**Abstract**

*Background:* A recent trial has shown that a 6-week one-to-one cognitive behavioural therapy (CBT) intervention targeting worry significantly reduces both worry and persecutory delusions. Whether this intervention can be delivered effectively in a group format is unknown.

*Aim:* To conduct a small feasibility study of a group adaptation of the worry intervention within adult community mental health services to inform the next stage of trial development.

*Method:* Over four months,13 participants with persecutory delusions were randomised to a weekly 8-session worry intervention group (WG, n=7) or waiting list control (CG, n=6). Group content was adapted from the individual CBT protocol used in the Worry Intervention Trial. Unblind assessments were at 0, 8 and 12 weeks. Feasibility outcomes assessed recruitment, retention, and therapy uptake. Efficacy outcomes were the Penn State Worry Questionnaire, Psychotic Symptom Rating Scale, and Green Paranoid Thoughts Scale at week 8. Linear mixed effects models were used to estimate treatment effects with 95% confidence intervals.

*Results:*  All participants in the WG completed treatment (mean sessions attended = 5.7, SD 1.3). Twelve participants completed measures at 8 weeks; all did so at 12 weeks. Compared to CG, WG led to improvements in worry (adjusted mean difference -6.0; 95% CI -15.4, 3.4) and delusions (adjusted mean difference -2.2; 95% CI -9.4, 5.1) at week 8.

*Conclusions:* Recruitment, retention and therapy uptake were feasible. Observed treatment effects were in the expected direction, but may be diluted in comparison to individually delivered interventions. A full pilot randomised control trial (RCT) with additional resources may be warranted.

**Key words:** cognitive behavioural group therapy; worry intervention; persecutory delusions.

**Introduction**

Persecutory delusions are erroneous beliefs held by individuals that others intend to cause them harm (Freeman & Garety, 2000). They are the second most common psychotic experience, occurring in almost 50% of those first attending services with non-affective psychosis diagnoses (Sartorius et al., 1986). The personal costs are high; believing others intend to cause one harm can lead to social isolation, heightened distress, and reduced quality of life (Freeman, 2016). Furthermore, the financial costs are significant and the annual cost to the public sector of schizophrenia alone is £7.2 billion in England (Andrew, Knapp, McCrone, Parsonage, & Trachtenberg, 2012).

Traditionally, approaches to the treatment of psychosis have adopted a diagnostic approach (for example focusing on ‘schizophrenia’ ), but these have yielded only modest effects (Leucht et al., 2013; Wykes, Steel, Everitt, & Tarrier, 2008). Factor analytic studies and those investigating the relative genetic and environmental contributions to specific psychotic experiences (Ronald et al., 2014; Zavos et al., 2014) have evidenced the independence of such experiences, including persecutory delusions. This has resulted in calls to develop models and targeted treatments for individual psychotic experiences.

Freeman (2016) provides a specific cognitive model of persecutory delusions, identifying six key evidence-based maintenance factors: worry, negative self-beliefs, anomalous experiences, sleep dysfunction, reasoning biases, and safety behaviours. A series of studies have shown that targeting each of these factors individually is beneficial (Foster, Startup, Potts, & Freeman, 2010; Freeman et al., 2014; Freeman, Bradley, Antley, et al., 2016; Freeman, Dunn, et al., 2015; Freeman, Waite, et al., 2015b; Waller et al., 2013). Amongst these, the most robust evidence to date relates to worry.

Worry has been found to predict the onset of persecutory thinking (Freeman et al., 2008; Freeman et al., 2012), to be associated with delusional distress (Freeman & Garety, 1999; Morrison & Wells, 2007), and to predict the maintenance of persecutory delusions (Startup, Freeman, & Garety, 2007; Vorontsova, Garety, & Freeman, 2013). A large scale RCT (The Worry Intervention Trial, WIT, Freeman, Dunn, et al., 2015), demonstrated that six sessions of individual cognitive behavioural therapy (CBT) targeting worry led to significant improvements in both worry (effect size, Cohen’s d = 0.5) and persecutory delusions (effect size, Cohen’s d = 0.5). Two-thirds of the change in delusions was accounted for by changes in worry. This trial indicates that worry is a contributory causal factor in persecutory delusions that is amenable to change. The worry intervention was provided with ‘high intensity’, including frequent therapist contact by telephone and email between sessions, and active learning with the therapist using behavioural tests.

