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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.

1. Introduction

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, practise 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 in 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 8-week 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.

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 programme 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, practised 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:
  - F32.0 = Mild depressive episode,
  - F32.1 = Moderate depressive episode,
  - F32.9 = Depressive episode, unspecified,
  - F33.0 = Recurrent depressive disorder, current episode mild,
  - F33.1 = Recurrent depressive disorder, current episode moderate,
  - F41.0 = Panic disorder,
  - F41.1 = Generalised anxiety disorder,
  - F41.2 = Mixed anxiety and depressive disorder,
  - 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;

- age 20–64 years, i.e. the population of working age;
- ability to speak and read Swedish;
- one or more (i.e. at least one) of the following cut-offs:
  - a score between 13 and 34 on the MADRS-S scale,
  - a score $\geq$ 7 on the HADS-A scale,
  - a score $\geq$ 7 on the HADS-D scale,
  - a score $\geq$ 10 on the PHQ-9 scale [15].

The exclusion criteria were the following seven:

- severe psychiatric symptoms requiring psychiatric care;
- risk of suicide;
- inability to participate in group sessions due to severe substance abuse;
- pregnancy;
- current psychotherapy of any kind;
- participation in any other psychiatric intervention study;
- thyroid disease (if newly diagnosed by the doctor).

2.4. Main outcome (SCL-90)

The main outcome in the present study was the SCL-90, originally termed the Symptom Distress Checklist (SCL). It was initially used to assess changes in a broad range of psychiatric symptoms and distress in psychiatric outpatients in reference to therapeutic interventions [22]. Since the initial development of this self-reported psychiatric rating scale it has been revised, updated and psychometrically validated [22–24]. Today, it is widely used for research purposes and it is also suitable for clinical outcome evaluations in different patient populations [25,26]. The SCL-90 is a 90-item questionnaire that measures symptom intensity on nine different subscales: ''Somatization'', ''Obsessive-compulsive'', ''Interpersonal sensitivity'', ''Depression'', ''Anxiety'', ''Hostility'', ''Phobic anxiety'', ''Paranoid ideation'' and ''Psychoticism''. Each item of the questionnaire is rated by the patient on a 5-point Likert scale. The instrument also includes three global indexes of distress:

- Global Severity Index (GSI), a measure of general psychiatric distress;
- Positive Symptom Distress Index (PSDI), a measure of the depth of the experienced problems;
- Positive Symptom Total (PST), a measure of the total number of psychiatric symptoms.

In this study, three psychometrically validated unidimensional subscales were also used to evaluate the severity of depression (SCL-D6), specific anxiety (SCL-ASS8) and interpersonal sensitivity (IPS5), referred to as the Hamilton subscales [24]. The SCL-90 has been standardised on a Swedish population and adjusted T-scores have been calculated (for the Hamilton subscales raw scores are used). T-scores have a normal mean of 50 and a standard deviation of 10. The cut-off level, indicating clinically significant problems, was set to T $\geq$ 70 [27].

2.5. Additional outcome (Mindful Attention Awareness)

The MAAS is a 15-item instrument designed to assess a core characteristic of dispositional mindfulness; namely open or receptive awareness and attention to what is taking place in the present. The scale was developed in 2003 by Brown and Ryan [28].

2.6. Randomisation

The mindfulness instructors called and informed the patients who were eligible to be included in the study. The instructors were also present at the patients' first study-related visit to the PHCC, where the patients provided blood samples and completed the questionnaire. This initial visit took place before any psychotherapy or counselling had begun, usually in a group environment. Patients were also briefed as to whether they would be included in either the intervention group or the control group. The randomisation protocol was designed by the Competence Center for Clinical Research at Lund University (a separate department from ours) and included a list with numbers 1–20 for each PHCC. Each number was related to allocation to the intervention or the control group. Participants were added to the list according to the order in which they signed the informed consent form at the medical consultation. Patients were not allowed to change group, once allocated to one of the two groups. Hence, it was not possible for the instructors or doctors, or any member of the research team, to have an influence regarding which group the patients were allocated to. The researchers were not involved in the treatment of the patients and had no other contact with them during the study period. The statisticians, who performed the statistical analysis, had no access to personal identifiers in their dataset. Thus, the entire analytic process was blinded.

