. Second, between-study variance was calculated using the restricted maximum likelihood (REML) method (Raudenbush, 2009). REML is more sensitive in meta-analyses using small sample sizes (Jackson et al., 2010), an anticipated feature of this review given the extant literature (Gonçalves & Byrne, 2012). Lastly, the sum of the product of all effect sizes and weights was divided by the sum of all weights in order to derive an overall sample-weighted population effect size estimate (Borenstein et al., 2009).

Mean effect sizes obtained were reversed. Thus a positive effect of CBT was represented by a positive effect size, and vice-versa (Borenstein et al., 2009). The threshold for statistical significance was an alpha value of 0.05, based on statistical norms found in the majority of research published (Borenstein et al., 2009). The magnitude of effect sizes obtained was considered using Cohen's (1992) guidelines:

0.20–0.49 = small, 0.50–0.79 = medium, and ≥0.80 = large. Effect sizes obtained were also interpreted on the basis of findings from meta-analyses that had assessed the effects of CBT on pathological worry in GAD for younger adults (Covin et al., 2008; Hanrahan et al., 2013). Meta-analyses assessed pooled mean effects sizes for end of treatment and 6-month follow-up data. Subgroup meta-analyses were pre-planned on the basis of anticipated heterogeneity between control subgroups (i.e. WCG, TAU, and AT; Gonçalves & Byrne, 2012; Hanrahan et al., 2013).

Effect sizes were also translated into NNTB (Altman & Andersen, 1999; Higgins & Green, 2011a; Cook & Sackett, 1995). This procedure is recommended in order to provide a clinically relevant interpretation of standardised treatment effect sizes (Kraemer & Kupfer, 2006). The method described by Kraemer and Kupfer (2006) for calculating NNTB was used. Accordingly, unadjusted effect sizes (Cohen's *d*) were converted to the corresponding area under the curve statistic (AUC) (Ruscio, 2008), and then NNTB was calculated using the following formula: 1/(2xAUC – 1) (Kraemer & Kupfer, 2006).

Moderator Analyses

Moderator analyses were pre-planned based on the extant literature (Gonçalves & Byrne, 2012; Hanrahan et al., 2013; Hendriks et al., 2008). Two categorical variables (control type and treatment mode) were assessed in turn using the using the METAF macro for SPSS (Wilson, 2005). This macro computes the analog to a one-way analysis of variance. The presence of a moderator was indicated by a statistically significant homogeneity Q statistic. Nine continuous variables were assessed through a series of random-effects univariate meta- regressions using the METAREG macro for SPSS (Wilson, 2005): age (mean), females (%), attrition rate (%), number of CBT sessions, baseline co-morbid psychiatric diagnoses (%), baseline depression diagnoses (%), mean baseline pathological worry score (standardised z-score due as trials either used PSWQ

or PSWQ-A), baseline depression symptoms (standardised z-scores due to range of measures), and pre- to post-treatment depression effect size (Hedges' g). For each meta-regression, significant moderators of PSWQ/PSWQ-A effect size were indicated by a statistically significant beta value of p <.006 (.05/9), based on a Bonferroni Adjustment to the significance level due to multiple univariate testing (Higgins & Thompson, 2002). Depression effect sizes at end of treatment were also calculated in order to test their potential as moderators of PSWQ effect size. As guidance suggests meta-regression should not be used where there are <10 studies, moderator analyses were not conducted for each control subgroup, or 6-month follow-up data (Higgins & Green, 2011a).

Analysis of Statistical Heterogeneity

The Q-statistic (Higgins & Thompson, 2002; Higgins, Thompson, Deeks, & Altman, 2003) enabled unexplained statistical heterogeneity between studies to be detected. A significant Q-value resulted in the rejection of the null hypothesis of homogeneity. Due to the small number of studies (k <10) included in sub-group and 6-month follow-up analyses, a *p*-value of .10 was used (Higgins & Green, 2011a). The I^2 statistic was computed as an indicator of the ratio of true statistical heterogeneity to the total variation in observed effects (Higgins et al., 2003). A rough guide to the interpretation of I^2 values has been proposed: 0–40% might not be important, 30–60% may represent moderate heterogeneity, 50–90% may represent substantial heterogeneity and 75–100% considerable heterogeneity (Higgins et al., 2003). The interpretation of I^2 values should also be based on: a) the magnitude and direction of effect size, and b) the evidence for heterogeneity, such as the associated *p*-value (Higgins & Green, 2011a).

Reporting Bias

In order to assess for between-study reporting bias, a funnel plot provided a graphical representation of the relationship between the standard error of included studies and their effect sizes (Sterne, Egger, & Smith, 2001). In the absence of reporting bias, a symmetrical distribution of studies around the pooled mean effect size (resembling an inverted funnel) would be observed. Straight lines were drawn to indicate the area in which 95% of studies would be expected to be found in the absence of heterogeneity and reporting bias.

The assessment of bias solely on the basis of the visual inspection of a funnel plot has been criticised (Terrin, Schmid, & Lau, 2005). Thus, two additional statistical methods were used to detect publication bias. First, the funnel plot regression method was used which is a regression test based on sample size and for which a significant beta value would be considered indicative of publication bias (Macaskill, Walter, & Irwig, 2001). Second, Rosenberg's fail-safe N test was used to indicate the number of additional negative studies needed to increase the *p*-value of the meta-analyses to above .05 (Rosenberg & Goodnight, 2005). The findings from Rosenberg's test were considered cautiously, given the test's emphasis on the significance of an arbitrary *p*-value (Higgins & Green, 2011a).

Results

Study Selection

The initial search resulted in 428 potentially relevant titles (see Figure 1), of which 273 titles remained after duplicates had been removed. A further 132 papers were excluded on the basis of the study abstract for the following reasons: medication trial (*n* = 49), review (*n* = 28), child/working-aged adults (*n* = 17), or other e.g. editorial (*n* = 38). Of 141 papers retrieved for detailed consideration, a further 124 were

excluded on the following basis: 75% of participants did not have a principal or co-principal diagnosis of GAD (*n* = 50), no intervention (*n* = 35), uncontrolled design (*n* = 16), non-CBT intervention (*n* = 14), sample did not have a mean age of ≥65 years (*n* = 6), or the absence of the PSWQ/PSWQ-A as an outcome measure (*n* = 3). Two of the remaining 17 studies (Barrera et al., 2015; Wetherell, 2001) were excluded because they included duplicate data from more appropriate eligible articles (Stanley et al., 2014; Wetherell et al., 2003). Lastly, one study was excluded because raw end of treatment PSWQ data was not available from the author on request (Mohlman et al., 2003). Fourteen original RCTs met all the inclusion criteria and so were included in this review. The total *N* across the trials was 985 and the average age of older adults with GAD was 68.16 years (*SD* = 2.52).

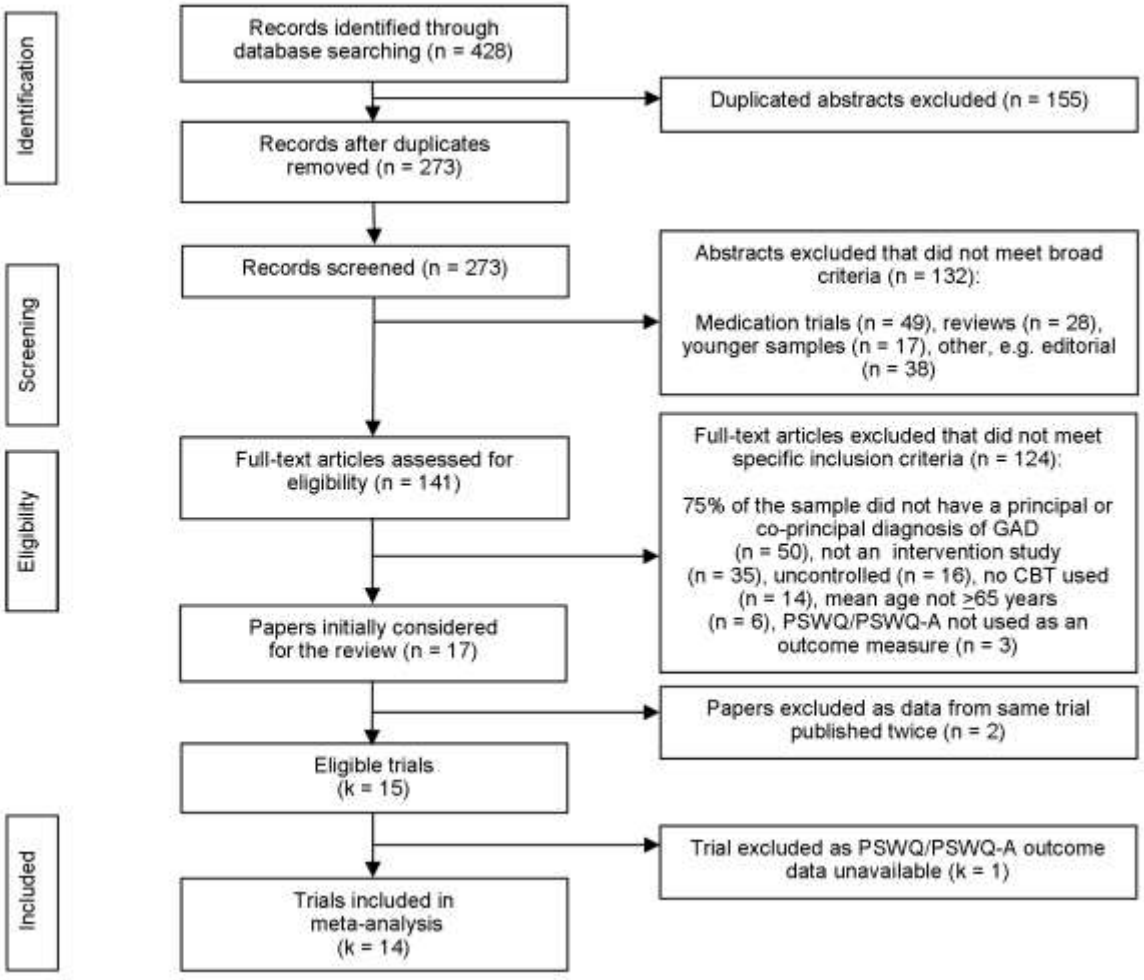

Figure 1. Flow diagram of study selection.

Study Characteristics

Table 1 summarises the 14 RCTs included in this meta-analysis. Studies are organised by control subgroups: waitlist control group [WCG], treatment-as-usual [TAU], and active treatment [AT]. Within each control subtype category trials have been ordered by quality ratings, highest rated studies first. All trials were community-based. However, there was heterogeneity between the studies with respect to trial factors. For example, sample sizes ranged from 8 to 223 (M = 70.36, SD = 59.99), and although on average 68% of participants were female this ranged between 48% and 84%. The majority of studies (9/14) compared CBT against a passive control condition. Participants in all three WCG trials were recruited via advertising and assumed not to be in contact with services during the wait period. TAU participants received treatments of varying intensity, and in 4/6 studies participants received enhanced care which included: weekly phone calls (Stanley et al., 2003b; Stanley et al., 2003c), biweekly phone calls (Stanley et al., 2009), and weekly 10–15 mins medication management sessions (Gorenstein et al., 2005). In the five AT studies, control group participants received the following interventions: non-directive psychotherapy (Stanley, Beck, & Glassco, 1996), a discussion group (Wetherell et al., 2003), acceptance and commitment therapy (Wetherell et al., 2011), telephone-delivered non-directive supportive therapy (Brenes, Danhauer, Lyles, Hogan, & Miller, 2015), and escitalopram (Wetherell et al., 2013).

On average, one-fifth of CBT participants (20%) dropped out of treatment before completion (range 0–44%). Follow-up data was sparse, with less than half of studies (5/14) presenting 6-month follow-up data (treatment-free) for both CBT and comparison group. Between-study heterogeneity was evident in terms of practice factors. For instance, although individual CBT was most commonly delivered (9/14 studies), a minority of the trials involved group CBT (3/14 studies). In addition, though

the average length of CBT delivered was 11.79 weeks (*SD* = 2.39), it ranged from 8 to 16 weeks. CBT was generally delivered face-to-face (11/14 studies), except for two trials which involved telephone delivery (Brenes, Ingram, & Danhauer, 2012; Brenes et al., 2015). In the Stanley et al. (2014) trial, for which the data from the CBT arm was collapsed, CBT was delivered to 51% of CBT participants by 'lay providers' (bachelor-level students).

Rates of comorbidity were high. On average, over half of participants (60%) met criteria for at least one other psychiatric diagnosis (range 39–80%) and a third of participants (32%) had a diagnosis of a depressive disorder (range 17–47%). Two studies (Mohlman & Gorman, 2005; Mohlman, 2008) excluded participants with major depressive disorder though included participants with dysthymia (25% of each sample).

Three trials provided no definition of treatment response (Brenes et al., 2012; Wetherell et al., 2009; Wetherell et al., 2011), with the remaining 11 studies providing inconsistent definitions. No study stipulated that a reliable and clinically significant change in symptoms of uncontrolled and excessive worry was required for participants to be considered a treatment responder.

Of studies reporting a definition of treatment response, based on ITT response rates, almost half of CBT participants (45%) were found to recover (range 19–83%). Average ITT response rates indicated few WCG participants recovered (2%), around a fifth recovered during TAU (23%), and two-fifths of participants recovered following AT (38%).

Study Quality and Bias

Overall quality ratings were out of 46 (higher scores represented papers rated as higher quality) and the average quality rating was 33.57 (*SD* = 5.68). The quality of the studies was varied (range 19-41). However, average scores were similar across the

three control subgroups, though more varied for TAU studies: WCG (*M* = 33.00, *SD* = 3.61), TAU (*M* = 33.67, *SD* = 7.69), and AT (*M* = 33.80, *SD* = 4.92).

Across many of the domains assessed, studies demonstrated high quality levels: clearly described outcome measures (14/14 studies), full description of participant demographics (12/14), assessment of treatment compliance (13/14), and adequate presentation of results for re-analysis (13/14). The quality domains rated lower in a number of studies included: full details of side effects of treatment profile by group (1/14 studies), power calculation (4/14), and adequate sample size (9/14). Excellent inter-rater reliability was observed ($\kappa = 0.99$; 95% CI_{95}: 0.94, 1.03) and the three raters disagreed on just four quality assessment items across the 14 papers (Appendix C).

Some risk of within-study bias was indicated for all papers (Appendix D). For example, although allocation to conditions was described as random in all studies, just 6/14 provided adequate details of the process of random sequence generation indicating potential risk of selection bias. Also, risk of performance bias was apparent in 7/14 studies in which assessor blinding and/or the testing of the integrity of assessor blinding was not reported. TAU studies were generally deemed at the lower risk of bias than WCG or AT studies, with the exception of the Stanley et al. (2003c) TAU paper which was at inconclusive/high risk of bias in all areas assessed.

Table 1

Characteristics of studies included in review and meta-analysis

CSG	Author (Year)	*N*	Age, years *M* (*SD*)	Female (%)	Baseline comorbid psychiatric diagnoses, % (Any depressive diagnosis, %)	CBT format (*N* sessions) (total length, min)[a]	Control condition	Overall attrition, %[b] (Dropout CBT, %) (Dropout control, %)	Follow-up period CBT, months (control, months)	Response definition	ITT response rate CBT, % (Control, %)	CCDAN score[c]
CBT vs. WLG	Brenes, Ingram, & Danhauer (2012)	60	69.2 (7.1)	83	80 (47)	Individual (12)	Info only	Not stated (13) (3)	6 (6)	Not defined	N/A	36
	Mohlman & Gorman (2005)	32	68.8 (5.6)	54	56 (25)[d]	Individual (13) (13x50min)	Waitlist	Not stated (9) (0)	12 (0)	No GAD and 20% reduction in 75% OMs	50 (0)	34
	Mohlman (2008)	8	66.4 (5.5)	63	75 (25)[d]	Individual (8) (8x90min)	Waitlist (CBT /APT group)	Not stated (0) (0)	6 (0)	No GAD and 20% reduction in 80% OMs	50 (0)	29
CBT vs. TAU	Stanley et al. (2014)	223	66.9 (6.6)	53	58 (39)	Individual (10 plus booster)	Usual care	25 (13) (22)	0 (0)	20% reduction in 75% OMs	29 (18)	41
	Stanley et al. (2009)	134	66.9 (5.8)	78	72 (45)	Individual (10)	Enhanced usual Care	22 (7) (22)	15 (15)	Meaningful change in 50% OMs	54 (48)	38

Table 1 (continued)

Characteristics of studies included in review and meta-analysis

CSG	Author (Year)	*N*	Age, years *M* (*SD*)	Female (%)	Baseline comorbid psychiatric diagnoses, % (Any depressive diagnosis, %)	CBT format (*N* sessions) (total length, min)[a]	Control condition	Overall attrition, %[b] (Dropout CBT, %) (Dropout control, %)	Follow-up period CBT, months (control, months)	Response definition	ITT response rate CBT, % (Control, %)	CCDAN score[c]
CBT vs. TAU	Wetherell et al. (2009)	31	72.2 (6.6)	84	39 (19)	Individual (12)	Enhanced community care	Not stated (20) (Not stated)	0 (0)	Not stated	N/A	36
	Stanley et al. (2003)b	85	66.2 (5.2)	75	65 (27)	Group (15)	Minimal contact (weekly)	22 (26) (10)	12 (0)	20% reduction in symptom severity	33 (7)	35
	Gorenstein et al. (2005)	42	68.2 (6.8)	50	- -	Individual 13 (13x50min)	Medication management	35 (39) (26)	6	Improved or much improved	39 (26)	33
	Stanley et al. (2003)c	12	70.6 (5.6)	83	58 (42)	Individual (8)	Usual care	Not stated (17) (33)	(0) (0)	20% reduction in 67% of OMs	83 (17)	19
CBT vs. AT	Brenes et al. (2015)	141	60–64 years	82	- (38)	Individual telephone (9–11) (50min each)	Telephone-directed, non-directive supportive therapy	13 (26) (18)	0 (0)	5.5 point decrease in PSWQ-A scores	72 (43)	41

Table 1 (continued)

Characteristics of studies included in review and meta-analysis

CSG	Author (Year)	*N*	Age, years *M* (*SD*)	Female (%)	Baseline comorbid psychiatric diagnoses, % (Any depressive diagnosis, %)	CBT format (*N* sessions) (total length, min)[a]	Control condition	Overall attrition, %[b] (Dropout CBT, %) (Dropout control, %)	Follow-up period CBT, months (control, months)	Response definition	ITT response rate CBT, % (Control, %)	CCDAN score[c]
CBT vs. AT	Wetherell Gatz, Craske (2003)	52 (36)[e]	67.1 (8.2)	80	52 (19)	Group (12) (12x90 min)	Discussion group	31 (31) (31)	6 (6)	20% reduction in 75% OMs	23 (23)	36
	Wetherell et al. (2013)	73 (34)[f]	69.5 (7.6)	71	Not stated (24)	Individual (16 plus escitalopram)	Escitalopram	18 (0) (0)	7[f] (7)	HAM-A score ≤10 and decrease ≥8.5 points on PSWQ	39 (16)	32
	Stanley, Beck, Glassco (1996)	48	68.3 (6.6)	71	48 (17)	Group (14) (14x90 min)	Supportive psycho-therapy	35 (31) (35)	6 (6)	20% reduction in 75% OMs	19 (35)	32
	Wetherell et al. (2011)	21	70.8 (6.5)	48	53 (38)	Individual (12) (12x60 min)	Acceptance and commitment therapy	42 (44) (0)	6 (6)	Not stated	N/A	28

Note. CSG = control subgroup; WCG = waitlist control group; TAU = treatment-as-usual; AT = active treatment; ITT = intention-to-treat; CCDAN = Cochrane Common Mental Disorders Anxiety and Neurosis Group quality assessment tool; PSWQ = Penn State Worry Questionnaire; PSWQ-A = Penn State Worry Questionnaire – Abbreviated; HAM-A = Hamilton Anxiety Rating Scale.

[a]CBT session duration (mins) is provided for those trials in which this was reported; [b]Attrition rate is based on total number of participants eligible for each trial pre-randomisation and is not reported for trials in which this was not explicitly stated; [c]Overall quality ratings from CCDAN tool out of 46 and higher scores represented papers rated as of higher quality; [d]Major depressive disorder excluded; [e]Trial contained two control groups therefore only data from the most active control (discussion group) was used; [f]Trial contained multiple treatment and control arms therefore data from the most relevant groups were extracted for analyses (CBT plus escitalopram vs. escitalopram only) and participants within these two study arms that had recovered after the open-label phase were also excluded (n = 3); [g]Follow-up period not treatment-free and therefore data was not included in six-month follow-up analyses.

Meta-Analyses

Between-group random effects meta-analyses were conducted for end of treatment and 6-month follow-up PSWQ/PSWQ-A data. Control subgroup meta-analyses were conducted at each time-point.

End of Treatment Analyses

CBT vs. any control. For all 14 primary studies (completer n = 772), the end of treatment population effect size estimate for CBT compared to any control was medium in favour of CBT, g = 0.66 (CI_{95}: 0.42, 0.90), and significant (z = 5.48, p <.001). Figure 2 (plot d) displays the corresponding forest plot. Significant statistical heterogeneity and substantial between-study inconsistency were found (Q(13) = 28.67, p = .001, I^2 = 55%, v = 0.10), which indicated significant variance in effect size distribution and further justified the use of a random-effects meta-analysis.

CBT vs. waitlist control group (WCG). The population effect size estimate for CBT compared to WCG (k = 3, n = 86) was a large effect size in favour of CBT, g =1.10 (CI_{95}: 0.38, 1.82), and significant (z = 3.01, p <.01). Figure 2 (plot a) displays the corresponding forest plot. The assumption of homogeneity was violated (based on the significance level of p < 0.1 adopted for subgroup analyses), and substantial inconsistency was found between studies (Q(2) = 5.38, p = .07, I^2 = 63%, v = 0.25).

CBT vs. treatment-as-usual (TAU). For CBT compared to TAU (k = 6, n = 444), the population effect size was medium and in favour of CBT, g = 0.67 (CI_{95}: 0.36, 0.98), and significant (z = 4.22, p <.001). Figure 2 (plot b) displays the corresponding forest plot. The assumption of statistical homogeneity was violated and moderate between-study inconsistency was indicated (Q(5) = 9.67, p = .09, I^2 = 48%, v = 0.07).