There has been increasing interest in group-based cognitive therapies for psychosis in recent years. It has been argued that group processes may provide a normalising and destigmatising environment, and allowing learning from, and help of, others (Newton, Larkin, Melhuish, & Wykes, 2007). The questions as to whether they could also be a more cost-effective option than individual therapies, and the implications this would have for NHS clinical guidelines and commissioners, has also been raised (Guaiana, Morelli Anna, & Chiodo, 2012; Owen, Sellwood, Kan, Murray, & Sarsam, 2015). However, there is evidence to suggest that the clinical effectiveness of group-based CBT interventions for psychosis may be lower than one-to-one formats (Barrowclough et al., 2006).

The current study was a small feasibility RCT conducted within routine clinical practice. The WIT intervention has not previously been delivered in a group format and the aim was to adapt the original manual for this purpose, and test it in a group setting, to inform the potential next stages of trial development. Primary outcomes were recruitment rates, retention, and therapy uptake. A secondary aim was to have a preliminary inspection of possible effects and confidence intervals, expecting that the worry intervention group would show evidence of a greater reduction in worry and persecutory delusions than the control group.

**Methods**

*Study design and participants*

This waiting list controlled non-blind feasibility RCT tested an 8-week worry intervention group plus standard care versus standard care alone. Participants were adults recruited from two Recovery Teams (RT) and an Assertive Outreach and Rehabilitation Support Team (AORT) in Oxleas NHS Foundation Trust.

Inclusion criteria were: aged 18-65 years; presence of a current persecutory delusion (as defined by Freeman & Garety, 2000) which had persisted for at least 6 months; current schizophrenia-spectrum diagnosis; a clinically significant level of worry as indicated by a score of 45 or more on the Penn State Worry Questionnaire (Behar, Alcaine, Zuellig, & Borkovec, 2003). Exclusion criteria were: a primary diagnosis of alcohol or substance dependency; organic syndrome or learning disability; a command of spoken English inadequate for engaging in psychological therapy; lacking capacity to give informed consent; or currently experiencing acute symptomatic distress requiring hospital admission. Recruitment was conducted by trial therapists who are both qualified clinical psychologists (LI and AM). Potential participants were approached by a member of their care team to ask whether they would be willing to meet with a trial therapist to discuss the study. Screening appointments were conducted to check for the main eligibility criteria (current persecutory delusion and clinically significant worry) and to provide potential participants with the information sheet. Written informed consent was taken. Half a day per week of clinician time was dedicated to recruitment activities.

Ethical approval for the study was given by the NHS Health Research Authority NRES Committee London – London Bridge (14/LO/2055). The trial was registered (ISRCTN11422802). The study was conducted within routine clinical practice by psychologists working within the adult mental health services, and hence funded by Oxleas NHS Foundation Trust.

*Randomisation*

Once sufficient numbers were recruited for two groups, participants were randomly allocated to either the first worry group (WG), commencing two weeks after randomisation, or a delayed start group (wait-list control; CG), starting fourteen weeks after randomisation. This allowed for an 8-week treatment phase, and a 4-week follow-up period before the second group commenced.

Randomisation was conducted using a web-based ‘Research Randomiser’ tool. Due to the small scale, in-service nature of the study, assessors were the trial therapists and hence not blind to the allocation of condition.