2.7. Intervention–mindfulness-based group therapy (MGT)

The programme used in the present study was based on the two mindfulness-based therapies: MBSR and MBCT [16–18]. It included structured and controlled meditative exercises. The period of intervention varied somewhat between the different sites. The first mindfulness session took place on 26 January 2012 with the final session occurring on 15 May 2012, in the 16 participating PHCCs. The MGT lasted eight weeks and was given in 2 h sessions, once a week. The participants were also instructed to practise mindfulness at home for 20 min/day and were given a compact disc, a training manual and a diary for this purpose. On average, the participants undertook 102 individual-based mindfulness sessions, including a mixture of daily mindfulness meditation sessions with mindful exercises in common daily situations (s.d. = 44, range 0–219). Two mindfulness instructors were present at each group session and each group consisted of a maximum of ten participants. Individual attendance at each group session was recorded.

2.8. Control group

The control group received TAU, which often included pharmacologic treatment, and in most cases also psychotherapy or counselling. The majority of the patients in the control group received CBT (n = 80, 76%) in, on average, 6.3 individual sessions. Other therapies included, for example, basic body awareness and other psychotherapies. There were no differences in pharmacologic treatment between the mindfulness and control group.

2.9. Follow-up

Post intervention, all patients were asked to come to the PHCC to provide blood samples and to complete the same questionnaires as those used at baseline. This was done at a specifically assigned time, which meant that most participants filled in the questionnaires at the PHCC and at the same time point together with other study participants.

2.10. Ethical considerations and handling of personal data

The study was approved by the Ethics Committee of Lund University prior to its commencement on October 5, 2011 (application no. 2011/491). All participants gave their written

Table 1
Characteristics at baseline in Mindfulness and Control groups.

	Mindfulness (n = 110)	Control (n = 105)	P-value[a]
Mean age in years (SD)	42 (11)	41 (11)	0.48
Men/women (%)	19/81	10/90	0.08
Antidepressants, yes/no (%)	35/52	35/55	0.88
Tranquiliser, yes/no (%)	16/67	16/69	0.94
CBT (n)		80	
Subscales			
Baseline somatization mean T-score (SD)	71 (19)	73 (20)	0.57
Baseline obsessive-compulsive mean T-score (SD)	72 (16)	74 (15)	0.27
Baseline interpersonal sensitivity mean T-score (SD)	64 (15)	66 (17)	0.44
Baseline depression mean T-score (SD)	72 (15)	73 (16)	0.81
Baseline anxiety mean T-score (SD)	74 (19)	76 (19)	0.48
Baseline hostility mean T-score (SD)	62 (16)	63 (17)	0.87
Baseline phobic anxiety mean T-score (SD)	66 (29)	67 (23)	0.94
Baseline paranoid ideation mean T-score (SD)	61 (17)	64 (20)	0.31
Baseline psychoticism mean T-score (SD)	66 (24)	69 (21)	0.42
Indexes			
Baseline GSI[b] mean T-score (SD)	73 (17)	75 (18)	0.37
Baseline PSDI[c] mean T-score (SD)	66 (11)	68 (11)	0.16
Baseline PST[d] mean T-score (SD)	66 (10)	67 (9.8)	0.46
Hamilton subscales			
Baseline SCL-D6[e] mean raw score (SD)	2.1 (0.81)	2.3 (0.8)	0.24
Baseline SCL-ASS8[f] mean raw score (SD)	1.3 (0.75)	1.4 (0.67)	0.27
Baseline IPS5[g] mean raw score (SD)	1.6 (0.82)	1.7 (0.89)	0.43

[a] Test for differences between Mindfulness and Control groups.
[b] Global Severity Index.
[c] Positive Symptom Distress Index.
[d] Positive Symptom Total.
[e] Severity of depression.
[f] Specific anxiety.
[g] Interpersonal sensitivity.

informed consent and the study was registered at ClinicalTrials.gov (identifier: NCT01476371).