CBT vs. active treatment (AT). When CBT was compared to AT (k = 5, n =242) the population effect size was small, g = 0.42 (CI_{95}: -0.05, 0.89), and non-significant (z = 1.75, p = .08). Figure 2 (plot c) displays the corresponding forest plot.

AT studies violated the assumption of statistical homogeneity, and substantial inconsistency between studies was observed ($Q(4) = 11.53$, $p = .02$, $I^2 = 65\%$, $v = 0.18$).

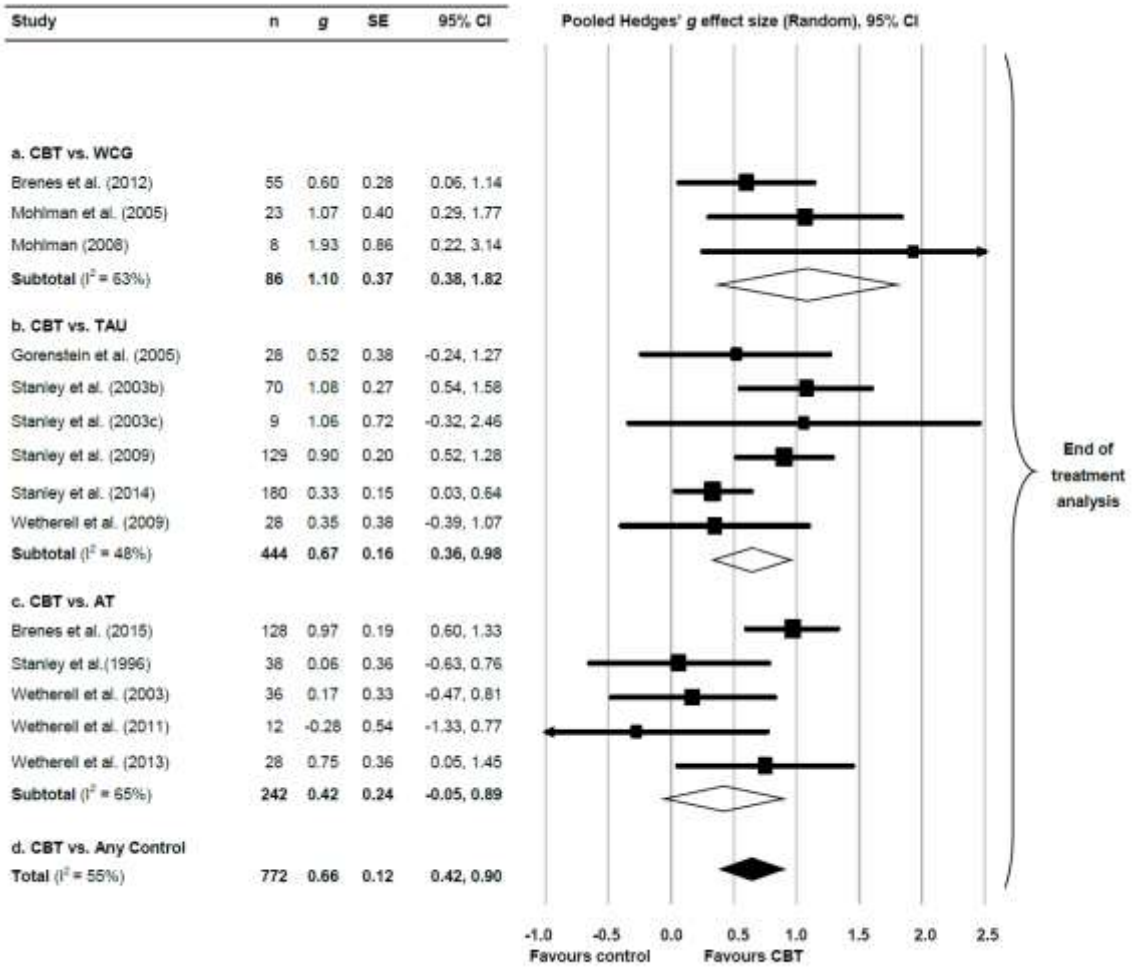

Figure 2. End of treatment and 6-month follow-up forest plots of PSWQ/PSWQ-A: Hedges' g. Forest plots show standard errors (SE), confidence intervals (95% CI), and inconsistency of study findings (I^2), for CBT vs. control conditions (a–g). *Note*. WCG = waitlist control group; TAU = treatment-as-usual; AT = active treatment; PC = passive control.

Follow-Up Analyses

CBT vs. any control. The population effect size for CBT compared to any control group (k = 5, *n* = 238) at 6-month follow-up, was in the small-to-medium range in favour of CBT, *g* = 0.46 (CI_{95}: 0.07, 0.85), and significant (z = 2.28, *p* =.02). See Figure 2 (plot g) for the corresponding forest plot. Studies violated the assumption of statistical homogeneity (given the significance level *p* <0.1 adopted for follow-up analyses), and between-study inconsistency was substantial (Q(4) = 8.24, *p* = .08, I^2 = 51%, *v* = 0.10).

CBT vs. passive controls. Due to the paucity of passive control studies that had 6-month control follow-up data, WCG and TAU studies were considered as a single subgroup. The 6-month follow-up population effect size estimate for CBT compared to passive controls (k = 2, *n* = 170) was large and in favour of CBT, *g* = 0.83 (CI_{95}: 0.52, 1.14), and significant (z = 5.21, *p* <.001). Figure 2 (plot e) displays the corresponding forest plot. Between-study statistical homogeneity was found (Q(1) = 0.03, *p* = .86, I^2 = 0%, *v* = 0.00).

CBT vs. active treatment (AT). The 6-month follow-up population effect size estimate for CBT compared to AT (k = 3, *n* = 68) was near zero, *g* = 0.06 (CI_{95}: -0.37, 0.49), and non-significant (z = 0.28, *p* = .78). Thus, at follow-up no advantage was found for either CBT or AT, with the corresponding forest plot displayed in Figure 2 (plot f). The assumption of statistical homogeneity was satisfied (Q(2) = 0.19, *p* = .91, I^2 = 0%, *v* = 0.00).

Numbers-Needed-To-Treat (NNTB)

Table 2 reports the NNTB illustrating a range from 2 to 30 patients. At post-treatment, 1 in 2 patients would be expected find additional benefit from CBT when compared to a WCG. However, when compared to AT, at the end of treatment, just 1 in 4 patients would be expected find additional beneficial from CBT.

Table 2.

Numbers-needed-to-be-treated for additional benefit to be expected (NNTB)

Time point	Comparison set	NNTB[a]
End of treatment	CBT vs any control	3
	CBT vs WCG	2
	CBT vs TAU	3
	CBT vs AT	4
6-month follow-up	CBT vs any control	4
	CBT vs PC	2
	CBT vs AT	30

Note. WCG = waitlist control; TAU = treatment-as-usual; AT = active treatment; PC = passive control.
[a]NNTB represents the number of participants that would needed to be treated for one participant to be expected to find additional benefit in favour of CBT with respect to PSWQ/PSWQ-A treatment effects.

Moderator Analyses

Control subtype (WCG vs. TAU vs. AT) did not significantly moderate PSWQ/PSWQ-A effect size ($Q(2) = 2.89$, $p = .24$), nor did treatment format (group vs. individual) ($Q(1) = 0.77$, $p = .38$). However, attrition rate was found to significantly moderate PSWQ/PSWQ-A effect size ($\beta = 0.62$, $z = -2.89$, $p = .0039$), and studies with lower attrition rates were found to report significantly greater PSWQ/PSWQ-A effect sizes in favour of CBT. Baseline to end of treatment depression treatment effect sizes also moderated PSWQ/PSWQ-A effect size ($\beta = 0.60$, $z = 2.76$, $p = .0057$). Thus, in studies in which CBT treatment gains for symptoms of depression were greater, associated PSWQ/PSWQ-A treatment gains were also significantly greater. None of the remaining variables assessed (including treatment length or format) were found to significantly moderate PSWQ/PSWQ-A effect size, given the significance value of $p < .006$ adopted.

Reporting Bias

The distribution of the 14 studies around the pooled mean effect size was slightly asymmetrical indicating some risk of systemic reporting bias (See Figure 3). The funnel plot regression method did not indicate the presence of significant reporting bias, $B = -0.001$, $t(13) = -0.63$, $p = .54$ (Macaskill et al., 2001). The fail-safe N suggested that the number of studies required with null results in order to overturn the

present findings would be 213 for a fixed-effects model and 12 for a random-effects model (Rosenberg & Goodnight, 2005). These findings generally indicated that the overall population effect size estimate was likely to be relatively robust. Funnel plots were not drawn out for control subgroup analyses or 6-month follow-up data, as it is difficult to detect bias with ≤10 studies (Higgins & Green, 2011a).

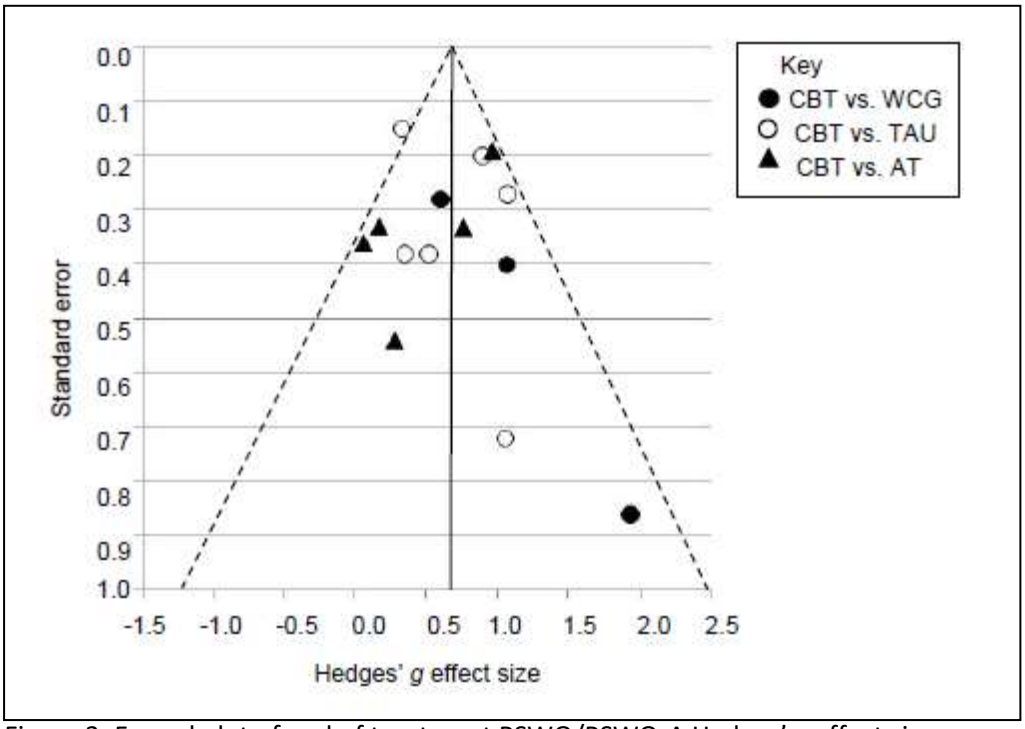

Figure 3. Funnel plot of end of treatment PSWQ/PSWQ-A Hedges' g effect sizes plotted for all 14 primary studies. Note. WCG = waitlist control group; TAU = treatment -as-usual; AT = active treatment.

Discussion

This review examined treatment effects of CBT for older adults with GAD in terms of uncontrolled and excessive worry and extends the preliminary analysis reported by Covin et al. (2008). The inclusion of more trials and greater analytic specificity has increased the generalisability of the results found. In comparison to allocation to a waiting list, CBT was found to produce a large effect with respect to uncontrolled and excessive worry symptoms immediately post-treatment. The NNTB value suggested that every other patient receiving CBT would be expected to find

additional benefit when compared to being on a waiting list. Results of CBT in comparison to TAU found there to be medium treatment effects in favour of CBT. At 6-month follow-up, large effects in favour of CBT were observed in comparison to passive controls. The associated NNTB obtained suggested that every other patient would be expected to benefit from CBT at 6-month follow-up. These findings combined would suggest that when compared to having no treatment at all (or TAU), CBT is an effective treatment for symptoms of uncontrolled and excessive worry in older adults with GAD.

Comparisons of CBT vs. AT for GAD were less encouraging. Results suggested small comparative post-treatment gains for CBT over AT, and no treatment advantage for CBT at 6-month follow-up. However, AT studies included in follow-up analyses included just 68 participants, which reduced the power of this subgroup analysis. Only one trial compared CBT to an extant treatment, the Wetherell et al. (2011) paper in which CBT was compared to acceptance and commitment therapy. For this reason, this review has not been able to comment on the relative efficacy of CBT for uncontrolled and excessive worry compared to other evidence-based psychotherapies. The generalisability of the Wetherell et al. (2011) trial was unfortunately limited by the small sample size (n = 21).

Moderators of Worry Treatment Effects

Moderator analyses showed that CBT treatment effects for worry were significantly moderated by treatment effects for depression symptoms, specifically that greater CBT treatment effects for depression were associated with greater CBT treatment effects for worry. These findings highlight a useful avenue for further research given current interest in transdiagnostic approaches for the treatment of comorbid anxiety and depression (Wilamowska et al., 2010; Wuthrich, Rapee, Kangas, & Perini, 2015).

Attrition rates also significantly moderated PSWQ/PSWQ-A effect sizes such that higher CBT attrition rates were associated with reduced CBT treatment effects for worry. Moreover, as completer-only analyses were conducted this finding has likely under-estimated the extent to which attrition moderated worry outcomes for all eligible trial participants (including dropouts before, or after, randomisation). This finding has highlighted the importance of acceptability and feasibility work in the early stages of the development of new therapies in order to reduce attrition (Salkovskis, 1995).

Comparisons with the Extant Literature

Findings from this review were broadly in line with the preliminary analyses presented by Covin et al. (2008). However, in the comparison of CBT and any control condition (passive or active), Covin et al. reported an effect size of greater magnitude (g = 0.82). There are a few possible reasons for this difference. First, the Covin et al. review included fewer studies, which increased the risk of positive selection bias. Second, Covin et al. used passive control data from the Wetherell et al. (2003) study in between-group analyses, whilst active control data from the trial was used in this review. As outlined previously, it has been suggested that passive controls can inflate population effect size estimates (Gallin & Ognibene, 2012).

The present study also adds weight to the suggestion by Covin et al. (2008) that CBT for symptoms of uncontrolled and excessive worry in GAD is less effective for older adults than for younger adults. In a subgroup meta-analysis of younger adult studies, Covin et al. found an overall mean of g = 1.69 in favour of CBT for pathological worry in a comparison between CBT and any control condition. Furthermore, in a meta-analysis of CT for worry (in which older adult studies were excluded), Hanrahan et al. (2013) reported an effect size of g = 0.93 in favour of CT, in a comparison of CT with any control condition.

Limitations and Further Research

The present review has a number of limitations. The selection criteria was stringent in order to ensure that studies included were of a sufficiently high quality to permit useful conclusions to be drawn. However, a number of the studies included were found to have significant risk of bias in a number of areas (e.g. random sequence generation was only described in 6/14 trials). There were also relatively few studies containing sufficient follow-up data and this increased the risk of positive selection bias and an inflated effect size estimate. Future studies with longer between-group follow-up periods (with larger samples) are required.

There was heterogeneity between primary studies with respect to trial and practice variables, such that percentage of women included in each trial ranged from 48% to 84%, and CBT duration ranged between 8 and 16 sessions. Heterogeneity was also present within control subgroups, for example, the intensity of TAU varied from scheduled weekly contact (Gorenstein et al., 2005; Stanley et al., 2003b; Stanley et al., 2003c) to primary healthcare provision as usual (Stanley et al., 2014; Wetherell et al., 2009). However, moderator analyses suggested trial and practice variables assessed did not significantly moderate PSWQ/PSWQ-A treatment effect sizes, with the exception of attrition rates, increasing the generalisability of findings. However, a number of the meta-analyses violated the assumption of statistical homogeneity reducing the generalisability of findings. This may have reflected that a number of the trials available to analyse were small studies, which may have potentially introduced ‘small-study effects’; a trend for smaller studies to show larger treatment effects and so to positively bias results (Sterne, Gavaghan, & Egger, 2000). Incomplete outcome data also meant completers-only effect size estimates were computed, which may have led to systematic positive result bias. Future trials are encouraged to report ITT data in

order that a more conservative estimate of worry treatment effects can be considered (Hollis & Campbell, 1999).

Lastly, the present review has focussed solely on outcomes with respect to uncontrolled and excessive worry (as measured by self-report measures, the PSWQ or PSWQ-A). This reliance on self-report measures of worry may have weakened the review findings. For example, Steer, Beck, Clark, and Ranieri (1995) found that PSWQ scores did not significantly correlate with clinician ratings of GAD severity. However, this was not a consistent finding and a subsequent study by Hopko et al. (2000) found clinician-rated GAD severity correlated significantly with PSWQ scores. Nevertheless, future trials are encouraged to include clinician-rated GAD outcomes to strengthen the validity and reliability of outcomes analysed. The anxiety disorders interview schedule (ADIS-IV; Brown & Barlow, 2014) is a valid clinician rated GAD measure which does assess worry.

Clinical Implications

In an analysis of gold standard trials, CBT has been found to be an effective treatment for uncontrolled and excessive worry in older adults with GAD. This is a level of evidence that is not currently available for other psychotherapeutic approaches in the treatment of GAD, and indicates that CBT should be routinely offered to older adults presenting to services with GAD. Treatment outcomes were not moderated by delivery mode (group vs. individual) or treatment length. Given the cost savings offered by group delivery and briefer interventions, these findings represent an opportunity for services to consider group CBT as a front line treatment option (Department of Health, 2011).

That said, this study adds to evidence that suggests that CBT for symptoms of uncontrolled and excessive worry in GAD may be less effective for older adults than for younger adults. Clinicians are therefore encouraged to explore ways to increase the

efficacy of CBT provided to older adults with GAD through the consideration of novel approaches such as the age-appropriate augmentation of CBT (Laidlaw & Kishita, 2015). Clinicians should also consider the implementation of evidence-based strategies to reduce attrition such as pre-therapy work to address assumptions about psychotherapy or motivational interviewing (Barrett, Chua, Crits-Christoph, Gibbons, & Thompson, 2008).

Conclusion

The main objective of this review was to consider the efficacy of CBT for the treatment of older adults with GAD. Previous reviews of CBT for GAD in older adults have considered the effectiveness of CBT for GAD on the basis of an anxiety composite, obscuring treatment effects for uncontrollable and excessive worry which is the hallmark feature of GAD. In response to identified methodological weaknesses of the extant literature, the present review considered CBT outcomes for GAD using two validated measures of excessive and uncontrollable worry (PSWQ/PSWQ-A). In doing this, the present review has been able to demonstrate that CBT is an effective treatment for uncontrolled and excessive worry symptoms in older adults with GAD. This review therefore represents an important contribution to outcome research on CBT for older adults with GAD.

Findings provide support for the ongoing use of CBT for the treatment of uncontrolled and excessive worry in older adults with GAD. However, results do not provide evidence that CBT is more effective than other active psychological interventions. In order for the relative efficacy of CBT for GAD to be assessed, there is a need for further ‘head-to-head’ RCTs. Researchers need to use longer follow-up periods for both treatment and control arms in order that the durability of treatment effects can be understood. As studies with higher attrition rates resulted in significantly

lower worry treatment effects, findings also highlight the importance of treatment acceptability. In conclusion, older adults with GAD should not be discarded as ‘life-long worriers’, but offered CBT in order to help them manage their worry more effectively.

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*Studies included in the review

Appendix A. CCDAN Quality Assessment Tool (Moncrieff et al., 2001)

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Appendix A. CCDAN Quality Assessment Tool (continued; Moncrieff et al., 2001)

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Appendix B. Cochrane Risk of Bias Tool (Higgins & Green, 2011)

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Appendix C. Interrater Reliability Fleiss' kappa

Total scores for each paper from each rater (out of 46)

Rater no.	Brenes 2012	Mohl 2005	Mohl 2008	Gorenstein 2005	Stan 2003b	Stanley 2003c	Stan 2009	Stan 14	Weth 09	Brenes 15	Stan 96	Weth 03	Weth 11	Weth 13
1	36	34	29	33	35	20	38	41	36	40	30	36	28	32
2	36	35	29	33	35	19	38	41	36	40	32	36	30	32
3	36	34	29	33	35	19	38	41	36	40	34	36	26	32

Total number of rating items (k = 14 x 23) = 322 (scores 0-2)

N of items for which there was total agreements = 318 items

N of items at least two of the raters disagreed = 4 items

$\kappa = 0.99$; (95% CI: 0.94, 1.03)

Appendix D. Bias Summary Table

Bias rating summary table

		Area of bias						
Control Subgroup	Author, (year)	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other
CBT vs. WCG	Brenes et al. (2012)	?	O	-	O	O	-	O
	Mohlman & Gorman (2005)	?	O	-	?	O	O	-
	Mohlman (2008)	?	?	-	O	O	-	-
CBT vs. TAU	Gorenstein et al. (2005)	O	?	-	?	O	O	O
	Stanley et al. (2003)b	?	O	-	?	O	O	O
	Stanley et al. (2003)c	?	?	-	?	-	-	-
	Stanley et al. (2009)	O	?	-	O	O	O	O
	Stanley et al. (2014)	O	O	-	O	O	O	O
	Wetherell et al. (2009)	O	?	-	O	O	O	O
CBT vs. AT	Brenes et al. (2015)	O	?	-	O	O	O	O
	Stanley et al. (1996).	?	?	-	?	O	O	O
	Wetherell et al. (2003)	?	?	-	O	-	O	O
	Wetherell et al. (2011)	?	O	-	?	O	-	-
	Wetherell et al. (2013)	O	O	-	?	O	O	-

Note. O = low risk of bias; - = high risk of bias; ? = inconclusive risk of bias; WCG = waitlist control group; TAU = treatment as usual; AT = active treatment.

Part Two: Research Report

An evaluation of the acceptability, feasibility, and effectiveness of an existing GAD treatment protocol with older adults in a group delivery format

Abstract

Objective. To evaluate an existing generalised anxiety disorder (GAD) treatment protocol in a group delivery format with older adults.

Design. A case series with an A-B design with follow-up was used to assess feasibility, acceptability, effectiveness, and potential change mechanisms across three study phases: baseline, intervention, and follow-up. Mixed methods enabled the triangulation of findings for convergence and complementarity purposes.