*Procedure*

In the week prior to each group starting, group members were invited to attend an informal coffee morning to meet one another, which aimed to reduce anxiety, and facilitate the collection of baseline measures. The group intervention comprised eight weekly group sessions, each lasting 1.5 hours. These sessions took place at an adult mental health team base. The group content was adapted from the individual treatment manual used in the WIT trial. The main components used in that trial were: psychoeducation about worry; identification and reviewing of positive and negative beliefs about worry; increasing awareness of the initiation of worry and individual triggers; formulation of a ‘worry cycle’; use of ‘worry periods’; planning activity at times of worry (which could include relaxation) and learning to ‘let go of worry’ which utilised an emotional processing and meta-cognitive awareness (EPMA) technique.

In the present study a key adaptation was to extend the therapy window to eight sessions delivered across consecutive weeks (in the original WIT trial the mean number of sessions was 5.5 delivered on an individual basis). This extension was to allow time for group processes such as icebreaking and setting ground rules, and to ensure that all participants understood key ideas and had the opportunity to contribute to group discussions. The original WIT manuals were adapted for use in the group and sessions utilised Powerpoint (showing adapted manual content), group discussion and group exercises. Paper versions of the Powerpoint slides and an adapted version of the WIT manual were given to participants.

Although most of the components outlined above were included in the group, some specific techniques were not suitable for use in a group setting and therefore were adapted or excluded. For example, in the original trial individualised ‘safe space’ images were developed with some participants as part of the ‘learning to let go of worry’ component. In the group setting, it was not possible to develop detailed verbal descriptions of individual images with each participant. Instead art materials were used to develop a visual ‘safe space’ image. In the original WIT trial an EPMA technique was used with some participants. This involves a participant recounting a recent specific incident of worry in the first person present tense, in order to access the full network of the fear structure to allow it to be more fully processed. EPMA was not used in the present study as it can be an emotionally intense and highly personal experience and it was not considered appropriate to do this in a group context.

As in the WIT trial, alongside the weekly meetings, group facilitators had between session contact with participants to provide support and encouragement in the application of techniques. This was negotiated and revised on an individual basis and included the use of phone calls, text messages and/or postcards.

The worry intervention group was delivered by two clinical psychologists (WG: LI and AM; CG: AM and NS) and supported by a psychology assistant (HG). Supervision was provided by a trial therapist from the original WIT study (KP). Adherence to a therapy manual and therapist competence were not formally assessed.

After the end of the study, once both groups had been offered the worry intervention group, participants were invited back to focus groups to give their feedback on the experience. These were facilitated by SP, a member of ResearchNet which is a network of co-production based research groups aiming to bring together service-users, carers and staff in patient experience focused research.

*Outcomes Measures*

As the primary objective was to assess the feasibility of trial procedures the key outcomes of interest were recruitment rates, participant retention and therapy uptake. Feasibility of recruitment was measured by looking at the number of participants randomised into the study as a proportion of a) the total number of potential participants referred and b) the number of those referred who were assessed for eligibility. Based on recruitment outcomes in the original WIT trial, rates exceeding 30% and 50% respectively were considered to indicate feasible recruitment. A rate of 80% of participants completing assessments at all time points was set as the indicator of participant retention feasibility. Finally, therapy uptake was considered to have met feasibility criteria if three quarters of participants attended at least 4 out of the 8 therapy sessions offered.

The following efficacy outcome measures were also utilised, however.

*Penn-State Worry Questionnaire (PSWQ, Behar et al. 2003).* This is an established worry questionnaire capturing the generality, excessiveness and uncontrollability of worry. It is a 16-item self-report questionnaire, where each item is rated on a 5-point Likert scale ranging from ‘not at all typical of me’ to ‘very typical of me’. High scores indicate high levels of worry. It is sensitive to change across 6-week and 12-week therapeutic interventions for generalised anxiety disorder (Borkovec & Costello, 1993) and has been frequently used to assess worry in persecutory delusions (Foster et al., 2010; Freeman, Bradley, Waite, et al., 2016; Freeman, Dunn, et al., 2015).