2.11. Power calculation

The power calculation was based on the Montgomery-Åsberg Depression Rating Scale (MADRS-S), which was used as one of the three screening instruments for inclusion in the present study. Thus, MADRS-S was considered as the primary outcome in the RCT that the present study was based on. The power calculation was based on the assumption that the MGT would be no worse than (i.e. non-inferior to) TAU in the improvement of the MADRS-S score after treatment [29,30].

2.12. Statistical analysis

All analyses were repeated for the nine subscales, the three global indexes and the three Hamilton subscales. The subscales were highly correlated: an average inter-item correlation of 0.64. Characteristics of the study population are presented as the mean and SD for scores and age, and as number and percentage for the other variables (Table 1). Differences in baseline characteristics between the mindfulness and control groups were tested using Student's t-test for means and Chi^2 test for proportions. Within groups, analyses (mean change between baseline and follow-up of the mindfulness group and control group) were performed using the paired t-test (Tables 2a and 2b). A linear regression model for the observed cases was used to examine the difference in effect between the mindfulness and control group on the outcome (change from baseline), adjusted for baseline score. We also used a random intercept linear regression model (mixed model), due to the correlation of measurements within individuals. An advantage with mixed models is that all available data are used under the missing at random assumption. This means that data from those who drop out, as well as data from those who complete the study, can be used. We also dichotomised the T-scores ($T \geq 70$) and tested the change from baseline to follow-up in the mindfulness and control groups using McNemar's test (Tables 3a and 3b) because of paired data. The difference in effect was examined using a logistic regression model on the observed cases, as well as a random-intercept logistic regression model using all available data. Odds ratios were estimated to examine a possible difference in the dichotomised outcome (T-score < 70 after treatment) between the mindfulness and the control group. We repeated all analyses with the control group, limited to only CBT in an explorative analysis. In an additional analysis, we also examined the MAAS (Tables 4a and 4b). This is a mean value created from 15 items on awareness and attention to what is taking place in the present [28]. The analyses in Table 2 were repeated for this scale [15]. STATA version 12 (StataCorp LP) was used for all statistical analyses.

3. Results

A total of 215 eligible patients at the 16 PHCCs were randomised to either mindfulness (n = 110) or treatment as usual (n = 105). The number of dropouts was higher in the mindfulness group (n = 18; 16%) than in the control group (n = 9; 9%). There were no significant differences in sociodemographic characteristics between the dropouts and those who remained in the study. The main reasons for dropout were due to work constraints and lack of time. Other reasons included moving house, sickness, no desire for treatment and disappointment at being randomised to the control group. We tested the potential influence of more severe psychiatric symptoms on the drop-out rate and found no significant association between the number of drop-outs and the score values.

Table 1 shows, at baseline, total and subscale scores (transformed to T-scores, except for the Hamilton subscales). Mean scores were similar in both the mindfulness and control groups (all P-values > 0.05). There were no significant differences in pharmacological treatment between the two groups. In both groups,

Table 2a
Mean T-Scores for all subscales (raw scores for Hamilton Subscales) and number of cases at baseline and follow-up in Mindfulness and Control groups for observed cases.