Methods. Eligible participants (N = 23) were required to have a clinical diagnosis of GAD, and were recruited through primary care and community mental health services. The adapted GAD protocol was delivered over 12 weeks. Participant outcomes were measured using the PSWQ, GAD-7, PHQ-9, IUS, and a daily worry diary. At the end of treatment, completer change interviews and facilitator focus groups were conducted. Mixed outcomes were merged using a triangulation protocol.

Results. Opt-in and dropout rates, alongside feedback (participant and facilitator), indicated that group delivery of the worry protocol was acceptable and feasible. Large PSWQ treatment effect sizes were found at the end of treatment and follow-up. A medium treatment effect size for depression was found at follow-up. Change mechanism findings suggested that addressing intolerance of uncertainty may have contributed to treatment gains.

Conclusion. The adapted GAD treatment protocol was found to be a feasible, acceptable, and effective treatment option for older adults with GAD. The protocol

shows real promise as a treatment for GAD in older age and further controlled studies against other active treatments are warranted.

Practitioner Points

- Group CBT appears an acceptable and effective treatment option for older adults with GAD.
- Older adults with co-morbid depression can still benefit from CBT for their GAD.
- GAD treatment protocols should consider session pacing, inclusion of more recaps, and regular behavioural experiments as specific modifications with older adults.

Introduction

Prevalence rates of generalised anxiety disorder (GAD) in older adults are estimated to be between 3.4% and 6.3% (Allgulander, 2006; Golden et al., 2011; Wittchen et al., 2011). GAD is, however, 'frequently missed' as a disorder by services due to factors such as comorbidity, medication use, and functional status (Ayers, Sorrell, Thorp, & Wetherell, 2007). For those who do receive a diagnosis, chronicity is an issue as around 90% of older adult GAD sufferers are diagnosed before the age of 60 years (Grant et al., 2005).

In the treatment of GAD, older adults prefer psychological therapy to medication (Mohlman, 2012). The National Institute for Health and Care Excellence (NICE) recommends cognitive behavioural therapy (CBT) and applied relaxation for the non-pharmacological treatment of GAD in adults (NICE, 2011). No specific recommendations are made for older adults due to a lack of credible evidence, though reviews suggest that CBT for GAD may be less effective for older adults than it is for younger adults (Covin, Ouimet, Seeds, & Dozois, 2008; Wolitzy-Taylor, Castriotta, Lenze, Stanley, & Craske, 2010). Reasons suggested include age-related cognitive impairment, high rates of comorbidity with depression, and difficulties with attendance due to physical comorbidities (Brenes, Ingram, & Danhauer, 2012; Mohlman 2008; Wuthrich & Rapee, 2013). Moreover, CBT for GAD in older adults may be only marginally more effective than active treatment control conditions (Gonçalves & Byrne, 2012; Gould, Coulson, & Howard, 2012; Hall, 2016). There is clearly a need to develop the GAD older adult evidence base.

The rising costs of mental health provision for older adults, as a result of increased life expectancy, have led to increased focus on the provision of cost-effective psychological treatments for this cohort (McCrone, Dhanasiri, Patel, Knapp, & Lawton-Smith, 2008). Group CBT offers the potential to increase the cost and time

effectiveness of treatment (Kwon & Oei, 2003). Non-specific benefits of group CBT include peer support, reduced social isolation, and shared empathy (Krishna et al., 2011; Lewinsohn & Clarke, 1999; Morrison, 2001; Yalom & Leszcz, 2005). These factors may be particularly relevant for older adults, given an increased risk of loneliness in those aged over 75, which has been associated with significant reductions in mental wellbeing (Capezuti, Boltz, & Renz, 2004; Dykstra, 2009; Hawkley & Cacioppo, 2010).

To date, trials of group CBT for older adults with GAD have reported conservative findings. Stanley et al. (2003) reported significant treatment effects in favour of group CBT when compared to usual care. However, in trials using active control groups, CBT has been found to be only marginally more effective than non-specific group psychotherapies (Stanley, Beck, & Glassco, 1996; Wetherell, Gatz, & Craske, 2003). Furthermore, Schuurmans et al. (2009) found sertraline to have a more significant treatment effect on worry symptoms than group CBT. However, much of the evidence base for group CBT for older adults with GAD does not reflect recent innovations in treatment approach based on trial evidence in younger adult samples (e.g. Dugas et al., 2010; Wells et al., 2010).

Cognitive treatments for GAD have received recent attention as excessive and difficult to control worry has gained recognition as the hallmark feature of GAD (American Psychiatric Association [APA], 2013). Treatment protocols have been developed based on the cognitive avoidance model (Borkovec & Costello, 1993), the metacognitive model of worry (Wells 2005), and the intolerance of uncertainty model (Dugas, Gagnon, Ladoceur, & Freeston, 1998). However, testing of such protocols with older adults has not kept pace with the younger adult evidence base.

The Dugas and Roubichaud (2007) Treatment Approach

The Dugas and Roubichaud (2007) treatment approach is based on a cognitive model of GAD proposed by Dugas et al. (1998). The model has four main features: intolerance of uncertainty, positive beliefs about worry, poor problem orientation, and cognitive avoidance (Dugas et al., 1998). Dugas et al. (1998) describe intolerance of uncertainty (negative beliefs about uncertainty and its consequences) as a higher order process, which drives the other three components. The model has been found to have considerable diagnostic and symptom specificity (Dugas, Marchand, & Ladouceur, 2005).

The accompanying GAD treatment protocol (Dugas & Roubichaud, 2007) focusses on excessive and uncontrollable worry with the aim of increasing participants' acceptance and tolerance of uncertainty. The protocol has six modules: 1) psychoeducation, 2) uncertainty awareness, 3) exposure, 4) problem-solving, 5) exposure to imagined worries, and 6) relapse prevention. Results for working age adults have been encouraging (Dugas et al., 2003; Dugas et al., 2010; Ladouceur et al., 2000). For example, whilst one-to-one CBT and applied relaxation were found to be comparable post-treatment, CBT via the protocol led to ongoing improvement at 24-month follow-up (Dugas et al., 2010). In group delivery for younger adults, CBT via the protocol led to significant improvements for all outcome measures post-treatment, alongside further treatment gains at 2-year follow-up (Dugas et al., 2003). Promising findings have also been reported for older adults in a multiple baseline study (n = 8) in which individual delivery of the protocol was examined (Ladouceur, Leger, Dugas, & Freeston, 2004). No studies have investigated the effectiveness of the Dugas and Roubichaud (2007) treatment approach with older adults in a group delivery format.

Study Rationale

This study evaluated group delivery of the Dugas and Roubichaud (2007) treatment protocol to older adults with GAD. The Salkovskis (1995) 'hourglass model' demonstrates how during stage 1, early uncontrolled evaluations of new therapies (or early attempts at adaptation in new populations) are essential foundations of future evidence-based practice. The aim of conducting randomised controlled trials and component analyses at stage 2 is to consolidate extant findings and to define causal and moderating factors. The final stage entails testing the therapy in real world settings using large-scale service evaluation and clinical audit. The present study of the group delivery of the Dugas and Roubichaud treatment protocol in an older adult sample was therefore an example of appropriate work at stage 1 of the 'hourglass model' (Salkovskis, 1995).

Primary Aim

The overall aim of this study was to evaluate the clinical effectiveness of the Dugas and Roubichaud (2007) treatment protocol for older adults with GAD attending group CBT.

Secondary Aims

1. To pilot the Overcoming Worry Group (OWG) with older adults with GAD.
2. To assess the feasibility of OWG.
3. To assess the acceptability of OWG.
4. To assess the durability of the effect of OWG.
5. To explore potential mechanisms of change of OWG.
6. To use outcomes from this study to shape methods and procedures for further studies.

Primary Hypotheses

i. Completion of OWG will result in a significant reduction in symptoms of GAD at the end of treatment (EOT).

ii. OWG-completers will maintain treatment gains over the 8-week follow-up (FU) period.

Secondary Hypotheses

i. Completion of OWG will result in a significant reduction in symptoms of depression at EOT.

ii. OWG-completers will maintain depression treatment gains over 8-week FU.

Method

The study received NHS ethical approval on the 17 April, 2015 (ref: 15/YH/0137; Appendix E) and permission to start research within Sheffield Health and Social Care NHS Foundation Trust on the 24 April, 2015 (ref: ZQ13; Appendix F). Ethical permission to proceed with the project was granted by Sheffield University research ethics committee on the 11 May, 2015 (ref: 177057; Appendix G).

Design

Case series are uncontrolled observational studies, suited to small *N* studies, in which a number of individual patients receive the same treatment procedure (Barlow, Nock, & Hersen, 2008). Case series are therefore an appropriate methodology for the early evaluation of a novel intervention (Salkovski, 1995). As illustrated in Figure 1, a case series design permitted group and individual level analyses, whilst qualitative methods enabled detailed examination of responders and non-responders (Heyvaert, Maes, Van den Noortgate, Kuppens, & Onghena, 2012).

An A-B design with follow-up was used in which baseline (BL) scores acted as a comparison from which to assess effects of intervention FU (Arntz, Sofi, & van Breukelen, 2013; Kratochwill & Levin, 1992; Kratochwill et al., 2013). As displayed in Figure 1, there were three study phases: BL, treatment, and FU. For those participants with a stable BL, it was possible to suggest that change occurred as a result of intervention, and not time (Arntz et al., 2013). The FU phase assessed the durability of intervention effects.

Mixed methods are recommended in the early evaluative stages of novel complex interventions (Campbell, 2000). Mixed methods enabled the triangulation of findings (convergence and complementarity) in order to increase the validity, reliability, and credibility of the present study (Erzeberger & Prein, 1997). The approach to mixed methods selected was based on a critical realist philosophy, which underpins CBT, and which has been shown to be compatible with small *N* research (Easton, 2010).

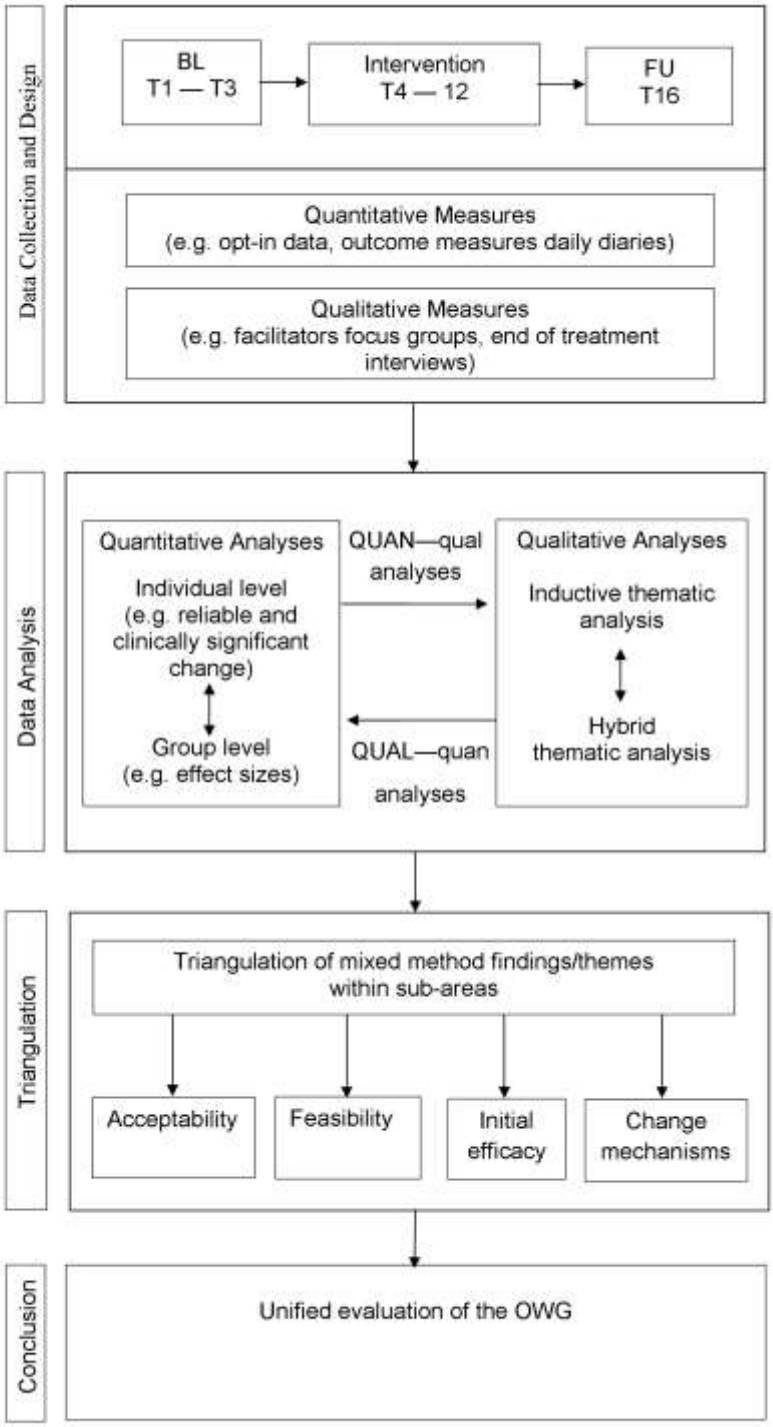

Figure 1. Graphic illustration of the mixed model case series design adopted. T=data collection point.

Participants

Potential participants were referred from the Sheffield Health and Social Care older adult community mental health teams (CMHT) and Sheffield Improving Access to Psychological Therapies (IAPT) services. The intervention was advertised through emails, team meetings, and presentations at relevant forums and service events. A pragmatic recruitment design was adopted and therefore patients were representative of routine practice. Recruitment started on the 12 May 2015, and continued until screening for the second treatment group started on 11 September 2015.

Screening sessions were conducted by OWG course facilitators, and during these sessions potential participants were given an information sheet about the research study and an expression of interest slip (see Appendices H and I). On receipt of an expression of interest slip, the chief researcher arranged a face-to-face meeting to discuss the research project and take formal consent if appropriate (see Appendix J for consent form). At screening, the following inclusion and exclusion criteria were applied:

Inclusion Criteria

- Aged over 65 years, and already in contact with mental health services.
- GAD as the primary complaint verified by a mental health clinician using the Anxiety Disorders Interview Schedule (ADIS-IV; Brown & Barlow, 2014), and to have scored $\geq$8 on the generalised anxiety disorder scale (GAD-7; Spitzer, Kroenke, William, & Löwe, 2006).
- Willing, and able, to attend the 12-week group CBT intervention.
- Able to read, write, and understand English.

Exclusion Criteria

- GAD was not the primary reason for referral or diagnosis.
- Insufficient understanding of English.

- Significant cognitive impairment preventing engagement and retention of information from the OWG over the course of the intervention and/or a diagnosis of dementia.
- Weighted risk (i.e. presence of active suicidal ideation and associated planning).
- Diagnosis of personality disorder.
- Experiencing symptoms of psychosis.
- Physically unable to attend the group.
- Evidence of current substance abuse.

Recruitment

Figure 2 describes the flow of participants through the study. Referrals for 37 potentially eligible participants were received (28 from IAPT and 9 from CMHTs). Of the individuals that attended screening, 23 met eligibility criteria (96%). Following screening, three eligible individuals (13%) opted out prior to the start of treatment (see Figure 2 for reasons). Of those who started treatment, 13 individuals (65%) gave consent for the research, and seven individuals (35%) chose not to participate in the research study, but attended the intervention. Out of 13 research participants, two (15%) dropped out of treatment prematurely (dropout group, $n = 2$), and 11 (85%) finished the course of treatment (completer group, $n = 11$). Reasons cited for dropout were poor physical health ($n = 1$) and family problems ($n = 1$). At FU, one research participant could not be contacted.

Table 1 presents demographic and clinical information for the research participants ($n = 13$). There were eight female participants (62%) and five males (38%). The age range of participants was 69-92 years ($M = 73.15$, $SD = 6.15$). All participants were White British. Eight of the sample were married (62%), and participants had left education at an average age of 15.08 years ($SD = 1.66$). Eight of the sample were taking anti-depressants (62%), and all participants had at least one physical health or

psychiatric comorbidity (including diagnosed depression *n* = 3, 23%). All participants met the diagnostic criteria for GAD using the anxiety disorders interview schedule (ADIS-IV; Brown & Barlow, 2014). GAD severity ranged between 3.1 and 6.9 (out of 8), and averaged 4.89 (*SD* = 1.32). At screening, the average score on the GAD-7 was 12.69 (*SD* = 4.73), and on the PHQ-9 it was 8.15 (*SD* = 6.26) (see measures section).

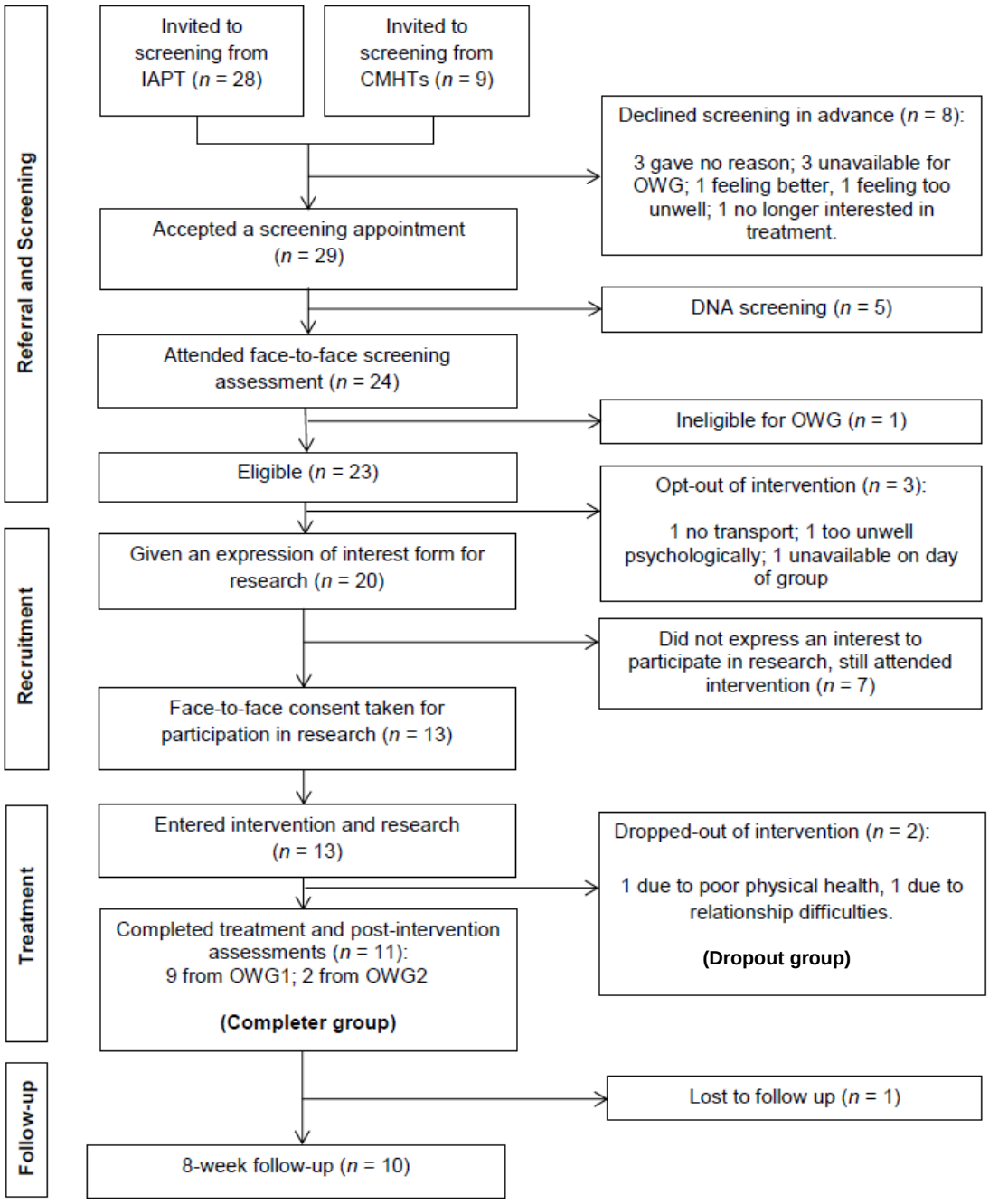

Figure 2. Diagram showing flow of participants. *Note.* IAPT = Improving Access to Psychological Therapies; CMHT = community mental health teams; DNA = did not attend; OWG = Overcoming Worry Group.

Table 1.

Demographic and clinical information at screening

Participant	Gender	Age	Marital status	Education leaving age	Medication	Other diagnoses	Screening scores			
							GAD-7	GAD severity	GAD diagnosis	PHQ-9
Completers										
1	F	72	D	15	AD	Depression	9	4.0	Y	5
2	M	75	M	14	PH	CVA	17	4.3	Y	2
3	M	73	S	13	-	OCD	9	5.5	Y	3
4	F	69	D	18	AD	AF, depression	16	5.9	Y	3
5	M	75	S	16	-	Prev MI's, cataracts	8	3.4	Y	15
6	F	75	M	16	PH	High blood pressure	10	6.1	Y	8
7	F	70	M	14	AD	High cholesterol, depression	14	3.2	Y	20
8	F	71	D	16	AD, PH	Breast cancer, depression	18	3.1	Y	6
9	F	69	M	14	AD	MCI, panic disorder	7	4.2	Y	6
10	F	72	M	18	AD	Heart problems	9	5.6	Y	1
11	F	68	M	15	AD, PH	Depression	9	6.8	Y	8
Dropouts										
12	M	92	M	14	AD	Heart murmur	19	4.6	Y	10
13	M	70	M	13	AD	Arthritis	20	6.9	Y	19

Note. M = married; D = divorced; S = single; AD = anti-depressants; PH = physical health medication; CVA = cardiovascular accident; OCD = obsessive compulsive disorder; AF = atrial fibrillation; MI = myocardial infarction; MCI = mild cognitive impairment; GAD-7 = generalised anxiety disorder scale; PHQ-9 = Patient Health Questionnaire[a]GAD severity = mean score on Anxiety Disorders Interview Schedule Fifth Edition (ADIS-IV).

