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Title: Can mindfulness groups treat common mental health problems? Problematic design and short follow-up fails to answer the question.

Commentary on: Sundquist J, Lilja Å, Palmér K, *et al*. Mindfulness group therapy in primary care patients with depression, anxiety and stress and adjustment disorders: randomised controlled trial. *Br J Psychiatry* 2015;**206**:128–35.

What is already known on this topic

It is important to increase the capacity to treat anxiety and depression[1] and group treatments may offer effective intervention[2]. Mindfulness-based cognitive therapy (MBCT) is currently recommended to prevent relapse in people who have had 2+ episodes of depression[2]. There is a lack of research addressing whether mindfulness groups can be successfully used to help milder to moderate depression, anxiety and adjustment disorders.

Methods of the study

In this randomised controlled study, the population was a primary care-based sample (n=215) from 16 general practices in Southern Sweden, with a GP clinical diagnosis of depression, anxiety, stress or adjustment disorders. A standardised clinical assessment was not used. Inclusion criteria were people experiencing mild to moderately severe depression or anxiety/panic; aged 20-64 years, and achieving one or more of the following cut-offs - scoring between 13-34 on the MADRS-S depression scale, a score of 7+ on the Hospital Anxiety and Depression - Anxiety or Depression scales, or 10+ more on the PHQ9 depression scale. People with both short and long-term problems seeking treatment were included; severe psychiatric symptoms and suicide risk were excluded as were those unable to participate in groups, or with substance misuse, pregnancy, current psychotherapy, thyroid disease or participation in other research.

The intervention was a structured mindfulness group based on the two mindfulness-based therapies (Mindfulness-Based Cognitive therapy (http://mbct.co.uk/) and Mindfulness Based Stress Reduction (www.mindfullivingprograms.com/whatMBSR.php)). It was delivered over 8 weeks by mindfulness instructors recruited locally (doctors, psychologists, counsellors, nurses and others). Six days of training was given - well under the national guidelines, for example in the UK (http://mindfulnessteachersuk.org.uk/). There was no clear test of competency or adherence to delivery during the study. The comparison group was standard treatment which could include medication, psychotherapy or counselling; overall 80 received Cognitive Behavioural Therapy. However the CBT failed to define the model of CBT, and no competency/adherence tests were reported, meaning that the quality of delivery of the comparison arm is open to question. Allocation was masked (i.e. the investigators did not know during the allocation to which group they were assigning each patient), and delivery was not blinded.

215 entered the study (110 mindfulness, 105 control). No single primary outcome was identified but the study was powered on the MADRS-S at 8 weeks with non-inferiority defined as a difference within 3.5 points. However, the study was powered only at 80%,

falling short of the 90% power requirement seen in well-designed studies. Only around 80% received a CBT approach and this was not standardised; a few were not offered a talking intervention at all. A sub-analysis compared those receiving CBT alone continued to show non-inferiority.

What does this paper add?

- At 8 weeks, 81 (mindfulness) and 86 (control) completed the MADRS-S questionnaire. The main results confirmed the non-inferiority assumption, with a 9 point improvement in the mindfulness group and 10 point in the control.
- For all scales and in both groups the scores decreased significantly, with no significant differences between the mindfulness and control groups.

Limitations

- It is not possible to test the new group model further, or introduce it into services as it is not described or available in manualised form. It uses a non-standard course of 8x 2 hour sessions (well short of the 26 hours usually offered in MBCT or MBSR).
- Treatment as usual is poorly defined. We know nothing of the models of CBT used, or the prior training, adherence and competency of practitioners.
- The follow-up is limited to immediately after the end of the eight week course. Most patients received just 6 CBT sessions, well short of the typical 12-20 sessions usually delivered in CBT meaning that patients in the CBT arm were mid-treatment at that time, preventing a direct comparison of end of treatment results.
- The study is underpowered and as a consequence the claimed non-inferiority cannot be substantiated.

What next in research

Mindfulness is currently only recommended for the prevention of recurrent depression[2]. Properly designed, adequately powered RCTs are required to address the impact of mindfulness groups. These should manualise and confirm adherence of delivery of the mindfulness group to a clinically clearly defined population, and clearly describe the comparator group so it is clear what they received. Comparator groups should be either standard care or, preferably, a manualised evidence-based alternative treatment such as CBT delivered in a consistent way.

Do these results change your practices and why?

The paper cannot change practice as the study is underpowered, and not reproducible. Results are hard to interpret; no lessons can be drawn concerning the usefulness of mindfulness groups in this population.

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Competing interests

CW is an author of a range of CBT-based books and online self-help resources including depression and anxiety; he is a director and shareholder in Five Areas Limited, which licenses these resources.