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#### Original article

## The effect of mindfulness group therapy on a broad range of psychiatric symptoms: A randomised controlled trial in primary health care

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#### ABSTRACT

Background: The need for psychotherapy in primary health care is on the increase but individual-based treatment is costly. The main aim of this randomised controlled trial (RCT) was to compare the effect of mindfulness-based group therapy (MGT) with treatment as usual (TAU), mainly individual-based cognitive behavioural therapy (CBT), on a broad range of psychiatric symptoms in primary care patients diagnosed with depressive, anxiety and/or stress and adjustment disorders. An additional aim was to compare the effect of MGT with TAU on mindful attention awareness.

Methods: This 8-week RCT took place in 2012 at 16 primary care centres in southern Sweden. The study population included both men and women, aged 20-64 years (n = 215). A broad range of psychiatric symptoms were evaluated at baseline and at the 8-week follow-up using the Symptom Checklist-90 (SCL-90). Mindful attention awareness was also evaluated using the Mindful Attention Awareness Scale (MAAS).

Results: In both groups, the scores decreased significantly for all subscales and indexes in SCL-90, while the MAAS scores increased significantly. There were no significant differences in the change in psychiatric symptoms between the two groups. The mindfulness group had a somewhat larger change in scores than the control group on the MAAS (P = 0.06, non-significant).

Conclusions: No significant differences between MGT and TAU, mainly individual-based CBT, were found in treatment effect. Both types of therapies could be used in primary care patients with depressive, anxiety and/or stress and adjustment disorders, where MGT has a potential to save limited resources. *Trial registration:* ClinicalTrials.gov identifier: NCT01476371.

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#### 1. Introduction

#### Q2 1.1. Psychiatric disorders

Psychiatric disorders, such as depressive, anxiety and stress and adjustment disorders cause substantial mental suffering and may lead to recurrence of more severe episodes and even suicide [1,2]. These very common psychiatric disorders also place a large economic burden on society. Cognitive behavioural therapy (CBT) has been acknowledged to be an effective way of treating, for example, depressive disorders [3,4]. In Sweden, CBT is used as one of the standard treatments for patients in primary health care but

other types of therapies are also recommended, such as interpersonal therapy (IPT) and psychodynamic therapy. Patients, who seek individual based psychotherapies may, however, have to wait for some time before seeing a therapist as the availability of such psychotherapeutic treatments is limited. A stronger focus on group therapy could help to save limited resources and increase access to psychotherapy.

#### 1.2. Mindfulness-based therapies

Mindfulness-based therapies might be suitable for group therapy sessions for patients with psychiatric disorders but such therapies need to be evaluated before they can be recommended in primary health care. Mindfulness-based therapies, such as mindfulness-based stress reduction (MBSR) and mindfulness-based cognitive therapy (MBCT) have been increasingly used

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during the past decade for a range of conditions [5-8]. Patients can, after an introduction to the therapy, practice mindfulness on their own, sometimes using their smartphones [9]. MBSR is based on uniform techniques and well-established instructions [10]. MBCT is a hybrid of CBT and MBSR [5]. A 2012 meta-analysis, based on 19 mindfulness and acceptance-based studies, showed substantial reductions of depressive and anxiety symptoms after treatment [11]. Another meta-analysis, published in JAMA Psychiatry in 2016 [12], revealed that MBCT appears effective as a treatment for relapse prevention for those with recurrent depression. A Canadian study [13] showed that recurrence rates in patients with depression, noted over 18-months of follow-up, did not differ between those who received MBCT (28%) and those who received maintenance antidepressants (27%).

#### 1.3. The PREVENT study

A recent 24-month randomised controlled trial [14], PREVENT, involving 95 primary care practices and 424 patients in the UK, found that both MBCT and maintenance antidepressant treatment were associated with durable positive outcomes in terms of recurrence, residual depressive symptoms and quality of life. PREVENT is the largest study so far conducted in primary care. Our research group also performed a large RCT in Sweden in 2011 on 16 primary health care centres (PHCC) involving 215 patients with depressive, anxiety or stress and adjustment disorders [15]. In that RCT, we administered mindfulness-based group therapy (MGT) using a modified form of MBSR [16-18]. The MGT was performed in a similar way in the group sessions as in individual sessions. As noted in our previous report, using the MADRS-S scale, the HADS-scale, and the PHQ-9 scale as our main outcomes, MGT was non-inferior to treatment as usual (mostly individual CBT) for patients with depressive, anxiety or stress and adjustment disorders.