OWG Facilitators

The delivery of OWG was facilitated by two senior clinical psychologists, working in an older adult CMHT. The psychologists had between 8 and 17 years of experience in older adult psychology services. One of the facilitators was an accredited CBT therapist, and other had significant CBT experience (6 years). The facilitators received monthly supervision from an accredited CBT consultant clinical psychologist to discuss the group and treatment integrity.

Primary Outcome Measure

The Penn State Worry Questionnaire (PSWQ: Meyer, Miller, Metzger, & Borkovec, 1990). PSWQ (Appendix K) measures trait worry and each item is rated from 1 (not very typical of me) to 5 (very typical of me). Eleven items are worded in the direction of pathological worry, and five items are reverse-worded. Total scores were obtained by summing the scores for the positively-worded items (2, 4-7, 9 and 12–16) with the reverse scores from negatively worded items (1, 3, 8, 10 and 11). Higher total scores are indicative of higher levels of excessive and difficult to control worrying, and for older adults a cut off score of $\geq$50 indicates GAD (Stanley et al., 2003). PSWQ has shown high internal consistency (α = .94), adequate test-retest reliability (r = .74), and adequate convergent and discriminant validity in older adults (Stanley, Novy, Bourland, Beck, & Averill, 2001; Wuthrich, Johnco, & Knight, 2014).

Secondary Outcome Measures

Generalised anxiety disorder scale (GAD-7: Spitzer, Kroenke, Williams, & Löwe, 2006). GAD-7 (Appendix L) is a 7-item scale that aims to assess GAD symptoms, anxiety-related items (over the last two weeks) are rated from 0 (not at all) to 3 (nearly all the time); a score of $\geq$5 is said to indicate GAD in older adults (Wild et al., 2014). In an older adult sample the GAD-7 has been shown to have good discriminant and convergent validity and good internal consistency (α = .82) (Spitzer et

al., 2006; Vasiliadis, Chudzinski, Gontijo-Guerra, Préville, 2015; Wild et al., 2012). Intercorrelation with the PHQ-9 was moderate, *r* = .64 (Löwe et al., 2008).

Patient Health Questionnaire (PHQ-9: Spitzer, Kroenke, & Williams, 1999). PHQ-9 (Appendix M) is a 9-item scale that is used to assess for major depressive disorder; depression symptom items (over the last two weeks) are rated from 0 (not at all) to 3 (nearly all the time) (Löwe, Kroenke, Herzog, & Grafe, 2004). A total score of $\geq$10 is considered to predict a diagnosis of depression, and increasing scores are considered indicative of greater symptom severity (APA, 1994; Phelan, 2010). With older adults, the PHQ-9 has been shown to have adequate internal consistency (α = .78), good test-retest reliability (*r* = .81), and adequate convergent and discriminant validity (Dear et al., 2013; Löwe et al., 2004; Phelan et al., 2010).

Daily diary. The daily self-monitoring diary (Appendix N) included a key target variable in relation to the treatment of GAD drawn from the GAD-7, 'I have been worrying too much about different things' (Spitzer et al., 2006). The diary also included a second variable which asked participants' to rate the extent to which they considered themselves to be trying out the things they had learned in the group.

Process Measures

The Intolerance of Uncertainty Scale (IUS; Freeston et al., 1994). IUS (Appendix O) aims to establish the reactions that individuals have to ambiguous situations, implications of uncertainty, and their efforts to control future events. There are 27 items in total, and all items are rated on a 5-point scale, 1 (not at all characteristic of me) to 5 (entirely characteristic of me). Items are added up, and higher scores indicate higher levels of intolerance of uncertainty beliefs. IUS is frequently used as a measure of process when evaluating the Dugas and Roubichaud (2007) treatment approach (Gosselin, Ladouceur, Morin, Dugas, & Baillargeon, 2006). Though the measure has not been validated for use with an older population, the

English version of IUS has been shown to have high internal consistency (α = .94) (Buhr & Dugas, 2002). Additionally, IUS has been shown to have moderate concurrent validity with the PSWQ (r = .60), adequate test-retest reliability over a five-week period (r = .74), and adequate convergent and divergent validity when assessed with symptom measures of anxiety, worry, and depression (Buhr & Dugas, 2002).

Elliott's Client Change Interview (Elliott, Slatick, & Urman, 2001). The change interview is a 30–90 min semi-structured interview used to provide a qualitative overview of factors clients find helpful in treatment (Appendix P; Elliott et al., 2001). Clients are asked to consider changes/stasis/deterioration, and associated expectations, significance, and attributions. The change interview has been used in a number of qualitative examinations of the helpful factors of therapy (Israel, Gorcheva, Burnes, & Walther, 2008; Levitt, Butler, & Hill, 2006; Mörtl & Von Wietersheim, 2008), and in mixed methods single-case research (Kellett & Hardy, 2013).

Measure of Treatment Integrity

Session-by-session treatment integrity was rated using a 14-item (6-point) fidelity coding guide developed specifically for assessing the integrity of group CBT (See Appendix Q; Hepner et al., 2011). Treatment integrity is rated from 0 to 84 (higher scores reflect sessions considered to have higher fidelity to the CBT). A qualified CBT therapist independently rated 8% of sessions (2/24 sessions).

Procedure

There were 16 main data collection points over three study phases (BL, intervention, and FU; see Table 2). Following referral, potential participants attended a screening appointment at which they were screened against inclusion/exclusion criteria. Eligible participants were provided with an information sheet and a letter of invitation to participate in the research study (with an expression of interest slip) (Appendices H

and I). Individuals were informed that their decision not to participate in the research would not affect treatment offered.

On receipt of a completed 'expression of interest' form, a face-to-face meeting was arranged between the chief researcher and the potential research participant. This was an opportunity for potential research participants to have any further questions about the research answered. At this point participants choosing to take part in the research were invited to complete a written consent form (Appendix J). Participants were informed of their right to withdraw at any point, and confidentiality and anonymity of data was assured. Consenting participants then filled out a full battery of outcome measures. Immediately prior to the start of the intervention, participants completed the GAD-7 and were given the daily worry diary.

Over the intervention phase, participants completed the GAD-7 prior to each intervention session, and the daily diary between sessions. Unless otherwise indicated (e.g. poor health), dropouts were invited to complete a dropout feedback form which asked about the acceptability, feasibility, and initial efficacy of the group and the research (Appendix R). At EOT, completers filled out the full battery of outcome measures and were invited to provide further consent to take part in a taped change interview (see Appendix S for consent form for EOT interview, see Appendix P for change interview schedule). Lastly, at 8-week FU participants completed all outcome measures.

Facilitating psychologists attended focus groups after both treatment groups to discuss their experiences of delivering the intervention, and the research. The focus group schedule (Appendix T) was designed and administered based on guidance by Krueger (2002). Each focus group lasted 30–60 mins and was guided and chaired by the lead researcher.

Table 2.

Study phases and data collection points for each research participant

Phase	Timepoint	Description	GAD-7	PHQ-9	PSWQ	IUS	Daily diary	Change interview
-	-	Referral	-	-	-	-	-	-
BL	1	Face-to-face screening	X	X	-	-	-	-
BL	2	Consent-taking	X	X	X	X	-	-
BL	3	Pre-treatment measures	X	-	-	-	X	-
I	4-14	12-week treatment	X	-	-	-	X	-
I	15	EOT measures	X	X	X	X	-	X
FU	16	8-week FU measures	X	X	X	X	-	-

Note. BL = baseline; I = intervention; FU = follow-up; EOT = end of treatment; X = measure administered; - = measure not administered;GAD-7 = generalised anxiety disorder scale; PSWQ = Penn State Worry Questionnaire; PHQ-9 = Patient Health Questionnaire 9; IUS = Intolerance of Uncertainty Scale.

The Intervention

The OWG treatment manual (Appendix U for an example) and accompanying materials were developed by the research team, based on group delivery of the Dugas and Robichaud (2007) GAD treatment manual for older adults. Adaptations to the Dugas and Roubichaud protocol included those described by Ladoceur et al. (2004) in their individual delivery of the protocol to older adults. For example, OWG included planned times for participants to share their knowledge and experiences of living and coping with anxiety and worry (e.g. group discussion exercises). OWG also reflected recommendations for adapting CBT for group delivery with older adults (such as slower pacing, multimodal learning, and memory aids; Bains, Scott, Kellett, & Saxon, 2014). To increase multi-modal learning, the OWG manual included presentations, group discussions, games, written tasks, and homework (such as behavioural experiments). An initial draft OWG was tested through a pre-pilot in September 2014 (n = 5). Changes made on the basis of feedback (participant and facilitator) included additional handouts (such as a handout with an example of a hypothetical worry draft), and more detailed facilitator 'tips for delivery' in the session guides.

The OWG was delivered over 12 weekly sessions, each lasting 2 hours. There were a maximum of 12 participants in each group. The OWG included three phases: awareness training (sessions 1–3), worry interventions (sessions 4–10), and relapse

prevention (sessions 11 and 12). Awareness training included ‘understanding worry’ and ‘noticing the difference between real and hypothetical worries’. There were four worry interventions: a) experiments to increase tolerance of uncertainty, b) evaluation of worry beliefs exercises, c) tasks to increase problem-solving skills, and d) a cognitive exposure to hypothetical worry exercise. The OWG ended with relapse prevention sessions in which content was recapped and participants developed bespoke relapse prevention plans (Hjemdal, Hagen, Nordahl, & Wells, 2013). All sessions had a consistent structure, starting with homework review and a recap on the previous week, and ending with homework setting. Throughout treatment, participants were asked to keep a daily diary to monitor their worry levels (see measures section).

Data Analysis

Mixed data was predominantly analysed in parallel using separate quantitative and qualitative analysis methods, as is often the case for triangulation studies in which convergence is being assessed (Tashakkori & Teddlie, 1998). However, for complementarity purposes, sequential mixed model analyses were also used to explore factors that may explain initial differences (quantitative or qualitative) in efficacy and change outcomes. ‘QUAN’ analyses were used to form subgroups of patients (recovered vs. not recovered patients), and the differences between these subgroups of participants were then analysed further using ‘qual’ methods. In addition, ‘QUAL’ analyses were used to form subgroups of patients (based on reported changes), and the differences between subgroups were then analysed further using ‘quan’ methods.

Quantitative analyses. Descriptive statistics were used to describe dropouts and completers in terms of demographic and clinical factors. Chi-squared tests explored any between-group differences (completers vs. dropouts) in baseline characteristics. Attendance, homework completion rates and treatment integrity ratings were calculated and summarised descriptively.

Individual level analyses. Individual participant outcomes were presented graphically to illustrate progress over time, and to display any trends occurring across study phases. BL data was visually examined for stability. Evidence of reliable improvement reliable improvement, and clinically significant improvement (CSI), is increasingly utilised to categorise 'recovery' in practice-based evidence, and was the criteria for recovery adopted in this study (Wise, 2004). The primary outcome measure used was the PSWQ, and the main outcome point was EOT. The Reliable Change Index (RCI) was calculated using the Jacobson methodology, thus change exceeding 1.96 times the standard error of the difference of the PSWQ was considered statistically reliable (Jacobson & Truax, 1991). For the PSWQ, this meant that an improvement in scores of >17 was classified as reliable improvement, calculated on the basis of a data from large older adult clinical sample (Wuthrich et al., 2014). CSI was recorded for participants who had moved from the clinical range to the normal range. The clinical cut-off for GAD in older adults, as measured by the PSWQ is $\geq$50, and thus CSI was considered if participants moved from $\geq$50 (pre) to <50 (post) (Stanley et al., 2003). The number and percentage of participants deteriorating reliably (i.e. showing deterioration in score of >17), and/or showing clinically significant deterioration (moving from the normal range to the clinical range), on the PSWQ was also reported.

Reliable and clinical change calculations were then repeated for the secondary measures using older adult data where available. For the GAD-7, the RCI was a change score of >5 and the clinical cut-off was 5 (Wild et al., 2014). The RCI for the PHQ-9 was a change score of >6 and the clinical cut-off was 10 (Löwe et al., 2004). For the IUS there was no clinical cut-off, or older adult data available, but a RCI of $\geq$14 was adopted as per previous studies of working aged adults (Boswell, Thompson-Hollands, Farchione, & Barlow, 2013).

Daily self-monitoring diaries were analysed using percentage of non-overlapping data methodology, an accepted indicator of treatment effectiveness (Parker & Vannest, 2009). Three methods of calculating non-overlapping data were used in recognition of the limitations of each: the Percentage of Non Overlapping Data (PND; Scruggs, Mastropieri, & Casto, 1987), the Percentage of All Non Overlapping Data (PAND; Parker, Hagan-Burke, & Vannest, 2007), and the Percentage Exceeding the Median (PEM; Ma, 2006). Non-overlapping data results can be classified in relation to treatment effectiveness as: 50-70% = questionable effectiveness, 70-90% = moderate effectiveness, and over 90% = high effectiveness (Wendt, 2009).

Group level analyses. Effect size calculations were used to provide a comparative mean change in the primary outcome measure (Fritz, Morris, & Richler, 2012). Effect size calculations (with 95% confidence intervals) were calculated as follows: (mean PSWQ score at BL – mean PSWQ score at EOT)/standard deviation of PSWQ scores at BL. Standard error of the mean pre-post change provided 95% confidence intervals. This was then repeated for secondary outcome measures (GAD-7, IUS, and PHQ-9). Effect sizes were considered according to Cohen's (1992) power primer: $d \geq 0.20$ = small effect, $d \geq 0.50$ = medium' effect, and $d \geq 0.80$ = large effect. In order to provide a conservative estimate of the clinical effectiveness of OWG, intention-to-treat analyses (ITT) were conducted, employing the 'last observation carried forward method' in relation to the effect size calculations (Hollis & Campbell, 1999). Alongside this, effect sizes obtained were benchmarked against similar group CBT studies for older adults with GAD. The significance of changes in GAD symptoms (GAD-7 and PSWQ), tolerance of uncertainty (IUS), and depression symptoms (PHQ-9) over the course of the OWG was considered using the Wilcoxon signed-rank test for paired samples (Wilcoxon, 1945).

Qualitative analyses. Digitally recorded completer interviews (n = 11) and facilitator focus groups (n = 2) were transcribed verbatim by the chief researcher. Two methods of data-driven thematic analysis (TA) described by Boyatzis (1998) were used (inductive and hybrid; Table 3). Data-driven approaches are reported to result in themes with higher interrater reliability and increased validity against relevant criteria (Boyatzis, 1998).

Inductive TA. Nine-step criterion-driven inductive TA (Table 3; Boyatzis, 1998) was used to analyse participant change interview data (questions 3-7). The criterion variable of 'recovered vs. not recovered' was selected based on the study aims. To enhance reliability, a second researcher (a trainee also using TA at a doctorate level) applied the coding frame to 30% of the raw data (Boyatzis, 1998). Overall agreement for themes was calculated using Cohen's kappa, and codes for which there were lower levels of agreement were further clarified, or dropped, to increase validity (Boyatzis, 1998).

Hybrid TA. Hybrid TA was used to analyse change interview data (questions 1 and 8), and facilitator focus group data, given that there was no evident criterion variable for this data (Boyatzis, 1998). Hybrid TA involved a 5-step process in which steps 2, 5, 6, and 9 were omitted (Table 3; Boyatzis, 1998). Therefore, in contrast to inductive TA, the development of meaningful themes was theory and research–driven (Boyatzis, 1998). The small data sets analysed using hybrid TA did not permit meaningful validity analyses.

Table 3.

Steps in inductive and hybrid thematic analysis (Boyatzis, 1998)

Step	Details	Inductive TA	Hybrid TA
1. Sampling	Define the sampling unit Consideration of units of analysis Consideration of units of coding Decide on whether there is a criterion variable or not	Yes	Yes
2. Selection of subsamples	Based on the identified criterion variable selected subsamples	Yes	No
3. Reducing raw information	Re-read/re-listen interviews Summary of each piece of raw data within each interview	Yes	Yes
4. Summary of information	Creation of an outline of each subsample transcript	Yes	Yes
5. Identification of themes within subsets	Compare summaries and note similarities within each subset	Yes	No
6. Comparing themes across subsets	List and compare items found to be similar in each subset Write a set of statements that differentiate the two subsets	Yes	No
7. Code creation	Develop usable codes Each code has five elements: label, definition, indicators, exclusions, examples	Yes	Yes
8. Assessment of reliability	Second rater applies code to subsample of data Calculation of overall percentage agreement scores If less than 60% agreement for a theme, return to step 7.	Yes	Yes
9. Assessment of Validity	Themes present in ≥30% both subsamples dropped, themes not identified by the second rater dropped	Yes	No

Note. TA = thematic analysis.

Data triangulation. In order to increase the transparency and replicability of data triangulation, an adapted version of a protocol used for triangulating mixed method qualitative data was developed (Table 4; Farmer, Robinson, Elliott, & Eyles 2006; Henwood et al., 2015). To increase the reliability of convergence codes assigned, a blind second researcher (a trainee clinical psychologist) recoded summary data;

convergence codes for which there were discrepancies were discussed until agreement was reached (Farmer et al., 2006).

Table 4.

Mixed methods triangulation protocol (adapted from Farmer et al., 2006)

Step	Actions
Sorting	Sort findings from each data source into four topic areas: acceptability, feasibility, initial efficacy, and change mechanisms. Draw out a convergence coding matrix in order to summarise differences and similarities between findings for themes within each of the four areas.
Convergence coding	Code findings for each theme as either of the four codes below: a. confirmatory (expansion) = merged data in agreement adds breadth. b. confirmatory (complementarity) = merged data in agreement and adds depth. c. discrepant = disagreement observed between merged data.. d. uncodeable = not possible to provide a convergence code. Provide supporting examples/data outcomes to substantiate all codes.
Reliability checking	Second blind rater provides assigns convergence codes based on summary findings. Discuss discrepancies and re-visit convergence coding (step 2) as appropriate. Calculate and report interrater agreement using Cohen's kappa.
Completeness assessment	Create a unified and broadened summary of the key findings within each of the four areas.

Ethical Considerations

Participants were informed that research participation was voluntary, and that they could attend the group without taking part in the study. Participants were informed of their right to withdraw from the study at any point, without giving a reason, and that this would not affect their healthcare. An adverse incident procedure was in place to ensure participant safeguarding. The study was monitored by the university and the host trust's governance department. All data was stored securely and anonymously.

Results

Results are organised into the following sections: (a) quantitative (uptake and attendance, individual level analyses, group level analyses, and benchmarking), (b) qualitative (participant and facilitator experience), (c) QUAN-qual, (d) QUAL-qual, and (e) mixed methods triangulation.

Quantitative Analyses

Uptake and attendance. Table 5 contains BL descriptives for completers (*n* =11) and dropouts (*n* = 2). Dropouts were significantly more anxious (GAD-7) at BL than completers (*U* = 1.0, z = -2.0, *p* = .048). No other BL characteristics differed significantly between completers and dropouts. Average weekly attendance and homework completion rates were 87% (range 64-100%), and 73% (range 43-100%), respectively. Treatment integrity ratings averaged 94% (range 93-94%).

Individual outcomes. Figures 3-8 display individual OWG outcomes, with interpretation of trends summarised in Table 6. In short, BL stability was apparent for 5/11 participants (45%), positive treatment effects for 7/11 participants (64%), and further gains over FU were observed for 3/10 participants (30%). Analysis of daily diary scores for the four participants that provided data during BL and treatment phases (Table 7), classified treatment as either 'ineffective' (participants 1 and 4) or of 'questionable effectiveness' (participants 6 and 8).

The reliability and clinical significance of individual change scores are displayed in Table 8, and are summarised in Table 9. At EOT 5/11 participants met the PSWQ recovery criteria (46%), increasing to 7/10 at FU (70%). No participant showed reliable or clinical deterioration on the PSWQ, including over FU.

Of those who were above the clinical threshold on the PHQ-9 at BL, 2/4 participants no longer met the criteria for depression at EOT (50%), which reduced to 1/3 at FU (33%).

From BL to EOT one participant showed reliable deterioration on the IUS (9%), no other participants showed reliable deterioration on any outcome measure. Over FU, reliable and clinically significant deterioration was shown on the GAD-7 by two participants (20%). One of these participants also showed clinically significant deterioration on the PHQ-9 from BL to FU (10%), and was the only participant that required further psychological input post-treatment.

Table 5.

Baseline descriptive characteristics of completers and dropouts

					Measures				
Participant status	Age, years *M* (*SD*)	Education[a] *M* (*SD*)	Female, *n* (married, *n*)	Anti-depressants, *n*	GAD-7[b] *M* (*SD*)	GAD severity[c] *M* (*SD*)	PHQ-9[b] *M* (*SD*)	IUS *M* (*SD*)	PSWQ *M* (*SD*)
Completers (*n* = 11)	71.73 (2.57)	15.36 (1.63)	8 (6)	7	12.06 (4.38)	4.74 (1.29)	8.82 (6.64)	69.27 (28.74)	65.45 (8.36)
Dropouts (*n* = 2)	81.00 (15.56)	13.50 (0.71)	0 (2)	2	18.33 (2.83)	5.75 (1.63)	14.50 (4.95)	107.00 (39.60)	78.00 (1.41)

Note. GAD-7 = generalised anxiety disorder scale; PHQ-9 = Patient Health Questionnaire; IUS = Intolerance of Uncertainty Scale; PSWQ = Penn State Worry Questionnaire.

[a]School leaving age in years.

[b]*M* outcome scores over baseline period (T1-T3).

[c]GAD severity is the mean score (out of 8) on the Anxiety Disorders Interview Schedule.