*Psychotic Symptoms Rating Scale-Delusions (PSYRATS-delusions;* Haddock, McCarron, Tarrier, & Faragher, 1999). This structured interview is a 6-item scale, where each item is rated on a 5-point ordinal scale. It assesses preoccupation, conviction, distress, and disruption associated with the delusion. Higher scores indicate greater delusional severity. It has been demonstrated to have good psychometric properties (Drake, Haddock, Tarrier, Bentall, & Lewis, 2007).

The *Green Paranoid Thoughts Scale – Part B* (GPTS; Green, Freeman, & Kuipers, 2008). Part B is a 16-item scale measuring persecutory ideation, where each item is rated on a 5-point Likert scale. Higher scores indicate higher levels of persecution. Good internal consistency and validity have been established (Green et al., 2008).

*Additional measures*

The *Wechsler Test of Adult Reading (WTAR; Wechsler 2001)* was administered at baseline. It consists of 50 words with irregular pronunciations which the participant is requires to read aloud. It provides an estimate of premorbid IQ and was used in analysis to establish whether adding IQ as a covariate impacted on the observed effects.

Adverse events were defined as all deaths, suicide attempts, serious violent incidents, admissions to secure units and formal complaints about therapy. They were monitored via liaison with clinical teams and checking medical notes.

*Statistical Analysis*

It was decided that a maximum 10 participants would be recruited into each worry group due to concerns that larger numbers might inhibit group discussions and be aversive. This was a small feasibility study and hence was not powered to ascertain p-values.

Adjusted treatment difference and confidence intervals were estimated using a linear mixed effects model, which accounts for repeated measures over time. Baseline (pre-group) score of the outcome was added as a covariate in the model. Assessment time point (week 8 and week 12), group allocation (WG or CG), and an interaction between assessment time point and group allocation were included as fixed effects to allow estimation of the treatment effect at two time points. Repeated measures were accounted for by fitting random intercepts for each participant. Given that this was a feasibility study, p-values are not reported. A sensitivity analysis was performed for the efficacy outcome measures where IQ was added as a covariate.

Standardised effect sizes were calculated using Cohen’s d (adjusted mean difference /pooled baseline standard deviation from weeks 8 and 12 respectively). Analysis was conducted after the study assessments were completed and followed intention to treat principles. Analyses were conducted by LI using SPSS version 20 (IBM Corp 2011) and validated by a statistician (AN).

**Results**

*Recruitment & Retention*

Figure 1 shows participant flow through the trial. In total 41 potential participants were referred to the study, 25 (61%) of whom proceeded to a screening assessment. 13 participants (32% of those referred, and 52% of those assessed for eligibility) were recruited and randomised to WG (n=7) or CG (n=6). These rates are commensurate with similar studies (Freeman, Dunn, et al., 2015; Freeman, Waite, et al., 2015) and in excess of the feasibility criteria set in the present study. Recruitment took place over 18 weeks (10/02/15-17/06/15) and was conducted with the equivalent of one clinician, half a day per week, across three teams. The recruitment rate was considered good given the limited resources.

***ADD FIGURE 1***

Of those assessed for eligibility but not recruited, the majority did not meet the central inclusion criterion i.e. did not have a persecutory delusion. Only four participants were eligible but chose not to participate. These predominantly cited a reluctance to participate in the research process rather than finding the proposed group unacceptable.

Of the 13 participants, 13 (100%) completed the baseline (pre-group) assessment, 12 (92%) completed the 8-week (end of group) assessment, and 13 (100%) completed the 12-week follow-up assessment. These rates all exceeded the retention criteria of 80%.

*Baseline and Clinical Characteristics*

The demographic details of the participants were largely similar across groups (table 1). The average age was 48, which is a little higher than other studies recruiting participants with psychotic experiences (Freeman et al., 2015; Myers, Startup, & Freeman, 2011). Most participants were single and living alone. All were unemployed. The majority (84%) had a case note diagnosis of schizophrenia. Most participants were currently being seen within Recovery Services, but one participant in each pathway was recruited from the Assertive Outreach and Rehabilitation Team.