#### 1.4. Present study

In the present study, we used the Symptom Checklist-90 (SCL-90) [19-21] and several of its subscales and indexes as our main outcome in order to assess potential effects of MGT on a broad range of psychiatric symptoms and distress. The main aim of this 8week RCT was to compare the effect of MGT with TAU on a broad range of psychiatric symptoms in primary health care patients with depressive, anxiety, and stress and adjustment disorders. An additional aim was to compare the effect of MGT with TAU on mindfulness attention awareness by using the Mindful Attention Awareness Scale (MAAS).

#### 2. Methods

#### 2.1. Sampling of primary health care centres

This RCT was conducted in the county of Scania, the most southern region in Sweden [15]. At the time of the RCT, Scania had 150 PHCCs that served a population of 1.3 million people. A total of 24 PHCCs from all parts of the region were randomly selected in order to achieve an accurate geographic representation of the whole county. J.S., the first author of the present study, contacted all of the directors at the 24 PHCCs via an email that provided details about the study. Sixteen of the contacted 24 PHCCs were interested in participating in the study. Patient enrolment commenced on 4th January 2012 and ended on 22nd March 2012. Newly diagnosed patients with depressive, anxiety and/or stress and adjustment disorders were eligible, in addition to individuals who already had a history of these disorders. If the patient agreed to take part, both the doctor and the patient signed the informed consent form that had detailed information about the RCT. The patients were assessed for any need of pharmacological treatment and were prescribed psychotropic drugs if deemed necessary at the medical consultation.

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#### 2.2. Recruitment and training of mindfulness instructors

We aimed to train two instructors per participating PHCC. Two of the 16 PHCCs were relatively small and located close to each other and were therefore given permission to work together. In total, 30 instructors (mainly psychologists and social counsellors but doctors, nurses and physiotherapists were also included) received the training programme at our department (Center for Primary Health Care Research, Malmö, Sweden). No previous meditative experience was required. The training was given during six days that were evenly spread between September 2011 and December 2011 and all sessions were led by Ola Schenström (O.S.) and L.M.J., the latter representing one of the authors of this study. O.S. was trained at the Center for Mindfulness in Medicine, Health Care, and Society, founded by Jon Kabat-Zinn at the University of Massachusetts, USA. O.S. is a renowned expert in mindfulness education in Sweden and L.M.J. is a psychiatrist and licensed psychotherapist with long clinical experience of mindfulness therapy. A key part of the training is the future instructors' own mindfulness training. They were trained in how to guide individuals and groups in mindfulness training so that the individual may develop a greater awareness of thoughts, feelings and bodily sensations and be able to cope better with stress and difficulties in everyday life. All of the 30 participants that took part in the six-day program completed the course, passed the oral exam and subsequently became certified mindfulness instructors.

Data from 27 of the 30 instructors' own mindfulness practice (average minutes/day) showed that the mindfulness instructors, on average, practiced for 27 minutes/day (SD = 17, median = 23, range = 6-68). We tested the effect of the average minutes/day the instructors spent on their own mindfulness practice on the patients' outcomes (change in score from baseline) using a mixed model (to take into account the potential correlation between instructors within PHCCs). We chose two outcomes, MAAS (mindfulness attention awareness) and GSI (Global Severity Index), and found no significant associations between the instructors' own personal practice and the patients' outcomes in the mindfulness group (MAAS:  $\beta = 0.008$ ; P = 0.47; and GSI:  $\beta = -0.04$ ; P = 0.46).

#### 2.3. Inclusion and exclusion criteria

Criteria 1-4 (below) all needed to be fulfilled for inclusion in the study. The listed ICD-10 codes in criterion 1 were based on clinical diagnoses, made by medical doctors:

• one or more of the following ICD-10 psychiatric diagnoses: 139 • F32.0 = Mild depressive episode, 141 • F32.1 = Moderate depressive episode, 142 • F32.9 = Depressive episode, unspecified, 143 • F33.0 = Recurrent depressive disorder, current episode mild, 144 • F33.1 = Recurrent depressive disorder, current episode mod-145 146 erate. • F41.0 = Panic disorder, 147 • F41.1 = Generalised anxiety disorder, 148 o F41.2 = Mixed anxiety and depressive disorder, 149 150

• F41.3 = Other mixed anxiety disorders, • F41.8 = Other specified anxiety disorders,

• F41.9 = Anxiety disorder, unspecified,

• F43.2 = Adjustment disorders, • F43.8 = Other reactions to severe stress,

• F43.9 = Reaction to severe stress, unspecified;

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