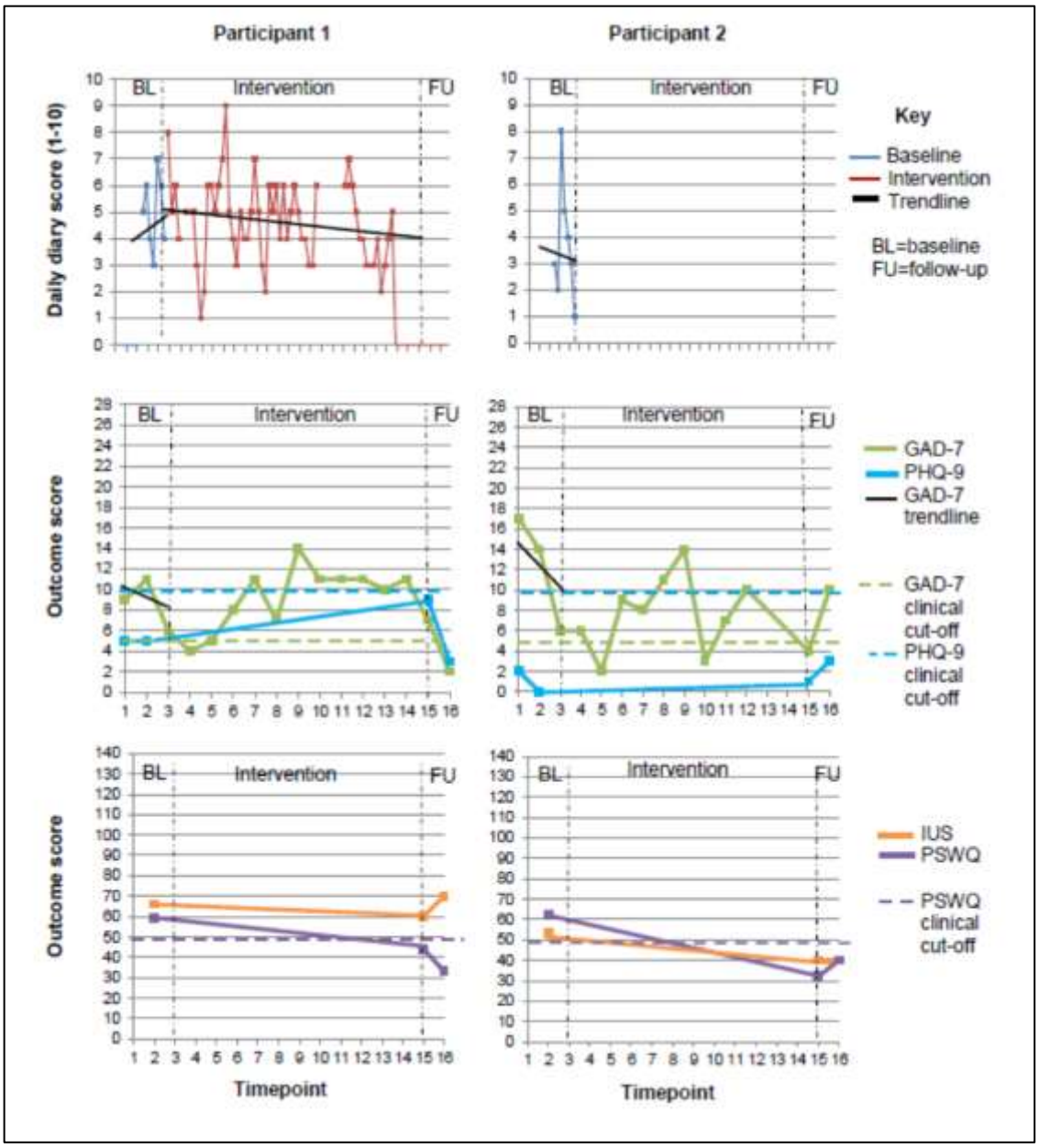

Figure 3. Outcomes for participant 1 (left) and participant 2 (right).

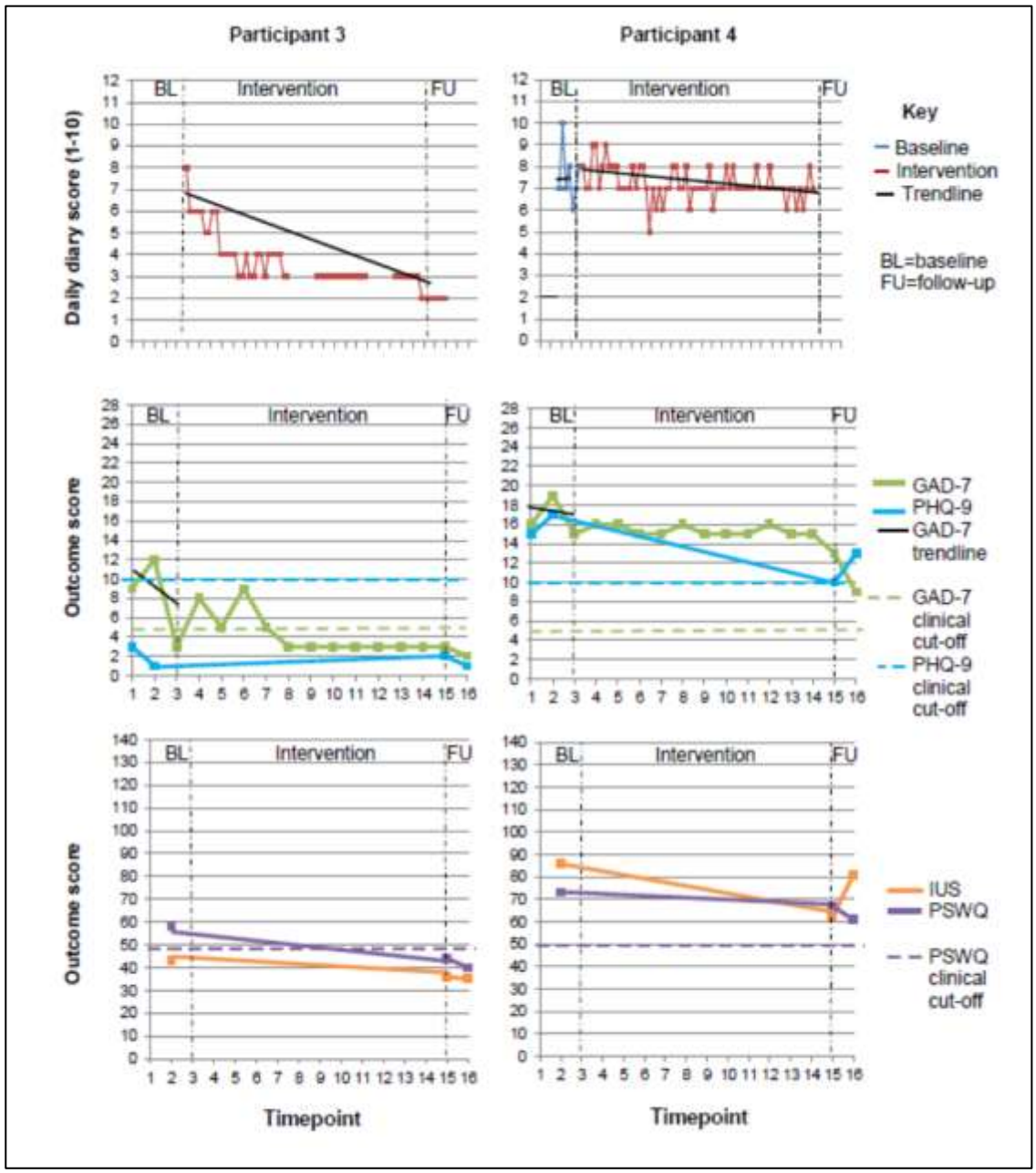

Figure 4. Outcomes for participant 3 (left) and participant 4 (right).

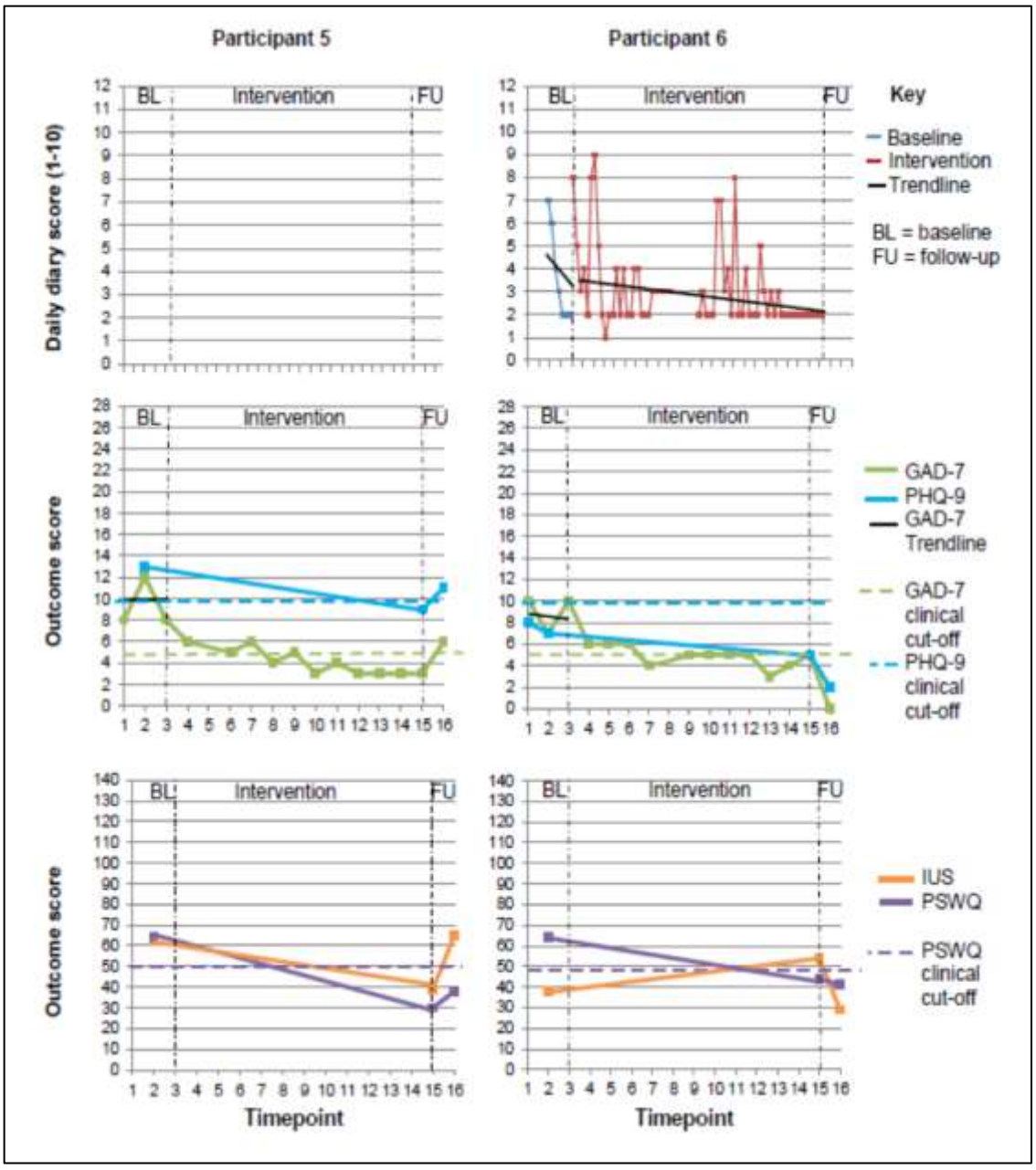

Figure 5. Outcomes for participant 5 (left) and participant 6 (right).

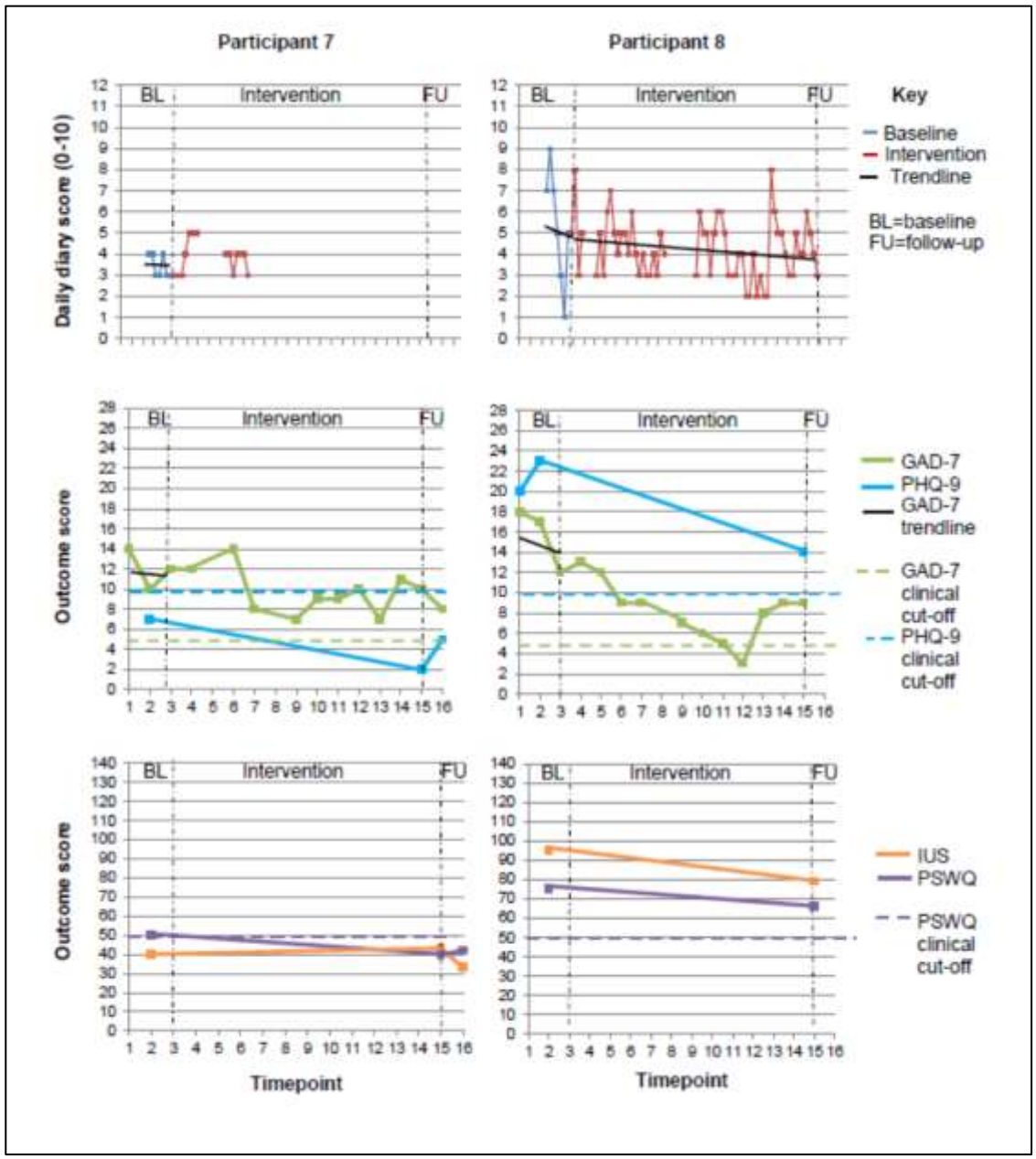

Figure 6. Outcomes for participant 7 (left) and participant 8 (right).

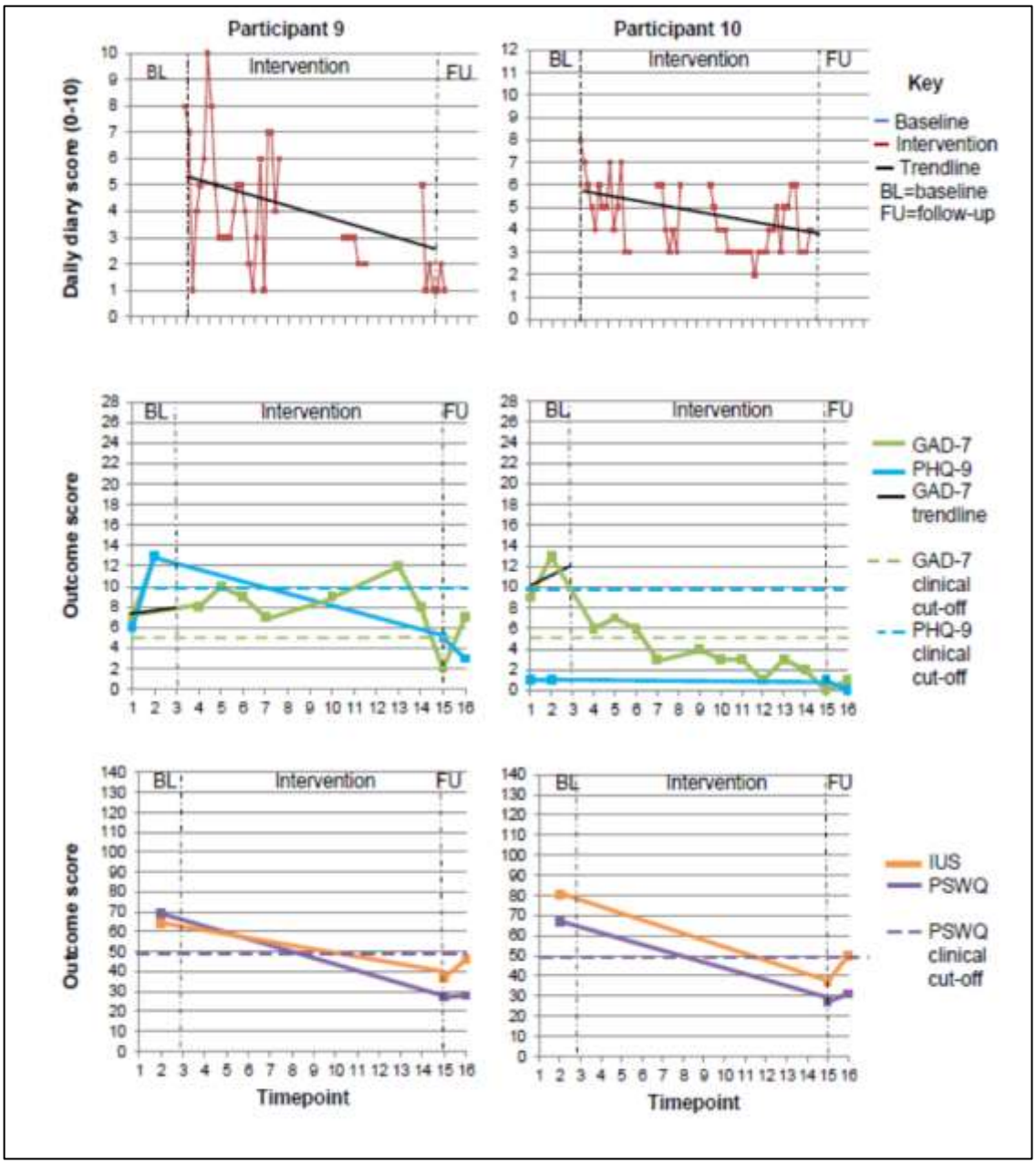

Figure 7. Outcomes for participant 9 (left) and participant 10 (right).

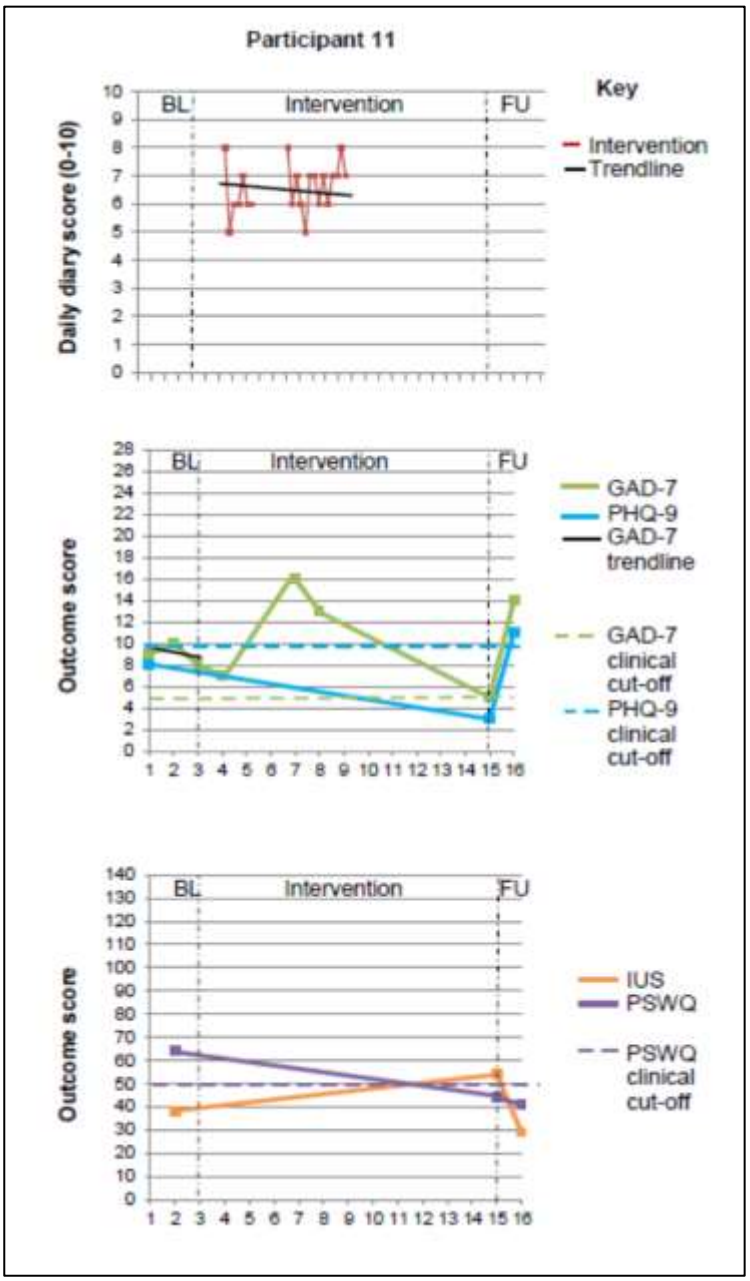

Figure 8. Outcomes for participant 11.

Table 6.

Trend interpretation of participant outcome graphs over study phases

Participant	Baseline	Intervention	Follow-Up
1	Not stable	No pattern	Further gains
2	Not stable	Effective	Deterioration
3	Not stable	Effective	No change
4	Stable	No change	No pattern
5	Not stable	Effective	Deterioration
6	Stable	Effective	Further gains
7	Stable	Effective	Further gains
8	Not stable	No pattern	No data
9	Stable	Effective	No pattern
10	Not stable	Effective	No change
11	Stable	No pattern	No pattern

Table 7.

Non-overlapping data indices from worry diaries[a]

P	PND (%)	PAND (%)	PEM (%)
1	8	7	47
2	-	-	-
3	-	-	-
4	1	1	13
5	-	-	-
6	2	1	54*
7	-	-	-
8	0	0	58*
9	-	-	-
10	-	-	-
11	-	-	-

Note. P = participant; PND = percentage of non-overlapping data; PAND = percentage of all non-overlapping data; PEM = percentage exceeding the median.
***Highly effective treatment(>90%).
** Moderately effective treatment (>70%).
*Treatment of questionable effectiveness (50-70%).
[a]Comparing baseline data with intervention data for the item: 'I have been worrying too much about different things' (1-10: 1 = not at all, 10 = very much).