	Mindfulness ($n = 110$)						Control ($n = 105$)					
	Baseline		Follow-up		Change[a]		Baseline		Follow-up		Change[b]	
	n	Mean score	*n*	Mean score	Mean change (SE)	*P*-value	*n*	Mean score	*n*	Mean score	Mean change (SE)	*P*-value
Subscales												
Somatization	107	71	84	62	−10.5 (1.9)	< 0.0001	100	73	89	62	−10.1 (1.8)	< 0.0001
Obsessive-compulsive	107	72	84	58	−12.9 (1.5)	< 0.0001	100	74	89	62	−12.1 (1.4)	< 0.0001
Interpersonal sensitivity	106	64	84	56	−6.7 (1.4)	< 0.0001	100	66	89	58	−7.2 (1.6)	< 0.0001
Depression	107	72	84	59	−12.7 (1.5)	< 0.0001	100	73	89	60	−12.3 (1.5)	< 0.0001
Anxiety	107	74	84	59	−13.7 (1.6)	< 0.0001	100	76	89	60	−14.1 (1.9)	< 0.0001
Hostility	107	62	84	52	−8.9 (1.4)	< 0.0001	100	63	88	55	−7.3 (1.6)	< 0.0001
Phobic Anxiety	107	66	84	58	−8.7 (2.5)	< 0.0001	100	67	88	61	−6.5 (2.4)	0.007
Paranoid Ideation	107	61	84	55	−5.9 (1.4)	< 0.0001	100	64	89	59	−4.3 (1.5)	0.005
Psychoticism	107	66	84	58	−9.3 (2.5)	< 0.0001	100	69	89	61	−6.9 (2.3)	0.003
Indexes												
GSI[c]	107	73	84	66	−6.4 (0.8)	< 0.0001	100	75	89	69	−6.1 (0.9)	< 0.0001
PSDI[d]	107	66	84	61	−3.7 (0.5)	< 0.0001	100	68	89	63	−4.3 (0.5)	< 0.0001
PST[e]	107	66	84	58	−7.4 (0.9)	< 0.0001	100	67	89	61	−5.9 (1.1)	< 0.0001
Hamilton subscales												
SCL-D6[f]	107	2.1	84	1.2	−0.86 (0.09)	< 0.0001	100	2.3	89	1.3	−0.92 (0.09)	< 0.0001
SCL-ASS8[g]	107	1.3	84	0.73	−0.53 (0.07)	< 0.0001	100	1.4	89	0.83	−0.53 (0.07)	< 0.0001
IPS5[h]	106	1.6	84	0.97	−0.58 (0.08)	< 0.0001	100	1.7	89	1.1	−0.53 (0.09)	< 0.0001

[a] Effect of MGT on change in score from baseline to follow-up tested with paired T-test.
[b] Effect of TAU on change in score from baseline to follow-up tested with paired T-test.
[c] Global Severity Index.
[d] Positive Symptom Distress Index.
[e] Positive Symptom Total.
[f] Severity of depression.
[g] Specific anxiety.
[h] Interpersonal sensitivity.

about 35% received a prescription of antidepressants and 16% received a prescription of tranquilisers (data not shown in table). The most common therapy in the control group was individual CBT ($n = 80$, 76%) and no patient in the mindfulness group also received CBT.

Table 2a shows mean T-scores (raw scores for the Hamilton subscales) and the number of observed cases at baseline and follow-up for the two groups, analysed separately. The mean scores for the nine subscales, the three indexes and the three Hamilton subscales decreased significantly in both groups. All *P*-values were less than < 0.0001, except for the three subscales (phobic anxiety, paranoid ideation and psychoticism) in the control group (*P*-values < 0.001).

In Table 2b, the difference between the mindfulness and control group in the change in scores over time is shown using a linear regression model on observed cases, and a mixed model on all

Table 2b
Analysis of differences in treatment effect between Mindfulness and Control groups.