Intelligence quotient estimates suggested that IQ scores were within the average range. Baseline scores on the outcome measures showed that participants had high levels of worry and persecutory ideation, and delusions that were distressing and preoccupying (table 2).

***ADD TABLE 1***

***ADD TABLE 2***

*Therapy uptake*

In the WG condition, the mean number of sessions attended was 5.7 (SD 1.3). One participant attended all 8 sessions, three attended 6, two attended 5, and one attended 4 sessions. Therefore all (100%) completed 4 or more sessions. Across the WG condition, 40 sessions out of a possible 56 were attended (71%). Of sessions missed, over a third (37.5%) were pre-planned due to prior engagements (e.g. holidays). The remainder were not discussed in advance. Greetings cards containing a summary of main themes covered plus individual goals for the week were sent to all WG participants after each session from session 3 onwards. All but one participant in the WG group also opted for between session phone calls. The mean number of successful (answered) phone calls made per participant across the 8-week group was 5.6 (SD 2.5) and mean number of unsuccessful phone call attempts (unanswered) per participant was 4.1 (SD 2.5).

*Efficacy Outcome*

Compared to CG, the treatment effect of CBT on worry was in the medium effect size range at 8 and 12 weeks (see table 2). The treatment effect on delusions was in the small effect size range at 8 weeks and no longer apparent at 12 weeks. The effect size found on general paranoia was close to 0. In all of these outcomes however, there were wide confidence intervals spanning zero, therefore the true direction of effect cannot be determined. Sensitivity analyses found that adding IQ to the model as a covariate did not change the pattern of results observed, although we did not have sufficient sample size to adequately estimate the impact of IQ on outcome.

*Adverse Events*

During the main trial period there were no adverse events reported. After completion of the follow-up period, individuals in the CG were offered an 8-week worry-intervention group. Towards the end of this group one participant had an informal psychiatric admission to hospital. This was due to deterioration in mental health linked to external stressors and medication changes and was not considered to be linked to study participation.

*Participant reflections*

Of the 13 participants, 4 provided focus group feedback on their experiences of the group intervention. A summary of key comments can be found in Panel 1.

***ADD PANEL 1***

**Discussion**

This is an initial feasibility RCT of a CBT worry intervention for persistent persecutory delusions adapted for group delivery. Encouragingly, it was possible to recruit and retain participants into the trial and therapy uptake was good with all feasibility criteria being met. Observed treatment effects were in the expected direction though lower than those demonstrated in individual therapy for delusions and general paranoia (Freeman, Dunn, et al., 2015). Participant feedback suggested that this was an acceptable and valued intervention. A next step might be to conduct a full pilot trial although some adjustments would be required. Factors warranting consideration are discussed below.

One third of those referred, and a half of those assessed for eligibility, entered the trial. These proportions are commensurate with similar studies. Over a 4-month period, 13 participants entered the study with a recruitment resource equivalent to one clinician for 0.5 days per week. This demonstrated that recruitment was feasible. Initially it had been intended to recruit up to twenty participants, with the anticipation of a greater recruitment resource. However job role changes for the researchers involved (LI, AM, HG) limited the rate at which potential participants were approached. The decision to proceed with a sample of 13 was taken because an extended recruitment phase has particular implications in group therapy trials. As the intervention cannot start until the group has been fully recruited to, there may be longer delays between recruitment and beginning intervention than would be observed in individual therapy studies. Concerns that participants may withdraw if there were too long a delay prompted the decision to commence the current study with a sample of 13. A larger study would benefit from external funding which could increase resources and thus expedite the recruitment process, reducing the time participants would have to wait for the intervention to commence.