Table 8.

Reliable change and clinical significance of participant change scores

		Outcome scores			BL to EOT		BL to FU		EOT to FU	
P	Measure	BL	EOT	FU	RC	CSC	RC	CSC	RC	CSC
1	GAD-7	9	7	2	No	No	No	No	No	↓
	PSWQ	59	44	33	No	↓	↓	↓	No	No
	PHQ-9	5	9	3	-	No	-	No	No	No
	IUS	66	60	70	No	-	No	-	No	-
2	GAD-7	12	4	10	↓	↓	No	Yes	↑	↑
	PSWQ	62	32	40	↓	↓	↓	↓	No	No
	PHQ-9	1	1	3	-	No	-	No	-	No
	IUS	53	40	40	No	-	No	-	No	-
3	GAD-7	8	3	2	No	↓	↓	↓	-	No
	PSWQ	58	44	40	No	↓	↓	↓	No	No
	PHQ-9	2	2	1	-	No	-	No	-	No
	IUS	43	36	35	No	-	No	-	No	-
4	GAD-7	17	13	9	No	No	No	No	No	No
	PSWQ	73	67	61	No	No	No	No	No	No
	PHQ-9	16	10	13	No	No	No	No	No	No
	IUS	86	61	81	↓	-	No	-	↑	-
5	GAD-7	9	3	6	↓	↓	No	No	No	↑
	PSWQ	64	30	38	↓	↓	↓	↓	No	No
	PHQ-9	13	9	11	No	↓	No	No	No	↑
	IUS	62	39	65	↓	-	No	-	↑	-
6	GAD-7	9	5	0	No	No	↓	↓	No	↓
	PSWQ	64	44	41	↓	↓	↓	↓	No	No
	PHQ-9	8	5	2	No	No	No	No	No	No
	IUS	38	54	29	↑	-	No	-	↓	-
7	GAD-7	12	10	8	No	No	No	No	No	No
	PSWQ	50	40	42	No	↓	No	↓	No	No
	PHQ-9	7	2	5	No	No	No	No	No	No
	IUS	40	43	33	No	-	No	-	No	-
8	GAD-7	16	9	ND	↓	No	-	-	-	-
	PSWQ	75	66	ND	↓	No	-	-	-	-
	PHQ-9	22	14	ND	↓	No	-	-	-	-
	IUS	95	79	ND	↓	-	-	-	-	-
9	GAD-7	10	2	7	↓	↓	No	No	No	↑
	PSWQ	69	27	28	↓	↓	↓	↓	No	No
	PHQ-9	10	5	3	No	↓	↓	↓	No	No
	IUS	64	37	46	↓	-	↓	-	No	No
10	GAD-7	11	0	1	↓	↓	↓	↓	No	-
	PSWQ	67	27	31	↓	↓	↓	↓	No	No
	PHQ-9	1	1	0	-	No	-	No	No	No
	IUS	80	37	48	↓	-	↓	-	No	-
11	GAD-7	10	5	14	No	No	No	No	↑	↑
	PSWQ	79	61	69	↓	No	No	No	No	No
	PHQ-9	9	3	11	No	No	No	↑	↑	↑
	IUS	135	57	118	↓	-	↓	-	↑	-

Note. RC = reliable change; CSC = clinically significant change; P = Participant; positive scores indicate improvement; BL= baseline mean; EOT = end of treatment; FU = follow-up; ND = no data; - = indicates not possible to calculate/no data available; ↓= improvement; ↑ =deterioration; GAD-7: RCI significant if >5; PHQ-9: RCI significant if >6; PSWQ: RCI significant if >17; IUS: RCI significant if >14; CSC for GAD-7 if pre score ≥5 and post score <5; CSC for PHQ-9 if pre score ≥10 and post score <10; CSC for PSWQ if pre score ≥50 and post score <50.

Table 9.

Summary of reliable and/or clinically significant improvement (top) and deterioration (bottom) on outcome measures[a]

	BL to EOT						BL to FU						EOT to FU					
	RC		CSC		RCSC		RC		CSC		RCSC		RC		CSC		RCSC	
Measure	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Improvement																		
PSWQ	7	64	8	73	5	46[b]	7	70	8	80	7	70[c]	0	0	0	0	0	0
GAD-7	5	46	5	46	4	36	4	40	4	40	4	40	0	0	1	25	0	0
IUS	7	64	-	-	-	-	4	40	-	-	-	-	1	10	-	-	-	-
PHQ-9	1	14	2	50	0	0	1	17	1	33	1	33	0	0	0	0	0	0
Deterioration																		
PSWQ	0	0	0	0	0	0[d]	0	0	0	0	0	0[e]	0	0	0	0	0	0
GAD-7	0	0	0	0	0	0	0	0	0	0	0	0	2	20	4	40	2	20
IUS	1	9	-	-	-	-	0	0	-	-	-	-	3	30	-	-	-	-
PHQ-9	0	0	0	0	0	0	0	0	1	10	0	0	1	10	2	20	1	10

Note. BL = baseline mean, EOT = end of treatment; FU = end of 8-week follow-up; RC = reliable change; CSC = clinically significant change; RCSC = reliable and clinically significant change; GAD-7= generalised anxiety scale; PSWQ = Penn State Worry Questionnaire; PHQ-9 = Patient Health Questionnaire; IUS = Intolerance of Uncertainty Scale; - = not possible to calculate as IUS does not have a clinical cut-off.

[a]Percentages reported are based on the number of participants for whom RC/CSC was possible for each calculation; [b]percentage of participants classified as recovered at the EOT; [c]percentage of participants classified as recovered at FU; [d]percentage of participants classified as harmed at the EOT; [e]percentage of participants classified as harmed at FU.

Group level outcomes. Figure 9 shows mean weekly GAD-7 outcomes and shows anxiety levels improved over BL, and continued to improve steadily over the course of treatment. Figure 10 displays mean outcomes for GAD-7 and PHQ-9, which show improvements in anxiety (GAD-7) and depression (PHQ-9) from BL to EOT, and relative stability over FU. Figure 11 displays mean PSWQ and IUS outcome scores, showing levels of worry (PSWQ) and intolerance of uncertainty (IUS) improved from BL to EOT. Over FU, worry levels showed slight improvement, whilst tolerance of uncertainty levels showed marginal deterioration.

Table 11 reports the statistical significance of change scores. Mean change in GAD-7 scores over BL were significant (z = -2.67, p = .08), unlike PHQ-9 scores (z = -1.19, p = .23); indicating BL stability for depression (PHQ-9) symptoms, but not for anxiety (GAD-7) symptoms. Change scores on all outcome measures indicated significant improvement from BL to EOT, and non-significant change from EOT to FU. Additional analyses found weekly GAD-7 scores did not change significantly between any two consecutive treatment sessions (see Figure 9 for a graphical display of weekly GAD-7 outcomes).

Completer and ITT effect sizes are displayed in Table 12. Completer worry (PSWQ) effect sizes were large at EOT, d = 2.59 (CI_{95}: -0.99, 4.12) and FU, d = 2.82 (CI_{95}: 1.16, 4.50). ITT worry (PSWQ) treatment effect sizes remained large at EOT, d = 2.04 (CI_{95}: 0.70, 3.38), and FU, d = 2.02 (CI_{95}: 0.69, 3.36). Completer depression (PHQ-9) treatment effect sizes were small-to-medium at EOT, d = 0.49 (CI_{95}: -0.71, 1.69), and medium at FU, d = 0.55 (CI_{95}: 0.66, 1.75). IUS effect sizes for completers were medium at EOT, d = 0.69 (CI_{95}: -0.52, 1.91).

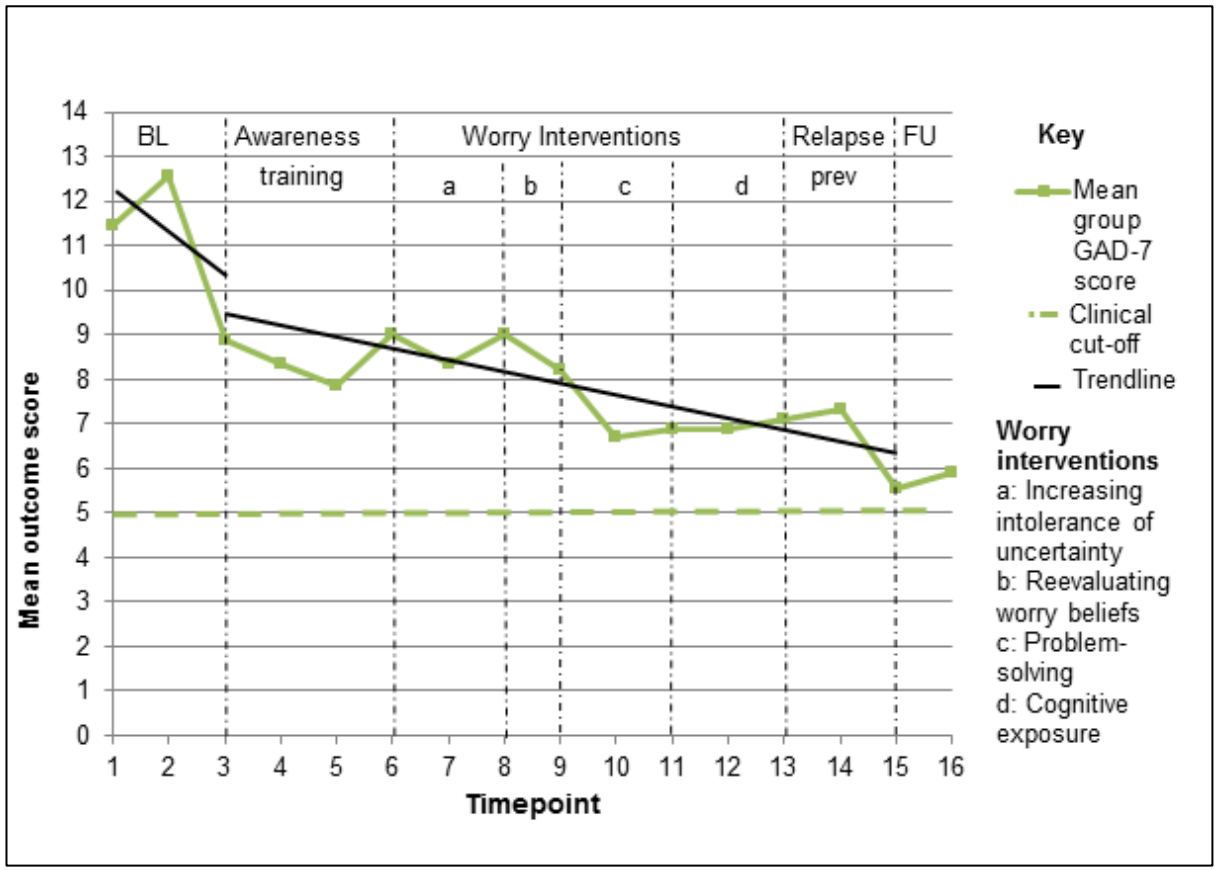

Figure 9. Mean GAD-7 outcomes over study and treatment phases. *Note.* BL = baseline; FU = follow-up; relapse prev = relapse prevention.

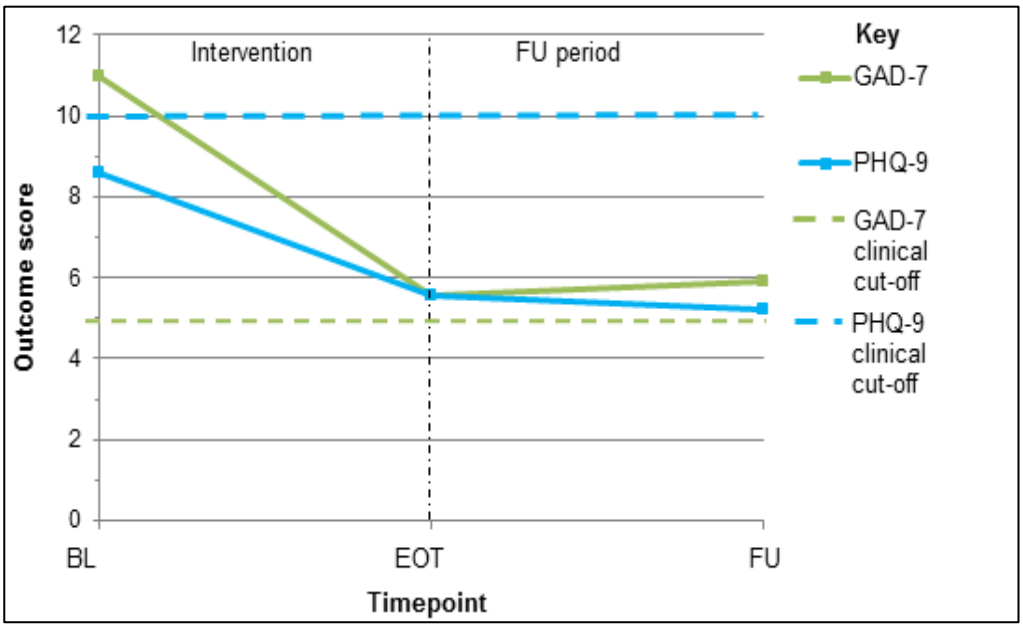

Figure 10. Mean GAD-7 and PHQ-9 outcomes across the study. *Note*. BL = Baseline; EOT = end of treatment; FU = follow-up.

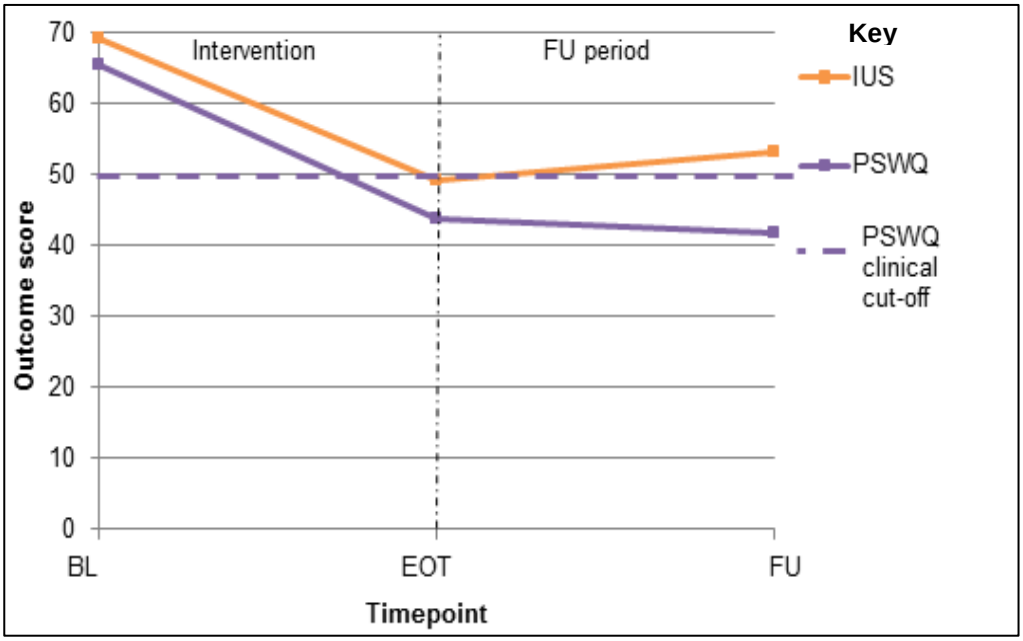

Figure 11. Mean PSWQ and IUS outcomes across the study. *Note*. BL = Baseline; EOT = end of treatment; FU = follow-up.

Table 11.

Group level significance of changes between main phases on all outcome measures

Measure	BL period	BL to EOT	BL to FU	EOT to FU
PSWQ	-	-2.93**	-2.94**	-0.36
GAD-7	-2.67*	-2.94**	-2.40*	-0.09
IUS	-	-2.36*	-2.67**	-0.61
PHQ-9	-1.19	-2.17*	-2.55*	-0.09

Note. BL = baseline mean; EOT = end of treatment; FU = follow-up; GAD-7=generalised anxiety disorder scale; PSWQ = Penn State Worry Questionnaire; PHQ-9 = Patient Health Questionnaire 9; IUS = Intolerance of Uncertainty Scale.
***p<.001;**p<.01; * p<.05.

Table 11.

Completer (top) and intention-to-treat (bottom) Cohen's d effect sizes

				Effect size calculations			
	BL	EOT	FU	BL to EOT		BL to FU	
Measure	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)	Cohen's *d* [CI_{95}][a]	Category[b]	Cohen's *d* [CI_{95}][a]	Category[b]
Completer							
PSWQ	65.45 (8.36)	43.82 (14.95)	41.80 (11.87)	2.59 [0.99, 4.12]	Large	2.82 [1.16, 4.50]	Large
GAD-7	12.06 (4.38)	5.55 (3.86)	5.90 (4.56)	1.49 [0.15, 2.82]	Large	1.41 [0.09, 2.73]	Large
PHQ-9	8.82 (6.64)	5.55 (4.34)	5.20 (4.69)	0.49 [-0.71, 1.69]	Small	0.55 [-0.66, 1.75]	Medium
IUS	69.27 (28.74)	49.36 (13.88)	53.20 (20.12)	0.69 [-0.52, 1.91]	Medium	0.56 [-0.65, 1.76]	Medium
ITT							
PSWQ	67.38 (8.98)	49.07 (18.74)	49.23 (17.70)	2.04 [0.70, 3.38]	Large	2.02 [0.69, 3.36]	Large
GAD-7	12.17 (3.88)	7.46 (5.91)	8.00 (6.06)	1.21 [0.03, 2.40]	Large	1.08 [0.09, 2.24]	Large
PHQ-9	9.54 (6.67)	6.92 (5.39)	7.31 (5.88)	0.39 [-0.71, 1.49]	Small	0.33 [-0.76, 1.43]	Small
IUS	75.08 (31.93)	58.23 (27.56)	63.46 (29.29)	0.57 [-0.54, 1.67]	Medium	0.39 [-0.71, 1.49]	Small

Note. ITT = Intention-to-treat; BL = baseline mean; EOT = end of treatment; FU = follow-up; CI = confidence interval; GAD-7 = generalised anxiety disorder scale; PSWQ = Penn State Worry Questionnaire; PHQ-9 = Patient Health Questionnaire; IUS = Intolerance of Uncertainty Scale.

[a]Cohen's *d* effect sizes are based on the following formula: (post-treatment mean – pre-treatment mean)/pre mean SD, effect sizes obtained were reversed therefore a positive treatment effect is reflected by a positive effect size, and vice-versa.

[b]Effect size categories are based on Cohen's (1992) guidelines: 0.20–0.49 = small, 0.50–0.79 = medium, and $\geq$ 0.80 = large.

Benchmarking. Table 12 presents benchmarked findings and shows that the OWG had an equivalent opt-in rate, lower dropout rate, and a larger EOT PSWQ effect size than comparators (Stanley et al., 1996; Stanley et al., 2003; Wetherell et al., 2003).

Table 12.

Bench-marking worry completer outcomes of group CBT for older adults with GAD

Author (year)	*N*[a]	CBT length	Opt in %[b]	Dropout %[c]	PSWQ ES[d]
Present study (2016)	13	12 x 2hr	87	15	2.59
Stanley et al. (2003)	39	15 x 1.5hr	94	26	0.90
Stanley et al. (1996)	26	14 x 1.5hr	96	31	0.70
Wetherell, et al. (2003)	26	12 sessions	82	31	0.53

Note. PSWQ ES = Penn State Worry Questionnaire effect size; [a]Total number of participants CBT treatment arm; [b]Uptake is defined as eligible participants that declined treatment; [c]Dropouts are defined as participants who did not finish treatment; [d]Cohen's *d* effect sizes are based on completer data using the following formula: (mean post-treatment PSWQ score – mean pre-treatment PSWQ score)/pre-treatment PSWQ SD, effect sizes obtained were reversed, thus a positive effect of CBT is represented by a positive effect size, and vice-versa.

Qualitative Analyses: The Participant Experience

Using hybrid TA, five participant themes emerged, regarding acceptability and feasibility of the OWG:

Theme 1: Enjoyable. Many of the participants (10/11) described the OWG as an enjoyable and social experience.

I've enjoyed it, I think some of the time it was just meeting people as well (Participant 8).

Theme 2: Better in a group than expected. Almost half of the participants (5/11) described coping better with group-based treatment than expected.

I thought I might not be able to do that and yet I did do that, and went to all 12 of them (Participant 5).

Theme 3: Supportive facilitators. Facilitators were described as supportive and patient by the vast majority of participants (9/11).

If you didn't understand you just had to say and they went over it again (Participant 11).

Theme 4: Not as expected. Almost half the participants indicated (5/11) that they had expected something different from the intervention.

A few of us went to find out why we behave like this, but obviously the group didn't cover that (Participant 1).

Theme 5: Why invent worries! The hypothetical worry exposure task was not liked by many of the participants (5/11).

We had one week it was, I forget what it was titled and you think about going into a care home. One week it was a bit oh, made you go a bit like that. I thought I don't know whether I like that (Participant 7).

Qualitative Analyses: The Facilitator Experience

Eight themes emerged from hybrid TA of the facilitator focus group transcripts.

Theme 1: OK together. Group delivery with other older adults was described by facilitators as an acceptable and 'normalising' treatment format.

People were very clear they liked being in a group with older people. It was something about similar stage and all that kind of thing (Psychologist 2, OWG2).

Theme 2: Drop the diary. Facilitators described the daily diary as unacceptable for many of the participants:

I don't think the worry diary works generally. I think most people don't like it, there's one or two that will do it, but most people don't like it (Psychologist 2, OWG2).

Theme 3: Too much paperwork for some. Facilitators suggested that they felt there were too many handouts for some of the participants.

One person felt and a few people agreed it's too many handouts (Psychologist 1, OWG1).

Theme 4: Familiar co-facilitator helped. Previous experience of co-delivery was described as a factor which increased the feasibility of delivery.

I think it worked well because you and I have worked together a lot. So it made facilitation easy (Psychologist 2, OWG1).

Theme 5: Structure helps. Facilitators described the regular structure of the weekly protocol as a positive/helpful aspect of delivery.

I like the overall format. The familiarity, we start off the same and it pretty much ends the same. I think people respond quite well to that (Psychologist 1, OWG1).