	Observed cases (adjusted for baseline score)				Mixed model			
	n	β[a]	*P*-value[b]	95% CI	*n*	β	*P*-value[c]	95% CI
Subscales								
Somatization	170	−0.74	0.74	−5.12; 3.65	380	0.07	0.98	−4.91; 5.06
Obsessive-Compulsive	170	−2.44	0.18	−5.99; 1.11	380	−1.01	0.62	−4.98; 2.96
Interpersonal Sensitivity	170	−0.81	0.65	−4.29; 2.67	379	0.28	0.89	−3.74; 4.30
Depression	170	−1.37	0.44	−4.91; 2.16	380	−0.76	0.72	−4.86; 3.33
Anxiety	170	−0.98	0.60	−4.62; 2.66	380	0.52	0.83	−4.36; 5.40
Hostility	169	−2.14	0.23	−5.62; 1.35	379	−1.68	0.43	−5.84; 2.48
Phobic Anxiety	169	−2.85	0.22	−7.44; 1.75	379	−2.31	0.48	−8.79; 4.17
Paranoid Ideation	170	−2.73	0.12	−6.14; 0.67	380	−1.50	0.45	−5.41; 2.42
Psychoticism	170	−3.70	0.15	−8.71; 1.31	380	−1.48	0.65	−7.87; 4.91
Indexes								
GSI[d]	170	−1.10	0.26	−3.00; 0.80	380	−0.36	0.76	−2.64; 1.92
PSDI[e]	170	−0.03	0.96	−1.15; 1.10	380	0.50	0.45	−0.79; 1.80
PST[f]	170	−1.89	0.19	−4.70; 0.92	380	−1.55	0.27	−4.33; 1.22
Hamilton subscales								
SCL-D6[g]	170	−0.04	0.70	−0.26; 0.17	380	0.04	0.75	−0.20; 0.28
SCL-ASS8[h]	170	−0.06	0.43	−0.23; 0.10	380	0.003	0.98	−0.18; 0.19
IPS5[i]	170	−0.12	0.23	−0.32; 0.08	380	−0.06	0.61	−0.28; 0.17

[a] Difference between Mindfulness and Control group in the score changes over time, adjusted for baseline score.
[b] Difference tested with a linear regression model.
[c] Difference tested with a random-intercept linear regression model using GLLAMM.
[d] Global Severity Index.
[e] Positive Symptom Distress Index.
[f] Positive Symptom Total.
[g] Severity of depression.
[h] Specific anxiety.
[i] Interpersonal sensitivity.

Table 3a
Number and percentage of dichotomised T-Scores for all subscales and number of cases at baseline and follow-up in Mindfulness and Control groups for observed cases.

	Mindfulness ($n = 110$)					Control ($n = 105$)				
	Baseline		Follow-up		Change[a]	Baseline		Follow-up		Change[b]
	n	T-score ≥ 70 Number (%)	n	T-score ≥ 70 Number (%)	P-value	n	T-score ≥ 70 Number (%)	n	T-score ≥ 70 Number (%)	P-value
Subscales										
Somatization	107	53 (49.5)	84	19 (22.6)	0.0001	100	47 (47.0)	89	23 (25.8)	0.0004
Obsessive-Compulsive	107	54 (50.5)	84	15 (17.9)	< 0.0001	100	58 (58.0)	89	25 (28.1)	< 0.0001
Interpersonal sensitivity	106	32 (30.2)	84	17 (20.2)	0.11	100	36 (36.0)	89	18 (20.2)	0.003
Depression	107	56 (52.3)	84	17 (20.2)	< 0.0001	100	54 (54.0)	89	19 (21.4)	< 0.0001
Anxiety	107	55 (51.4)	84	16 (19.1)	< 0.0001	100	56 (56.0)	89	19 (21.4)	< 0.0001
Hostility	107	28 (26.2)	84	6 (7.14)	0.0008	100	29 (29.0)	88	9 (10.23)	0.0003
Phobic anxiety	107	32 (29.9)	84	16 (19.1)	0.09	100	34 (34.0)	88	17 (19.3)	0.03
Paranoid ideation	107	26 (24.3)	84	12 (14.3)	0.03	100	31 (31.0)	89	18 (20.2)	0.046
Psychoticism	107	30 (28.0)	84	12 (14.3)	0.02	100	41 (41.0)	89	20 (22.5)	0.002
Indexes										
GSI[c]	107	54 (50.5)	84	28 (33.3)	0.02	100	59 (59.0)	89	32 (36.0)	0.0001
PSDI[d]	107	38 (35.5)	84	15 (17.9)	0.0003	100	40 (40.0)	89	19 (21.4)	0.001
PST[e]	107	39 (36.5)	84	17 (20.2)	0.008	100	43 (43.0)	89	24 (27.0)	0.009

[a] Effect of MGT on change in dichotomised score from baseline to follow-up tested with McNemar's test.
[b] Effect of TAU on change in dichotomised score from baseline to follow-up tested with McNemar's test.
[c] Global Severity Index.
[d] Positive Symptom Distress Index.
[e] Positive Symptom Total.