Retention rates were high. All but one participant completed the assessment at 8 weeks and all did so at 12 weeks. In terms of therapy uptake, no WG participants dropped out of therapy and an average of 6 out of 8 sessions were attended, with 71% of therapy sessions offered across all participants attended. All participants completed at least 4 sessions, but it should be acknowledged that 3 out of 7 participants (43%) missed at least three sessions and therefore for those individuals some significant content was missed.

Focus group interviews conducted with four participants revealed that the group was, overall, highly valued (see Panel 1). There was a sense of the group targeting an important issue (participant 3 P3: *“It is a well needed group. Really well needed.”)* and being beneficial (P4: “*It has changed my life… I feel so much better.”)*. When considering change in worry across the group, positive benefits were described. These included improved self-esteem and activity (P1: *“since coming to the group I’ve come to realise I am equal to everyone else and that has probably helped me. Since the group finished I’ve been a lot more active.”*),being able to “*notice worry more so I can catch it at an early stage”* (P3), and “*not worrying while I’m out so much”* (P4). Further benefits were developing coping strategies and meeting others with similar experiences. The importance of the group context was noted not only in terms of normalising the experience of worry (P2: “*it was comforting knowing that other people are going through the same things as you. So you are not totally alone with it”)* but also having a supportive environment (P4: “*the group was always friendly. They listened to each individual, and everyone tried to help”).* Although feedback from the focus groups was largely positive, only 4 of the 13 participants partook in these discussions which may have given a biased perspective (those who attended may have felt more favourably towards the group than those who did not). Furthermore there were aspects of the group that received critique. Participants reported that the group felt too short (discussed later) and one participant (P2) said that the assessments were too numerous. This participant also described feeling pressure to attend sessions because they were under a community treatment order (*“I felt like I would get in trouble if I didn’t attend the groups because it would come up in my tribunal and I thought it would go against me”*). Although the therapist had reassured the participant that this was not the case the focus group revealed that they had continued to have concerns that their care team would think differently.

Observed effect sizes during this feasibility trial were in the expected direction such that WG may have had a beneficial impact on worry at 8 and 12 weeks and on delusions at 8, but not 12 weeks. Confidence intervals were wide however, and spanned 0 and a fully powered RCT would be required to adequately estimate the true size and direction of effect. The observed effect on worry seemed to be partially linked to worry increasing in the control group, rather than there being a simple decrease in the intervention group. Such a pattern was not observed in other trials (Foster et al., 2010; Freeman, Dunn, et al., 2015). This could be due to specific environmental factors affecting this sample or simply chance given the small sample size. Overall, effect sizes have been diluted from the individual delivery method, and changes in the delusions did not translate into changes into general levels of paranoia. In the test of one-to-one therapy in the Worry Intervention Trial, all primary and secondary outcome measures improved with the CBT intervention, which was an assessor-blind trial.

One area that participants and therapists agreed required adaptation was the duration of the group intervention. Focus group participants were unanimous that a longer group was needed (either with longer sessions, more sessions, or both). This viewpoint was mirrored by therapists who felt that time pressures had impacted on efficacy. For example, when translating techniques that had been discussed (for example worry periods) into homework task, therapists aimed to develop tailored plans for each individual (identifying personalised times, places, and frequencies of worry (or worry-free) periods, and strategies for ending a worry period). This was considered important in order to give each group member the greatest chance of success with the technique but it was extremely time-consuming. Consequently plans were not as detailed as might be attained, when delivering the intervention individually. This was also evident when developing relapse management plans, which might account for P2’s comment *“During the group it helped me with coping strategies but afterwards I went back to the same worrying again”*. Participants highlighted that they appreciated both ‘didactic’ components (where key techniques were communicated), and less structured supportive group discussions, but it frequently felt difficult to allow adequate time for both. One focus group participant highlighted that they would have liked more time to practice techniques within sessions. These time pressures would have been exacerbated if 10 participants per group had been recruited.