Theme 6: Invisible research. The research study was not something facilitators reported that they felt aware of during treatment.

I think it was quite good that I forgot who was in the research, everyone just did the same things every week (Psychologist 2, OWG2).

Theme 7: Doing helped. Facilitators described the behavioural experiments as a helpful element of treatment.

I think the behavioural experiments are really key. Really good at keeping that consistency of doing things differently (Psychologist 1, OWG2).

Theme 8: Positive feedback. Facilitators shared positive feedback from participants, and their networks.

He'd [participant's husband] got his wife back and he was very positive about the group and that it should continue. Generally people were very positive (Psychologist 2, OWG2).

QUAN-qual Findings

Table 13 illustrates that four themes maximally differentiated the experience of participants who met the criteria for recovery at the end of the OWG (n = 5) from those that did not (n = 6). Following second rating of 30% of the transcripts one potential theme was dropped due a low level of agreement between raters, and further detail was added to the coding template for theme 3a. Following this, good interrater agreement was achieved, $\kappa = .74$ (CI_{95}: 0.49, 0.99), $p < .001$ (see Appendix V).

Table 13.

Summary of themes differentiating recovered and non-recovered participants

		Participant Status					
		All participants (n = 11)		Recovered (n = 5)		Not recovered (n = 6)	
Theme	Label	No. of statements[b]	% pts[c]	No. of statements	% pts	No. of statements	% pts
1(a-b)	Difference vs. identification						
1a	Difference	3	27	3	60	0	0
1b	Identification	12	55	1	20	11	67
2(a-b)	Opening up vs. holding back						
2a	Opening up	4	36	3	60	1	17
2b	Holding back	2	18	0	0	2	33
3(a-b)	Doing for learning vs. reporting back						
3a	Doing for learning	9	27	9	60	0	0
3b	Reporting back	9	45	1	20	8	67
4	Somatic changes	10	26	9	60	1	17

Note. pts = patients

[a] recovery has been defined in this study as reliable and clinically significant improvement on the Penn State Worry Questionnaire (PSWQ) from baseline to the end of treatment.

[b] total number of times each code was identified.

[c] percentage of participants for which each theme was identified at least once.

Theme 1: Difference vs. identification. Many of the participants who recovered reported feeling somewhat different from the rest of the group (3/5; Theme 1a 'Feeling different').

There was only one lady who didn't come very often so it was four or five men and me (Participant 10).

In contrast, participants who did not recover more frequently described similarity with the other group members (4/6; Theme 1b 'identification').

I think yeh, other people are thinking the same (Participant 7).

Theme 2: Opening up vs. holding back. Participants who recovered were more likely to mention that they or others had shared their thoughts and feelings during OWG (3/5; theme 3a ‘opening up’).

I felt that my confidence grew you know as the weeks went by and I felt more comfortable you know at saying how I felt (Participant 6).

Non-recovered participants did not mention sharing their feelings in the group, and a few went on to describe the OWG as somewhere they or others had ‘held back’ (2/6; theme 3b).

I wanted to bring something up but I decided not to (Participant 8).

Theme 3: Doing for learning vs. reporting back. For participants who recovered, trying new things was often linked to better coping or personal learning (3/5; theme 3a ‘personal learning’).

I forget what I was worrying about but I said to myself this is a hyp-o-thetical worry and it stopped. They do still come back but I’m controlling it and it is happening less (Participant 9)

In contrast, non-recovered participants frequently described the importance of sharing achievements with the group (4/6; theme 3b ‘reporting back’).

I’ve done loads of things, and that’s been good cos each week we’ve gone back and reported what we’ve done (Participant 7).

Theme 4: Somatic changes. Lastly, for those that recovered, somatic changes were often apparent (3/5; theme 4).

It's less than it were because I don't have this errr, when the anxiety comes on it's like a quivering in my body (Participant 5).

Only one non-recovered participant mentioned having noticed physiological changes since treatment (1/6).

Qual-QUAN Findings

Quantitative analysis of change interview data found that participants reported an average of 1.91 positive changes at the end of OWG (*SD* = 0.94). Almost all changes observed (95%) were described as either 'somewhat' or 'extremely' unlikely without treatment. Observed changes were most frequently attributed to the following: learning about hypothetical worries (19% of changes), trying new things (19%), and general course content (19%). Over half of the observed changes (59%) were described by participants as 'very important'.

Triangulation of Mixed Findings

Table 14 displays convergence codes assigned to triangulated mixed method findings. Acceptability and feasibility findings were coded as 'confirmatory'. Initial efficacy (GAD symptoms) findings were coded as 'discrepant' for the likelihood of change without treatment, and 'confirmatory' for all other effectiveness findings. Mixed data convergence coding was not possible for initial effectiveness (depression symptoms) or durability findings given mono-method findings. Initial inter-rater reliably for convergence codes assigned was excellent, $\kappa = .88$ (CI_{95}: 0.64, 1.12), $p < .001$, and complete agreement on all nine codes was reached following discussion (Appendix W). Evidence for each code will be discussed further in the discussion.

Table 14

Triangulation of mixed method findings

Research question	Quantitative findings	Qualitative findings	QUAN-qual/QUAL-quan findings	Merged findings outcome[a]
Acceptability (mode of delivery)	Dropout rate (15%) Average attendance rate (87%)	Facilitator focus group theme 1 ('OK together')	None	Confirmatory: Convergent and complementarity
		Change interview themes 1 ('Enjoyable') and 2 ('Better in a group than expected')	None	
Acceptability (protocol content)	Average homework completion rate (73%), diary completed by 4/11 participants	Facilitator focus group themes 2 ('Drop the diary') and 3 ('Too much paperwork')	None	Confirmatory: Expansion
		Change interview theme 4 ('Not as expected') and 5 ('Why invent worries!')	None	
Feasibility	Average treatment integrity rating (94%)	Facilitator focus group themes 4 ('Familiar co-facilitator'), 5 ('Structure helps') and 6 ('Invisible research')	None	Confirmatory: Expansion
		Change interview theme 3 ('Supportive facilitators')	None	
Initial efficacy (GAD symptoms)	Significant baseline changes in GAD-7 scores ($z = -2.67$, $p = .08$)	None	Participants most commonly considered change to be 'somewhat unlikely' without treatment	Discrepant
Initial efficacy (GAD symptoms)	PSWQ recovery rates, baseline to end of treatment = 46%; large completer PSWQ pre-post effect size, $d = 2.59$	Facilitator focus group theme 8 ('Positive feedback')	Participant change interviews theme 4 (Somatic changes')	Confirmatory: Convergent and complementarity

Table 14 (continued)

Triangulation of mixed method findings

Research question	Quantitative Findings	Qualitative findings	QUAN-qual/QUAL-quan findings	Merged findings outcome[a]
Initial efficacy (Depression symptoms)	PHQ-9 clinical recovery rates at EOT = 50%, small-medium PHQ-9 effect size at EOT, *d* = 0.49	None	None	Discrepant
Durability (symptoms of GAD)	PSWQ recovery rates at FU = 70% Large PSWQ FU effect sizes, *d* = 2.82. No participants showed reliable or clinical deterioration in PSWQ scores from EOT to FU	None	None	Confirmatory: Convergent and complementarity
Durability (symptoms of depression)	PHQ-9 clinical improvement rates at FU = 33% ; medium PHQ-9 treatment effect sizes at FU: *d* = 0.55, one participant (1/10) showed reliable and clinical deterioration on the PHQ-9 at FU	None	None	Not codable
Change mechanisms	Significant change scores on IUS from baseline to the end of treatment, non-significant change scores from the end of treatment to follow-up on the IUS	Facilitator focus groups theme 7: 'Doing helps'	Most frequent attributions for change: Learning about hypothetical worries (19%), trying new things (19%), general OWG course content (19%). Participant change interviews themes 1 ('feeling different vs. identification'), 2 ('holding back vs. opening up')	Confirmatory: Convergent and expansion

Note. BL = baseline; EOT = end of treatment; FU = follow-up; GAD-7 = generalised anxiety disorder scale; PSWQ = Penn State Worry Questionnaire; PHQ-9 = Patient Health Questionnaire; IUS = Intolerance of Uncertainty Scale.

[a]Merged findings were assigned to one of four convergence codes: convergence and complementarity (in broad agreement and adds depth), convergence and complementarity (in broad agreement and adds breadth), discrepant (findings do not agree), and not codable (findings were mono-method and convergence coding therefore not possible).

Discussion

This study evaluated delivery of the Dugas and Roubichaud (2007) protocol for older adults with GAD in a group setting. An adapted protocol, the OWG, was pre-piloted to test for initial feasibility and acceptability. Following minor changes, the OWG was formally piloted to assess acceptability, feasibility, initial effectiveness, durability, and potential change mechanisms. There were four study hypotheses: (i) that there would be significant reductions in GAD symptoms following treatment, (ii) that treatment gains for GAD symptoms would be maintained over 8-week FU, (iii) that there would be improvements in depression symptoms post-treatment, and (iv) that depression treatment gains would show durability over FU.

Summary of Findings

Acceptability. OWG was an acceptable treatment. The opt-in rate (87%) was comparable to rates reported in trials of individual CBT for older adults with GAD (91%: Stanley et al., 2009; 93%: Stanley et al., 2014). In addition, the dropout rate (15%) was lower than previous studies of group CBT for older adults with GAD (26-39%: Stanley et al., 1996; Stanley et al., 2003; Wetherell et al., 2003). Feedback from participants and facilitators was confirmatory. Participants reported that they had enjoyed treatment and that being in a group had been better than expected. Facilitators commented that participants had appeared to benefit from being with one another for treatment. The two participants that dropped out cited health and family problems as their reasons for dropout, as opposed to factors pertaining to the acceptability of the group.

Rates of dropout (15%), attendance (87%), and homework completion (73%) suggested course content was generally acceptable. Qualitative findings were expansive, and indicated that the volume of paperwork, the daily diary, and the hypothetical worry exposure exercise were experienced as unhelpful by some

participants. Written tasks appeared to have been poorly received, which may have reflected cohort experiences of formal education (for example, as punitive) (Laidlaw, Thompson, & Gallagher-Thompson, 2004).

Feasibility. Treatment integrity ratings suggested that per protocol delivery was feasible. Facilitator feedback was confirmatory and also suggested that feasibility had been enhanced in two ways: delivery with a familiar co-facilitator and the structure of the protocol. Facilitators also reported that the research methodology had been feasible and unobtrusive, and that they felt unaware of which patients were in the research. This would appear to have reduced the risk of performance bias; differential treatment of patients on the basis of research participation status (Higgins & Green, 2011). Participants indicated that the approach of the facilitators (such as patience and openness to recapping) had increased the accessibility of the treatment protocol. Both psychologists had considerable experience in older adult services (8-17 years). A recent study by Stanley et al. (2014) found equivalent outcomes of CBT for older adults with GAD when delivered by paraprofessionals and experienced therapists. However, present findings appear to support the suggestion that geropsychology competence can increase the feasibility of CBT delivery with older adults (Karel, Gatz, & Smyer, 2012).

Initial efficacy (symptoms of GAD). As hypothesised (i), large completer and ITT effect sizes for symptoms of GAD were found post-treatment. PSWQ effect sizes herein exceeded effect sizes reported in previous trials of group CBT for older adults (*d* = 0.53-90: Stanley et al., 1996; Stanley et al., 2003; Wetherell et al., 2003), and immediately following treatment, 45% of participants met the recovery criteria for symptoms of worry. Facilitator feedback findings were complementary, and positive feedback from participants, family members, and multidisciplinary colleagues was reported. Encouragingly, no participants showed clinical and/or reliable deterioration for symptoms of worry (PSWQ) or anxiety (GAD-7) over the course of treatment.

Participant interview findings indicated that recovered participants were more likely to have noticed reduced somatic symptoms than those who did not recover. Donegan and Dugas (2012) found that following treatment with the Dugas and Roubichaud (2007) protocol, change in worry accounted for significant change in somatic symptoms, and vice-versa.

However, BL stability (GAD-7 scores) was not demonstrated for 6 out of 11 participants, thus for these individuals it was not possible to assert that change was a result of the intervention, and not time (Arntz et al., 2013). This was discrepant with participant change interview findings which found that for almost all participants change was described as being somewhat to extremely unlikely without the OWG.

Durability (symptoms of GAD). None of the participants showed significant deterioration in worry symptoms (PSWQ) over FU. This finding suggested durability of worry treatment gains, and provided support for study hypothesis (ii). Furthermore, GAD recovery rates increased over FU. Comparable remission rates (60-77%) have been reported for the delivery of the worry protocol to working aged adults, suggesting equivalence of treatment effects irrespective of age (Dugas & Roubichaud, 2007).

Comorbidity. In support of study hypothesis (iii), following treatment there was a significant overall improvement in participants' depression symptoms (PHQ-9). CBT targeting late-life GAD has commonly found to reduce symptoms of depression (Gorenstein et al., 2005; Stanley et al., 2003; Wetherell et al., 2003). Promisingly, the small-medium depression effect size observed herein was equivalent to that reported in a comparable practice-based trial of group CBT targeting mixed anxiety and depression (d = 0.40; Bains et al., 2014).

Mean change in depression symptoms (PHQ-9) was found was to have been non-significant over FU which suggested depression treatment gains were maintained for most participants, as per the final study hypothesis (iv). However, one (non-

recovered) participant showed clinically significant deterioration in depression (PHQ-9) and anxiety (GAD-7) symptoms during FU. Exploring reasons for positive and negative changes over FU (e.g. using the change interview at FU), could provide valuable insight into the durability of the protocol and guidance on relapse prevention.

Potential change mechanisms (GAD symptoms). IUS scores indicated significant positive change in participants' ability to tolerate uncertainty following treatment, and this converged with facilitator feedback that behavioural experiments were a helpful aspect of treatment. Convergence of mixed method findings, therefore suggested enhanced tolerance of uncertainty contributed to positive treatment gains. This finding is consistent with research that has demonstrated that improved tolerance of uncertainty mediated positive change in pathological worry following CBT for GAD in younger adults (Bomyea et al., 2015). Participant interview findings were expansive. For example, participants who recovered often linked trying new things to learning or development. In contrast, non-recovered participants more frequently linked trying new things to the importance of sharing achievements with the group. For some non-recovered participants, additional support to notice and assimilate learning from between-session tasks may have been beneficial (Glenn et al., 2013; Rees, McEvoy, & Nathan, 2005).

Clinical Implications

Large ITT treatment effects for symptoms of GAD were observed. This contrasts extant literature which has reported modest treatment effects for GAD in older adults (Gonçalves & Byrne, 2012). Group delivery of the Dugas and Roubichaud (2007) protocol therefore appears a promising approach for older adults with GAD. Given that older adults with GAD are found to prefer psychotherapy over medication, this is an important finding in relation to patient choice (Mohlman, 2012). Group delivery also presents implications for increasing the time and cost-effectiveness of

psychological interventions for older adults with GAD (McCrone et al., 2009). However, research has found that older adults with anxiety (aged 65-74 years) generally select individual over group therapy, therefore work to address preconceptions of group therapy is indicated (Mohlman, 2012; Morrison, 2001).

Findings suggest potential improvements to OWG. Low rates of diary completion alongside facilitator feedback indicated that it may be advisable to discard the daily diary and streamline handouts. The hypothetical worry exposure exercise was also poorly received, which suggests the OWG protocol needs to be amended to better prepare participants for this task (i.e. spend more time on the rationale). Further consideration of cohort factors (such as differing experience of education between participants and clinicians) may lead to increased protocol acceptability; as suggested in the Comprehensive Contextualization Framework (CCF; Laidlaw et al., 2004).

Lastly, small to medium, durable, treatment effects for depression symptoms have been demonstrated. This suggests that the protocol may be an effective treatment option for the estimated 28-60% of older adults with a diagnosis of GAD and comorbid depression (Parmalee, Katz, & Lawton, 1993; Porensky et al., 2009).

Theoretical Implications

Current findings suggest that the key target of the Dugas and Roubichaud (2007) protocol, intolerance of uncertainty, may be an important treatment target for older adults with GAD. Reviews have found that CBT for GAD may be less effective for older adults than for younger adults (Covin et al., 2008; Hall, 2016). However, this study has reported equivalent remission rates to those found for younger adults (Dugas et al., 2003). Findings suggest that older adults may not require unique psychotherapeutic treatment approaches for GAD (Wolitzy-Taylor et al., 2010). However, age-related modifications to existing CBT protocols appear advantageous (such as pacing and recaps) (Ayers et al., 2007).

Effect sizes obtained were greater than those found in a case series study (n = 8) of the individual delivery of the worry protocol (Ladouceur et al., 2004). Facilitator and participant feedback suggested that the non-specific benefits of group therapy, such as reduced social isolation and peer support, may have been important (Krishna et al., 2010; Lewinsohn & Clarke, 1999; Morrison, 2001; Yalom & Leszcz, 2005).

Methodological Limitations

There were a number of study limitations that should be considered. Whilst the small sample size limits generalisability of findings, the sample size was appropriate to study aims. This evaluation has been consistent with stage 1 of the hourglass model for the development of new/newly adapted therapies (Salkovskis, 1995).

A number of the weaknesses of this study reflect the methodological compromises of conducting practice-based outcome research (Barkham & Margison, 2007). For example, BL data was not collected on more than two occasions for any of the measures (except the GAD-7). This reduces confidence in the changes observed being directly attributable to OWG, as three stable BL observations are required to control for the confounding effect of time on treatment outcomes (Tate et al., 2008). As participants attended different groups, this also reduces comparability of phases, as participants were exposed to different group climates (Lo Coco, Gullo, Lo Verso, & Kivlighan, 2013). However, potential between-group variability was reduced where possible (e.g. both groups had the same facilitators, setting and were held at the same time of the day).

Instability of mean baseline data (GAD-7) reduced confidence in conclusions with respect to the role of the OWG in change scores observed. However, this finding was in contrast with change interview data that suggested that almost all the participants considered change was ‘somewhat to extremely unlikely’ without OWG. One reason for this discrepancy may have been that the last baseline data point was

immediately prior to the first group treatment session. Yalom and Leszcz (2005) suggested a key factor in group therapy can be 'universality', and it may have been that for some participants the prospect of seeing other older adults with GAD offered hope, which in turn reduced outcome scores (Gum, Synder, & Duncan, 2006; Synder et al., 1991). Also, durability and initial efficacy (for depression symptoms) findings were mono-method, which meant it was not possible to assess mixed method convergence, reducing the reliability and validity of these findings.

Participants were young-old (average age of 73 years), as is common in CBT trials for GAD in older adults (Hall, 2016). Laidlaw and Kishita (2015) propose that the oldest-old (individuals in their 8^{th} and 9^{th} decade) may have more complex health comorbidities, and intergenerational structures, that need to be accounted for in adapted CBT protocols. In line with this, the oldest OWG participant (aged 92 years) dropped out due to poor health. Trial findings may therefore not generalise easily to the increasing numbers of oldest-old presenting to services (Laidlaw & Kishita, 2015).

Future Research

A pilot RCT is indicated in order to assess the efficacy and cost-effectiveness of OWG. An active comparison group is recommended, as passive controls can inflate treatment effects (Mohr et al., 2009). As FU was relatively short, future trials are encouraged to include a longer FU period to examine durability of treatment effects more comprehensively. Researchers should consider pluralistic measures to strengthen the validity and reliability of psychotherapy outcome assessments such as proxy ratings (clinician and/or significant others), or magnetic resonance imaging scanning which has been used to detect successful pharmacological treatment of GAD in older adults (Andreesccu et al., 2015; Brown & Barlow, 2014; Ketter, 2010; Steel, Geller, & Carr, 2005). Evidence has suggested intolerance of uncertainty may play a role in the etiology and maintenance of a range of emotional disorders (including GAD and

depression; Boswell et al., 2013). Application of the Dugas and Roubichaud (2007) protocol, which targets intolerance of uncertainty, led to significant reductions in levels of intolerance of uncertainty, worry, and depression. Future studies should examine the potential role of intolerance of uncertainty as a mediator of transdiagnostic treatment gains following delivery of the Dugas and Roubichaud protocol (Bomyea et al., 2015).

Conclusions

This study suggests group delivery of the Dugas and Roubichaud (2007) worry protocol is an acceptable and feasible treatment option for older adults with GAD. In comparison to previous trials of group CBT for older adults with GAD, large treatment effects at the end of treatment and at follow-up were found. Change mechanism findings suggest that addressing intolerance of uncertainty may have enabled change in chronic worry. The protocol shows real promise as a treatment for GAD in older age and further controlled studies against active treatments are warranted.

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Appendices

Appendix E. Ethical Approval for Research Study

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - South Yorkshire
Unit 001
Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone: 0191 4283563

17 April 2015

Miss Josephine Hall
Clinical Psychology Unit
Department of Psychology
The University of Sheffield
Western Bank
Sheffield S10 2TN

Dear Miss Hall

Study title:	**Group Cognitive-Behavioural Therapy (CBT) for Generalized Anxiety Disorder (GAD) in Older Adults: A Pilot Case Series Study. Version One.**
REC reference:	**15/YH/0137**
IRAS project ID:	**177057**

Thank you for your letter of 6 April 2015, responding to the Committee's request for further information on the above research [and submitting revised documentation].