Table 3b
Analysis of differences in treatment effect between Mindfulness and Control groups.

	Observed cases (adjusted for baseline score)				Mixed model			
	n	Odds ratio[a]	P-value[b]	95% CI	n	Odds ratio	P-value[c]	95% CI
Subscales								
Somatization	170	1.18	0.71	0.51; 2.73	380	1.59	0.48	0.44; 5.65
Obsessive-compulsive	170	1.94	0.13	0.83; 4.57	380	1.64	0.49	0.40; 6.67
Interpersonal sensitivity	170	0.85	0.71	0.35; 2.03	379	0.51	0.35	0.12; 2.11
Depression	170	1.06	0.88	0.47; 2.39	380	0.95	0.92	0.31; 2.93
Anxiety	170	1.19	0.69	0.51; 2.75	380	0.91	0.89	0.27; 3.09
Hostility	169	1.70	0.42	0.46; 6.20	379	1.29	0.81	0.17; 9.85
Phobic anxiety	169	1.09	0.85	0.46; 2.57	379	0.77	0.68	0.21; 2.76
Paranoid ideation	170	1.46	0.49	0.51; 4.20	380	1.18	0.85	0.22; 6.20
Psychoticism	170	2.19	0.09	0.89; 5.42	380	0.82	0.77	0.21; 3.16
Indexes								
GSI[d]	170	0.85	0.77	0.29; 2.51	380	0.33	0.22	0.05; 1.95
PSDI[e]	170	0.58	0.42	0.16; 2.16	380	0.13	0.42	0.0009; 18.21
PST[f]	170	1.56	0.31	0.66; 3.70	380	1.13	0.87	0.28; 4.45

[a] Difference between Mindfulness and Control group in the odds of T-score < 70, adjusted for baseline score.
[b] Difference tested with a logistic regression model.
[c] Difference tested with a random-intercept logistic regression model using GLLAMM.
[d] Global Severity Index.
[e] Positive Symptom Distress Index.
[f] Positive Symptom Total.

Table 4a
Mean of MAAS[a] and number of cases at baseline and follow-up in Mindfulness and Control groups for observed cases.

Scale	Mindfulness ($n = 110$)						Control ($n = 105$)					
	Baseline		Follow-up		Change[b]		Baseline		Follow-up		Change[c]	
	n	Mean score	n	Mean score	Mean change (SE)	P-value	n	Mean score	n	Mean score	Mean change (SE)	P-value
MAAS	108	3.4	85	4.1	0.52 (0.14)	0.0002	102	3.3	89	3.7	0.42 (0.14)	0.004

[a] Mindfulness Attention Awareness Scale.
[c] Effect of TAU on change in MAAS from baseline to follow-up tested with paired T-test.
[b] Effect of MGT on change in MAAS from baseline to follow-up tested with paired T-test.

available data. In these models, the T-scores are analysed as continuous variables. Both models showed no significant differences between the mindfulness and control group (all P-values > 0.05) in the change in scores before and after treatment.

In Tables 3a and 3b, we examined the clinically significant response after the intervention by dichotomising the T-scores. Clinically significant problems (T-score ≥ 70) are shown in Table 3a at baseline and at follow-up. For all subscales and the three indexes, clinically significant problems decreased after the intervention (all P-values < 0.05, except for interpersonal sensitivity and phobic anxiety in the mindfulness group, P-value = 0.11 and P-value = 0.09, respectively). In Table 3b, the

Table 4b
Analysis of differences in treatment effect between Mindfulness and Control Groups.