An obvious amendment for a future trial would be to lengthen intervention sessions and to increase the total number of sessions (we would suggest a minimum of twelve 2-hour sessions). This would allow more time to get a balance between technique-oriented and more general supportive discussions as well as having longer to cover key ideas and to practice strategies in sessions. However, there could still be difficulty in getting the level of detail in each participant’s plan that is possible in one-to-one therapy, as the time and focus allocated to each individual must be balanced with retaining interest from other members.

In terms of effectiveness, the group process may increase the opportunity for normalisation of experiences and offers the possibility of group members encouraging each other to try out different strategies. Focus group feedback indicated that this was particularly appreciated. There may be a trade-off however in terms of how many techniques can be covered and in what depth. In addition to time pressures already discussed, it should be borne in mind that whilst individual therapy can be paced according to each client’s needs, a group goes at a single pace experienced by all group members. We observed that in order to include all participants, we went at a slower pace than might be appropriate for some members, and this could impact on the size of effect yielded in contrast to what might be achieved in individual therapy. This could be particularly noticeable if participants present with the cognitive difficulties sometimes observed in psychosis.

Future trials could consider incorporating an individually delivered therapy arm (rather than CG) and an economic evaluation. A full RCT of this design would allow comparative effectiveness and cost-effectiveness of group versus individual treatment to be established, which has important clinical implications. Gold-standard evidence demonstrates that individual cognitive therapy targeting worry has moderately-sized beneficial effects on both worry and persecutory delusions after an average of 5.5 sessions per participant (Freeman, Dunn, et al., 2015). A group version of this intervention therefore must demonstrate additional benefits in terms of either effectiveness or cost-effectiveness to justify incorporation into routine clinical practice. Although at first glance, groups may seem like a less costly option, we suspect this would not be evident with this particular intervention. Whilst multiple patients can be seen at once, the need for a greater duration and number of sessions, as well as the presence of two staff members may offset this. A group format may also inadvertently increase the number of missed sessions. Over a third of non-attendance in the present study was due to pre-planned activities (such as holidays). In individual therapy, sessions would be scheduled around these, and it would be possible for the subsequent session attended to recommence at the point at which the previous session finished. In a group context however this is not possible and the participant will return at a different point to that at which they left. The participant therefore not only misses potentially critical content, but also experiences a disjoint between sessions. Therapists in the present study offered follow-up contacts to help participants ‘catch up’ but this places further demands on therapist time, and is unlikely to compensate entirely for the missed content. These issues must be considered when weighing up the cost-benefits of different formats of delivery.

The study had a number of limitations. The sample size was small and only one therapy group and one waiting list control group were facilitated. A full RCT would require multiple groups to be facilitated in each arm, but the present study does not establish whether recruiting to multiple groups is feasible or not. Furthermore, the in-service nature of the study meant that the clinicians delivering the therapy groups were also the assessors and hence unblind to treatment allocation, which may have biased participants’ responses. This study determined it was feasible to retain participants over a one-month follow-up period, but not whether sufficient retention could extend for a longer period (such as 6 months) which would be required in a full RCT.

This study provides an early indication that it may be feasible to run a larger trial to test the effectiveness of a group-based worry intervention for persecutory delusions. However, a larger scale pilot would need to test feasibility more extensively before a full RCT could be justified. Any future pilot would need to establish whether multiple groups in each arm could be recruited to, ensure assessors were blind to treatment allocation, and have a longer follow-up period. Given the robust evidence showing that an individually delivered intervention is effective, a future pilot might consider comparing the group and individual therapy formats, rather than utilising a wait-list control. At full scale trial level, this could determine whether the benefits of the group-based intervention are outweighed by the challenges. Preliminary economic evaluation should be conducted to establish whether a group format is a cost-effective alternative to individual therapy.

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*Ethical Statements:* The authors assert that all procedures contributing to this work comply with ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1965, and its most recent revision.

*Conflicts of Interest:* The authors have no conflict of interest with respect to this publication.

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