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Helen Wilson, nrescommittee.yorkandhumber-southyorks@nhs.net . Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

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

Appendix E. Ethical Approval for Research Study (continued)

Conditions of the favourable opinion

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

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

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

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

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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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

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

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

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

Ethical review of research sites

NHS sites

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

Appendix E. Ethical Approval for Research Study (continued)

Approved documents

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

Document	*Version*	*Date*
Covering letter on headed paper	2	06 April 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of Sheffield University Insurance]	1	04 March 2015
Interview schedules or topic guides for participants [Completer Change Interview Schedule]	1	13 March 2015
Interview schedules or topic guides for participants [Dropout Interview Schedule]	1	13 March 2015
Interview schedules or topic guides for participants [Facilitator Focus Groups Interview Schedule]	1	13 March 2015
Interview schedules or topic guides for participants [Feedback Form]	2	06 April 2015
IRAS Checklist XML [Checklist_17032015]		17 March 2015
Letter from sponsor [Letter from University of Sheffield, Sponsor]	1	26 February 2015
Letter from statistician [Letter from Statisician, University of Sheffield]	1	26 February 2015
Letters of invitation to participant	2	06 April 2015
Non-validated questionnaire [Why Worry Daily Diary]	1	13 March 2015
Other [Consent form for tape recording]	1	13 March 2015
Other [End of Therapy Interview Consent Form]	2	06 April 2015
Participant consent form	2	06 April 2015
Participant information sheet (PIS)	2	06 April 2015
REC Application Form [REC_Form_15042015]		15 April 2015
Referee's report or other scientific critique report [Scientific Critique Report]	1	26 February 2015
Research protocol or project proposal	7	06 April 2015
Summary CV for Chief Investigator (CI) [Jo Hall's Brief CV]	1	03 March 2015
Summary CV for student [Jo Hall's Brief CV]		
Summary CV for supervisor (student research) [Steve Kellett brief CV]	1	03 March 2015
Summary, synopsis or diagram (flowchart) of protocol in non-technical language	2	06 April 2015
Validated questionnaire [PHQ-9]	1	02 March 2015
Validated questionnaire [Intolerance of Uncertainty Scale]	1	03 March 2015
Validated questionnaire [GAD-7]	1	03 March 2015

Statement of compliance

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

Appendix E. Ethical Approval for Research Study (continued)

After ethical review

Reporting requirements

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

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

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

User Feedback

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

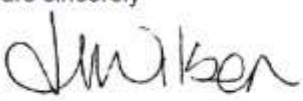
HRA Training

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

15/YH/0137	**Please quote this number on all correspondence**

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

Yours sincerely



pp

Dr Ian Woollands
Chair

Email: nrescommittee.yorkandhumber-southyorks@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Dr Andrew Thompson, The University of Sheffield

Mr Daniel Last, Sheffield Health and Social Care, Research Development Unit

Appendix F. Trust Approval for Study

Sheffield City Council

Sheffield Health and Social Care NHS

NHS Foundation Trust

Medical Directorate
Research Development Unit
Fulwood House
Old Fulwood Road
Sheffield
S10 3TH

Tel: 0114 2718804
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E-mail: rdu@shsc.nhs.uk
www.shsc.nhs.uk

24th April 2015

Miss Josephine Hall
Clinical Psychology Unit
Department of Psychology
Western Bank
Sheffield
S10 2TN

Dear Miss Hall

RDU ID:	**ZQ13**
Full Project Title:	**Group Cognitive-Behavioural Therapy (CBT) for Generalized Anxiety Disorder (GAD) in Older Adults: A Pilot Case Series Study. Version One**
REC No:	**15/YH/0137**

I can confirm on behalf of Sheffield Health and Social Care NHS Foundation Trust that you now have **NHS Permission to start research within that Trust.**

We also advise you of the following conditions and guidance:

1. **We are required to report on and request that you notify us of the following (as soon as they are available);**
   - **The actual start date of the study and an estimated end date**
   - **The date of the first participant's first visit**
   - **The date of the last participant's first visit**
   - **The date of the last participant's last visit**
   - **The actual end date of the study**
2. The study is to be conducted in accordance with the Research Governance Framework.
3. A favourable opinion must have been given by the REC
4. All amendments (including changes to the local research team) need to be submitted in accordance with guidance in IRAS. Please also notify us of any changes to the status of your project.
5. Please note that the NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by selected audit of research, usually chosen randomly.
6. We recommend the enclosed documents for maintenance of your project site file to ensure all documentation is readily accessible for our audit.
7. Permission has been granted based on the following documentation:
   Jo_Hall_NhsRdForm_ReadyForSubmission.pdf 77057/770325/14/56
   Jo_Hall_NhsSsiForm_ReadyForSubmission.pdf 177057/770327/6/224/280646/321871
   Research_Protocol.docx
   Consent_form1.docx
   Consent_recording.docx
   Covering_letter.docx

Appendix G. Confirmation of University Approval and Sponsorship

The University Of Sheffield.

Research & Innovation Services.

Research & Innovation Services
New Spring House
231 Glossop Road
Sheffield
S10 2GW

Ms J Hall
Clinical Psychology Unit
C/o Ian MacDonald

Telephone: +44 (0) 114 222 1400
Email: c.wynn@sheffield.ac.uk

24th April 2015

Project title and URMS number:
Group Cognitive Behavioural Therapy for Generalised Anxiety Disorder in older adults. A Pilot Case Series Study
URMS 143818

Dear Ms Hall,

LETTER TO CONFIRM THAT THE UNIVERSITY OF SHEFFIELD IS THE HUMAN INTERVENTIONA STUDY'S RESEARCH GOVERNANCE SPONSOR

As you are aware, as a University-sponsored human-interventional study the study was subject to the University's risk assessment procedure, and your support in facilitating the procedure by completing the checklist is appreciated. The outcome of the risk assessment procedure is that the University has categorised the study as being low risk. As a result of this, an independent clinical trials assessment (ICTA) team, which includes University academics with clinical trials expertise, will:

- meet periodically with your Head of Department in order to verify that the Chief Investigators of clinical trials that have been categorised as potentially low risk (including this trial) are adhering to the self-certification statements that they signed. Therefore, I would be very grateful if you could ***sign and date the enclosed self-certification statement at Annex 2 and arrange for your Head of Department to countersign it. The form should then be returned to Catherine Wynn in Research and Innovation Services. Once this form is signed and returned, the trial will be authorised to commence.***

The ICTA team expects to find that the study has in place present and effective systems and practices for a) safeguarding the dignity, rights, safety & well-being of participants recruited to the study and b) for ensuring the validity of the data collected, analysed, recorded and reported. The ICTA team intends to work in a spirit of cooperation and its approach will be guided by pragmatism and proportionality.

Research and Innovation Services has reviewed documents which confirm that the study has been scientifically approved and ethically approved. Accordingly, once the self-certification statement has been signed and returned, as the trial's research governance sponsor the University will authorise the trial to start. You are expected to deliver the study in accordance with the University's policies and procedures, which includes the University's Good Research and Innovation Practices Policy: www.shef.ac.uk/ris/other/gov-ethics/grippolicy. Should your study have been ethically approved via

Appendix G. Confirmation of University Approval and Sponsorship (continued)

the NHS National Research Ethics Service (NRES) then you need to register the trial in a publicly accessible trial register.

As the Chief Investigator you are responsible for monitoring the study on an ongoing basis. Your Head of Department is responsible for independently monitoring the study as appropriate. The monitoring responsibilities are listed at **Annex 1**.

Yours sincerely

cc. Head of Department
Professor Paul Overton

cc. Supervisor
Dr S Kellett

Appendix H. Participant information sheet

The University Of Sheffield.

Sheffield Health and Social Care NHS

NHS Foundation Trust

The Overcoming Worry Group Research Study

Information Sheet

We would like to know whether the Overcoming Worry Group we run is helpful. This will mean services can adapt in the future and improve what is offered to be what is needed. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Thank you for reading this.

"Why do this study?"

The study aims to find out what type of help is useful for people over the age of 65 living with excessive worry. This study will help us ensure the service we provide is appropriate for you and others. This is a preliminary study to look at what is helpful before any future research in this area is planned.

"Why have I been chosen for this study?"

You have been identified as someone who may benefit from attending the Overcoming Worry Group.

"Does taking part in this study this affect my other care, for example my medication or other appointments?"

No. Everything continues as usual.

"Do I have to take part in the study?"

No. Taking part is completely voluntary. Your healthcare will not be affected in any way if you decide to not take part. If you decide to take part you will be given this information sheet to keep (and be asked to sign a consent form).

"What if I change my mind?"

You can withdraw at any time from the research without it affecting any of your care. You do not have to give a reason. If you decide to leave the research project before the end of the project, you will be offered the chance to give us feedback in writing on your decision. This would be voluntary, and if you decide not to give us feedback this will not affect the rest of your healthcare in anyway.

"What does taking part in the study involve?"

You will be asked to complete a brief daily worry diary, and some questionnaires about your mental health difficulties. We can give you as much help as you need to fill these in. You will be asked to complete the questionnaires a number of times over the course of the study, we will let you know each time you need to complete them. At the end of the study you will be invited to take part in an end of therapy interview to tell us how you have found the Overcoming Worry Group that will be recorded using an encrypted digital recorder. This will be entirely voluntary.

Appendix H. Patient information sheet (continued)

The University Of Sheffield.

Sheffield Health and Social Care NHS

NHS Foundation Trust

You will be given a separate consent form for this decision, at the end of the Overcoming Worry Group.

"What are the benefits, and possible risks, of taking part in this study?"

You can attend the Overcoming Worry Group regardless of whether you decide to take part in this study. If you do take part in the study, it will help give us some important information about how our services can be improved. We do not anticipate that there will be any risks from taking part, although some of the questionnaires may ask you to think about your worry, and you may find this upsetting. In line with Trust Policy, in the event that any issues that require further action become apparent, the appropriate Safeguarding Adults Team will be contacted.

"Will the information collected in the study be confidential?"

Yes, all information collected will be stored anonymously, and confidentially, and kept in a secure locked setting. Your name and personal information will not be mentioned in any reports arising from the study.

"What will happen to the results of the study?"

When we have collected all the results for this study we will analyse them, and then publish the results. We will also send you a summary of the research findings. You will not be identified in any publications.

"What will happen to my data after the study is finished?"

When the study is finished all personal data will be destroyed, including any digital recordings which will be deleted.

"Who has reviewed the study?"

The study has been reviewed and given favourable opinion by Sheffield Health and Social Care Trust NHS Research Ethics Committee and the University of Sheffield Clinical Psychology Ethics Committee.

"What if I have further questions?"

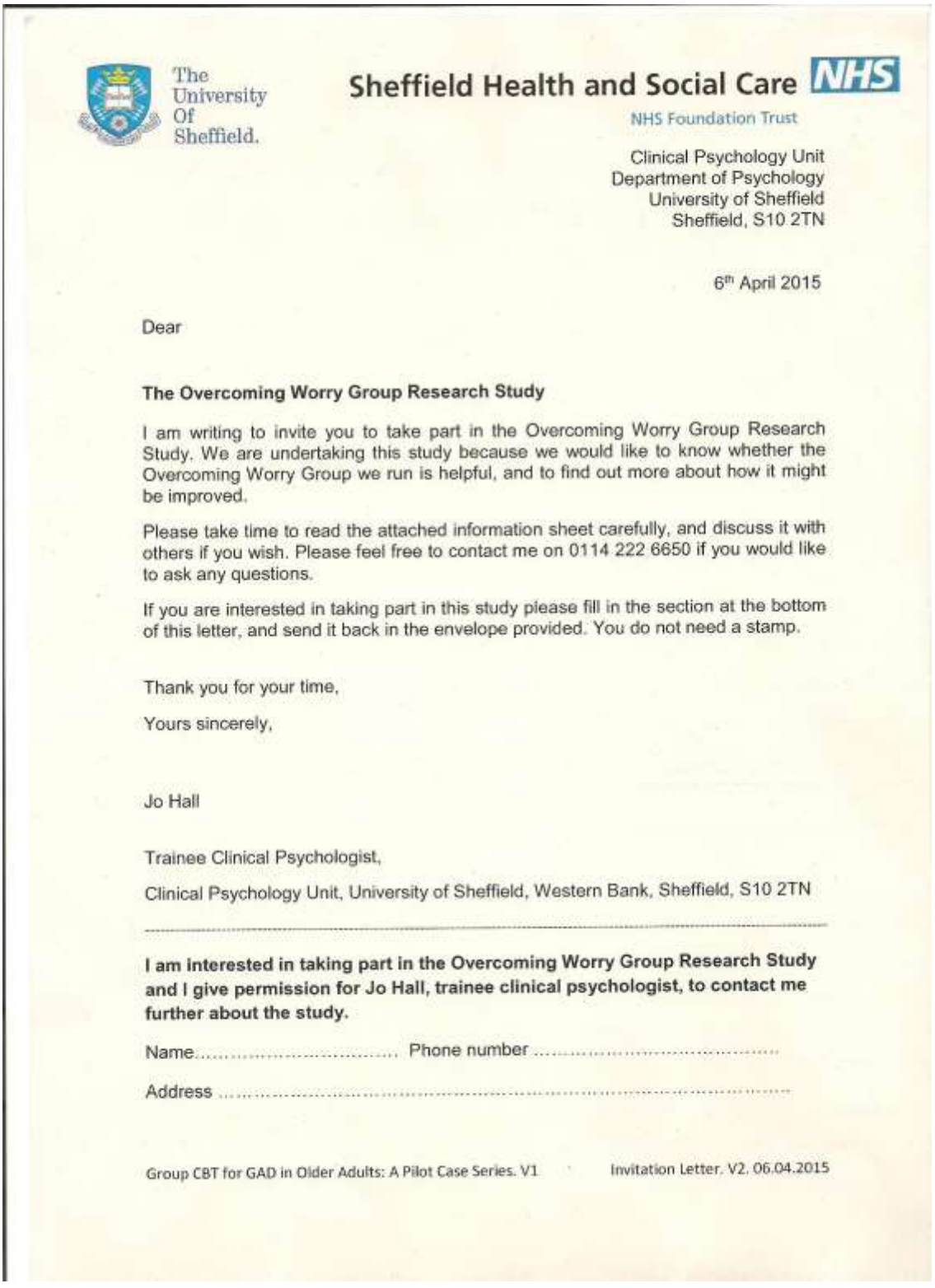
Please call 0114 2226650 and leave a message for Jo Hall, trainee Clinical Psychologist and Chief Investigator, who will call you back as soon as possible.

"What if something goes wrong?"

This study is being sponsored and indemnified by the University of Sheffield. Please initially contact Jo Hall, chief investigator on 0114 2226650. If you feel your concerns are not being dealt with, you can contact the University's 'Registrar and Secretary', Dr Philip Harvey. He can be contacted at the following address: Dr Philip Harvey, The Registrar and Secretary's Office, University of Sheffield, Firth Court, Western Bank, Sheffield S10 2TN, UK.

Thank you for taking the time to read this information. 6th April 2015. Version 2.

Appendix I. Expression of Interest Form



The University Of Sheffield.

Sheffield Health and Social Care NHS

NHS Foundation Trust

Clinical Psychology Unit
Department of Psychology
University of Sheffield
Sheffield, S10 2TN

6th April 2015

Dear

The Overcoming Worry Group Research Study

I am writing to invite you to take part in the Overcoming Worry Group Research Study. We are undertaking this study because we would like to know whether the Overcoming Worry Group we run is helpful, and to find out more about how it might be improved.

Please take time to read the attached information sheet carefully, and discuss it with others if you wish. Please feel free to contact me on 0114 222 6650 if you would like to ask any questions.

If you are interested in taking part in this study please fill in the section at the bottom of this letter, and send it back in the envelope provided. You do not need a stamp.

Thank you for your time,

Yours sincerely,

Jo Hall

Trainee Clinical Psychologist,

Clinical Psychology Unit, University of Sheffield, Western Bank, Sheffield, S10 2TN

I am interested in taking part in the Overcoming Worry Group Research Study and I give permission for Jo Hall, trainee clinical psychologist, to contact me further about the study.

Name..... Phone number .....

Address .....

Group CBT for GAD in Older Adults: A Pilot Case Series. V1 Invitation Letter. V2. 06.04.2015

Appendix J. Consent Form

The University Of Sheffield.

Sheffield Health and Social Care NHS
NHS Foundation Trust

The Overcoming Worry Group Research Study

Consent Form

Name of Researcher: Jo Hall Participant Identification Number:

Please tick box

1. I confirm that I have read and understand the information sheet dated 6th April 2015, version 2, for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline. ☐
3. I understand that my responses will be kept strictly confidential. ☐
4. I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research. ☐
5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
6. I agree for the data collected from me to be used in future research. ☐
7. I agree to take part in the above research project. ☐

Name of Participant	Date	Signature

To be signed and dated in presence of the participant

Jo Hall, Lead Researcher	Date	Signature

Appendix K. Penn State Worry Questionnaire

(PSWQ: Meyer, Miller, Metzger, & Borkovec, 1990)

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Appendix L. Generalised anxiety disorder scale

(GAD-7: Spitzer, Kroenke, Williams, & Löwe, 2006)

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Appendix M. Patient Health Questionnaire

(PHQ-9: Spitzer, Kroenke, & Williams, 1999)

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Appendix N. Daily Worry Diary

My Worry Diary

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Appendix O. Intolerance of Uncertainty Scale (IUS: Freeston et al., 1994)

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Appendix P. Change Interview Protocol

(Elliott, Slatick, & Urman, 2001).

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Appendix P. Change Interview Protocol
(continued; Elliott, Slatick, & Urman, 2001)

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Appendix P. Change Interview Protocol
(continued; Elliott, Slatick, & Urman, 2001)

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Appendix P. Change Interview Protocol
(continued; Elliott, Slatick, & Urman, 2001)

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Appendix Q. Treatment Integrity Checklist
(continued; Hepner et al., 2011)

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(continued; Hepner et al., 2011)

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Appendix Q. Treatment Integrity Checklist
(continued; Hepner et al., 2011)

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Appendix Q. Treatment Integrity Checklist
(continued; Hepner et al., 2011)

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Appendix Q. Treatment Integrity Checklist
(continued; Hepner et al., 2011)

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Appendix R. Dropout Feedback Form

The University Of Sheffield.

Sheffield Health and Social Care NHS
NHS Foundation Trust

Clinical Psychology Unit
Department of Psychology
University of Sheffield
Sheffield, S10 2TN

Date

Dear

Feedback Form: The Overcoming Worry Group and Research Study

I understand that you have made a decision to leave the Overcoming Worry Group/ Research Project (will be deleted as appropriate). I am writing to find out more about the reasons for your decision, in order that we can improve the Overcoming Worry Group Research Project.

Your feedback is completely voluntary, your healthcare will not be affected in any way if you decide not to complete all, or some, of the questions attached. If you would like to discuss this letter, or the research project, with me over the telephone I am very happy to arrange this with you. Please contact me on 0114 2226650, and leave a message to be contacted back.

I would like to take this opportunity to thank you for your time,

Yours Sincerely,

Jo Hall

Trainee Clinical Psychologist

Clinical Psychology Unit, University of Sheffield

Western Bank, Sheffield, S10 2TN

Appendix R. Dropout Feedback Form (continued)

The University Of Sheffield.

Sheffield Health and Social Care NHS
NHS Foundation Trust

Feedback Questions about the Overcoming Worry Group and Research Study

1. What were your main reasons for leaving the Overcoming Worry Group/ Research Project?

2. What (if anything) would have made it easier for you to stay in the Overcoming Worry Group/Research Project? (For example, if the group was held at a different time of the day would that have been better for you?)

3. What was your experience of the Overcoming Worry Group whilst you attended?

4. What was your experience of the research element of the Overcoming Group? (completing the forms and questionnaires)

Appendix R. Dropout Feedback Form (continued)

The University Of Sheffield.

Sheffield Health and Social Care NHS

NHS Foundation Trust

5. What sessions or topics in the Overcoming Worry Group were most and least helpful to you?

6. Thinking about how you were before your started the overcoming Worry group and how you are now, do you notice any changes since you have been attended the group?

7. Thank you for all your answers, is there anything else you would like to add to any of your previous answers?

Thank you for your time

Please send us back this form in the envelope attached.
You do not need a stamp

Appendix S. Consent Form for End of Therapy Interview

The University Of Sheffield.

Sheffield Health and Social Care NHS
NHS Foundation Trust

The Overcoming Worry Group Research Study

End of Therapy Interview Consent Form

Name of Researcher: Jo Hall Participant Identification Number:

Please tick box

1. I confirm that I have re-read and understand the information sheet dated 6th April 2015 version 2, for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐
2. I understand that my participation in an end of therapy interview is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question, or questions, I am free to decline. ☐
3. I understand that my responses will be kept strictly confidential, and stored securely at all times. ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
5. I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research. ☐
6. I agree for the data collected from me to be used in future research. ☐
7. I agree to take part in an end of therapy interview. ☐
8. I agree to have my end of therapy interview recorded on an encrypted digital recorder. ☐

_____	_____	_____
Name of Participant	Date	Signature

To be signed and dated in presence of the participant

_____	_____	_____
Jo Hall, Lead Researcher	Date	Signature

Appendix T. Facilitator Focus Group Schedule

Introduction

- Welcome
- I am holding this focus group to get an idea of the feasibility and initial of the OWG and research.
- I will be recording today, I will be transcribing the data and analysing it. I will be transcribing the data and analysing it. I may use quotes in the report, but these will be anonymised and personally identifiable information will not be included in any reports written.

I am going to ask you some structured questions about the intervention and the research element of the project to start with, and then finish with a more general discussion at the end.

1. What was your experience of facilitating/observing the OWG?
   - How did you find the content of the OWG was to deliver?
   - How easy/difficult was it to stick to the content of the OWG?
   - How did the content of the OWG seem to fit with the groups' difficulties?
   - Was there anything that helped you to facilitate the OWG?
   - In what ways did the OWG seem to help/or not help the participants?
   - Did you receive any feedback (positive/negative) about the OWG that was particularly memorable? Can you give some specific examples?
   - What do you think could have made the group more feasible to facilitate?

2. What was your experience of the supporting the research element of the group?
   - How easy/difficult was it to support the research part of the OWG?
   - Was there anything that helped you to facilitate the research part of the OWG?
   - Did you receive any feedback (positive/negative) about the research part of OWG that was particularly memorable? Can you give some specific examples?
   - What do you think could have improved the feasibility of the research element of the OWG?

3. Thank you for all your answers, is there anything else you would like to add to any of your previous answers? Or any other thoughts you have had whilst we have been discussing the group?

Appendix U. Example Treatment Manual

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Appendix V. Interrater Reliability Data for Change Interview Data

Rater Crosstabulation

Count

Code identified		Rater 2				
		3.00	4.00	5.00	5.50	Total
Rater 1	3.00	6	0	0	0	6
	4.00	0	4	0	0	4
	5.00	0	0	3	1	4
	5.50	0	0	2	0	2
Total		6	4	5	1	16

Symmetric Measures

		Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Measure of Agreement	Kappa	.736	.128	4.797	.000
N of Valid Cases		16			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

Appendix W. Interrater Reliability Data for Convergence Codes

Rater Crosstabulation

Count

		Rater 2				
		1.00	2.00	3.00	4.00	Total
Rater1	1.00	3	0	0	0	3
	2.00	0	1	1	0	2
	3.00	0	0	2	0	2
	4.00	0	0	0	4	4
Total		3	1	3	4	11

Symmetric Measures

		Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Measure of Agreement	Kappa	.875	.115	4.929	.000
N of Valid Cases		11			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.