Scale	Observed cases (adjusted for baseline score)				Mixed model			
	n	β[a]	*P*-value[b]	95% CI	*n*	β	*P*-value[c]	95% CI
MAAS[d]	173	0.31	0.06	−0.02; 0.64	384	0.20	0.28	−0.16; 0.57

[a] Difference between Mindfulness and Control group in the MAAS changes over time, adjusted for baseline score.
[b] Difference tested with a linear regression model.
[c] Difference tested with a random-intercept linear regression model using GLLAMM.
[d] Mindfulness Attention Awareness Scale.

difference in clinically significant response on the dichotomised scale was examined using a logistic regression model on observed cases and a mixed model on all available data. Both models showed no significant differences between the two groups (*P*-values > 0.05), i.e. we found no evidence of differences in the odds of a clinically significant response between the mindfulness and control groups.

In an explorative analysis, we limited the control group to only CBT ($n = 80$). No significant differences were found (results not shown in tables).

In our additional aim, we examined whether mindful attention and awareness changed after the intervention. This is captured by the MAAS and the results are shown in Tables 4a and 4b. In both groups the scores increased significantly (*P*-value = 0.0002 in the mindfulness group and *P*-value = 0.004 in the control group), indicating increased capacity to be aware of what is taking place in the present after treatment. The potential difference in change in scores between the mindfulness and the control group was examined with a linear regression model and a mixed model. There were no significant differences between the groups, but the adjusted mean difference (β) indicated that the increase in MAAS was slightly higher in the mindfulness group than in the control group (β = 0.31, *P*-value = 0.06).

4. Discussion

This is one of the first RCTs, performed in a primary health care setting, to show that both MGT and TAU can reduce a broad range of psychiatric symptoms, assessed by the different subscales and indexes in the SCL-90 instrument. Furthermore, there were no significant differences in treatment effect, i.e. change in psychiatric symptoms, between the two groups.

4.1. Overall findings and comparisons with previous literature

Our study is broadly in agreement with the findings made by Kuyken et al. [14]. However, the UK study was primarily focused on relapse/recurrence while the present study aimed to examine a broad range of psychiatric symptoms before and after treatment. Our findings concur with a 2011 meta-analysis of 39 studies [31] which showed that depressive symptoms (20 studies) and anxiety (19 studies) decreased after MBSR. However, many of these studies had no control group and the sample sizes were relatively small. The advantages of our study are the use of a control group, the relatively large sample size and the randomised design. In another meta-analysis, based on 19 studies, it was found that mindfulness is also associated with sizeable decreases in symptoms of anxiety and depression [11]. That finding also concurs with the current study. A comprehensive meta-analysis [32] from 2013, including 209 studies ($n = 12{,}145$), showed that mindfulness-based therapies were generally effective in reducing psychological symptoms and did not differ from traditional CBT; findings that concur with the present study.

Although there are previous studies on the impact of mindfulness on psychiatric symptoms, there remains a paucity of information based on RCTs. A previous review, based on 15 different studies, revealed that variety in the methodologies and subject samples was a problem [33]. In approximately 50 percent of the studies (8/15) there was a clear reduction of symptoms of anxiety or depression after mindfulness-based therapy. None of these studies included, however, an active control group. The authors of that review remarked that, in future studies, there should be a greater focus on the role of an active control group as a means of comparing the effect of mindfulness-based therapies with standard treatments. Furthermore, studies carried out since 2012 have reinforced this message by calling for more analyses using an RCT design [34]. In a clinical trial conducted in Denmark [35], a total of 336 women, who had undergone surgery for breast cancer, participated in an 8-week mindfulness-based group programme. The researchers found that the two-month therapy programme yielded relevant results on both a statistical and clinical basis, particularly with regard to depression and anxiety during the follow-up.

Previous research has also indicated that individuals who practise mindfulness can gain several benefits [36]. These include a greater tolerance of stress, with resulting lower susceptibility to feelings of anxiety and pressure. Patients who embrace the particular breathing methods associated with mindfulness can learn to be mindful of the present. Characteristic behaviour, e.g. adverse reactions to emotional situations, can thus be modified by using mindfulness to cope and react in a more composed manner [36]. Studies carried out since 2003 have also noted the affirmative effects of mindfulness on affective experience [37], as well as on personal perception and pain symptoms [38,39].

