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**Group mindfulness-based therapy for persecutory delusions: A pilot randomised
controlled trial.**

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Dear Editors,

Effect sizes from psychosocial interventions are typically lower for delusions than hallucinations (e.g. Van der Gaag et al, 2014), highlighting a need to improve and extend psychological therapies for individuals with delusions. Chadwick and colleagues (see Chadwick et al., 2005; Chadwick, 2014) developed mindfulness-based therapy for people with psychosis. Data from randomised controlled trials indicate benefits of mindfulness on total psychotic symptoms (Louise et al., 2018) and on voice-specific outcomes (e.g. Chadwick et al., 2016) – but no data assess persecutory delusions specifically. Moreover, whilst researchers have evaluated mindfulness groups for people who hear voices, no published study assesses mindfulness groups specifically for people with persecutory delusions. Indeed, in the UK, whilst voices groups are routinely offered both by NHS services and mental health charities to facilitate peer-support, this is not so for persecutory delusions, and clinicians express concerns about the feasibility and benefit of bringing together in groups people whose primary symptom concerns fear and mistrust of others.

The present study is a single-centre pilot randomised controlled trial for people with persecutory delusions of group mindfulness plus standard care versus standard care alone. The study aims were to: (1) assess recruitment and retention; (2) assess acceptability of the group mindfulness intervention; (3) generate an indicative effect size on the pre-set primary outcome (depression); (4) monitor possible harmful effects (adverse events and deterioration in depression); (5) explore group process.

Methods

27 people with a diagnosis of a Schizophrenia Spectrum Disorder including a current distressing persecutory delusion were randomised to receive either group mindfulness based therapy (12 sessions) alongside treatment as usual (TAU: n=14) or TAU alone (n=13).

The pre-set primary outcome was depression, measured using the BDI II (Beck et al., 1996) at baseline and post intervention. Depression was chosen as the primary outcome because it has been shown to predict the persistence of persecutory delusions over time (Fowler et al., 2011), is conceptually aligned with the aims in mindfulness for psychosis (Chadwick, 2014), and is valued by service users. Mindfulness participants also completed the 7-item Satisfaction with Therapy Scale (Freeman et al., 2016). To explore group process, post-treatment all mindfulness participants rank-ordered by subjective importance to group participation seven statements relating to non-specific therapeutic factors (catharsis, hope, universality, interpersonal learning, self-discovery, cohesion, altruism) and an eighth relating to mindfulness specifically (see Chadwick et al., 2009). The research assistant assessed therapy fidelity immediately after six randomly chosen sessions; participants completed checklists indicating adherence to four key elements of the session protocol.

Results

The consort diagram (Figure 1) shows the trial profile. Participant characteristics at baseline were broadly equivalent in the two arms of the study. All participants were taking medication, and the majority were single (85%), unemployed (56%) and male (78%) of varying ethnicity (81% White British; 11% White Other; 4% Indian; 4% Pakistani), with a diagnosis of Paranoid Schizophrenia (67%).

Recruitment, retention and acceptability

Of the 73 individuals put forward for the study, 37% consented, 38% declined, and 25% were ineligible. In line with good practice recommendations for pilot studies (Julious, 2005), the study achieved its aim to retain a minimum of 12 participants per arm and did so within its pre-set recruitment timeframe (28 weeks). Study retention rate was high (96%),

with one drop-out from TAU and none from mindfulness. Data completeness for participants retained in the study was 90% at post therapy. All participants in the treatment arm attended at least 50% of therapy sessions (range 6-12, mean 10 sessions), therapy satisfaction was high (modal score of 4-5/5 on each of the seven therapy satisfaction items). All participant ratings indicated 100% adherence to the group therapy protocol for six randomly sampled sessions. Overall, these data attest to the feasibility and acceptability of the intervention.

Depression and group process

A small effect size on depression was found in favour of the mindfulness intervention ($d = 0.2$, 95% CI -0.95,0.85). In the treatment arm, mean baseline BDI score was 23.1 ($SD = 16.7$), and post therapy mean was 15.2 ($SD=13.6$). In TAU, mean baseline BDI score was 25.9 ($SD = 12.4$), and post therapy mean was 22.9 ($SD = 12.2$). Eight participants (64%) receiving mindfulness showed a clinically meaningful reduction in depression pre-post intervention and none showed a clinically meaningful increase (MCID on the BDI was set at 5). In TAU, six (46%) showed a clinically meaningful reduction and one (8%) a clinically meaningful increase. There were no serious adverse events or hospitalisations during the course of the study. Data from subjective ratings of therapeutic factors showed learning mindfulness and altruism (“Helping others and being important in their lives”) to be jointly ranked as the subjectively most important aspects of group participation.

Discussion

All 14 mindfulness participants attended at least 6 sessions (‘completers’), with no drop out, and satisfaction with mindfulness was uniformly high. A small effect was found on depression (primary outcome) and 64% who received the mindfulness group showed a

clinically meaningful reduction in depression pre-post therapy. There were no adverse events associated with participation in mindfulness groups, or the wider study, and none of the mindfulness participants showed a clinically meaningful deterioration in depression (one person in TAU did).

The study sheds light on the therapeutic process, highlighting for the first time in research on mindfulness for psychosis the subjective importance of altruistic connection with others – this finding is particularly striking in a study of people with persecutory delusions. The study has limitations. As befits a pilot trial, the sample size was intentionally small and not powered to detect statistically significant effects, and there was no follow up. Mindfulness practice was not formally assessed between sessions and there was no active control condition.

In conclusion, the pilot study showed it is possible to recruit and retain people with current persecutory delusions into a group mindfulness study and the intervention was found to be safe, acceptable, and to reduce depressive symptoms.

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Keywords: Delusions, distress, mindfulness, paranoia, persecutory delusions; RCT, therapy

Author contributions

All authors contributed to the design of the study and supported the trial. Chadwick was chief investigator on the grant. Chadwick & Ellett wrote the manuscript draft. All authors approved the final version.

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Figure 1. CONSORT Diagram