4.2. A theoretical rationale for how mindfulness therapy reduces psychiatric symptoms

The theoretical rationale for how mindfulness therapy may reduce psychiatric symptoms lies in the way that mindfulness therapy is given and in the suggested changes in the function and structure of the brain. For example, in the present study, the patients were instructed and trained to become aware of the present moment in a non-judgemental and compassionate way using the breath, the body, sounds, and, finally, thoughts and emotions and to relate to them in a wider, decentred perspective as "mental events" rather than accurate reflections of reality or ruminations, which is the opposite to observe thoughts. The instructors emphasised on changing awareness and relationship to thoughts through acceptance rather than directly modifying or removing them per se (as in CBT). Another emphasis of the training was that the patients became increasingly aware of dysphoric and depressive thoughts and emotions and could connect them in a wider perspective as mental events, rather than as aspects of the self [40]. Mindfulness training may change the patterns of brain activity that underlie depression and anxiety. Preliminary functional neuroimaging studies are consistent with an account of mindfulness therapy [41] improving emotional regulation by enhancing cortical regulation of limbic circuits and attentional control. A recent review [42] found growing evidence that

mindfulness techniques might influence the function and structure of the brain. This review of 36 studies analysed MBSR/MBCT interventions combined with functional and/or structural imaging techniques. The authors concluded that the amygdala seems to play a larger role in the neuronal working mechanism in MBSR, than it does in traditional meditation. MBSR induced emotional and behavioural changes that were associated with functional and structural changes in the brain. The hippocampus and prefrontal cortex showed increased activity after MBSR while more disparate results were found for the insula and cingulate cortex. A recent [43] longitudinal study (n = 13) showed that 8-week MBSR training had antidepressant effects and that there were plastic changes in both resting and meditation state brain activity. There were changes in whole brain networks towards connectivity states (anterior cingulate cortex) and the putamen was identified as a potentially important subcortical region during meditation.

4.3. Significance for treatment in primary care in Sweden and internationally

In 2008, in a Swedish study, it was suggested that switching resources to group therapy in primary care could be advantageous to treat patients with depression [44]. Such a switch would increase psychotherapeutic resources as CBT therapists remain in great demand. Once patients have become acquainted with mindfulness, they are in a position to practise the therapy on their own. This has positive clinical ramifications since it means the treatment has the potential to be utilised by a far greater number of patients, compared to more traditional and costly forms of psychotherapy. In Sweden, the number of CBT therapists does not meet the demand from patients and there can be a long waiting time before treatment can begin.

4.4. Limitations and strengths

The present study has some limitations. It is possible that the generalisability of our findings could be affected by the dropout rate. However, on this basis, we have no reason to suggest that the dropout rate in our study was potentially greater than in previous studies of a similar nature. In addition, the period of follow-up was not particularly long and comprised an analysis of symptoms after the 8-week programme had concluded. As a result, we are not able to ascertain whether the improvement of symptoms would have remained the same if the follow-up period had been of a longer duration. Our study also has several strengths, such as the use of an RCT together with an active control group. We believe this study contributes considerably to the existing research in this field, which is sparse. In addition, our study of 215 randomised patients took place in 16 PHCCs in both rural and urban neighbourhoods.

4.5. Future studies

Based on the results of the present study and previous research, we suggest that future studies also use an active control group and have an RCT-design. We also suggest that future studies include participants from different ages and sociodemographic groups. For example, future studies could include elderly people as well as children and adolescents from different types of schools and neighbourhood environments. Another aspect worth investigating further is whether the length and frequency of the mindfulness practice has an effect on the outcome under study. Finally, more studies of how the function and structure of the brain is influenced by mindfulness are valuable in order to increase the understanding of the neurophysiological and neuroanatomical correlates to mindfulness effects.

5. Conclusions

No significant differences in treatment effect between MGT and TAU, mainly individual-based CBT, were found. Both types of therapies could be used in primary care patients with depressive, anxiety and/or stress and adjustment disorders, where the group-based nature as well as short training (six days) of instructors in MGT has a large potential to save limited health care resources and increase availability of therapists.

Disclosure of interest

The authors declare that they have no competing interest.

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