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Effects of Mindfulness Meditation on Chronic Pain: A Randomized Controlled Trial

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Disclosure: None of the authors have conflicts of interest to declare. None have any specific skills or training in mindfulness meditation and only obtained information about mindfulness from books and articles before the investigation. None of the authors taught or participated in any part of the mindfulness course except for the initial informational meeting. At that meeting, both authors actively participated in explaining the logistics of the project.

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Abstract

Objective. This randomized controlled clinical trial investigated the effects of mindfulness meditation on chronic pain.

Design. A total of 109 patients with nonspecific chronic pain were randomized to either a standardized mindfulness meditation program (mindfulness-based stress reduction [MBSR]) or to a wait list control.

Methods. Pain, physical function, mental function, pain acceptance, and health-related quality of life were measured. The SF36 vitality scale was chosen as the primary outcome measure; the primary end point was after completing the MBSR course. Within a 2.5-year period, 43 of the 109 randomized patients completed the mindfulness program, while 47 remained in the control group. Data were compared at three time points: at baseline, after completion of the course/waiting period, and at the 6-month follow-up.

Results. Significant effect (Cohen's d = 0.39) was found on the primary outcome measure, the SF36 vitality scale. On the secondary variables, significant medium to large size effects (Cohen's d = 0.37–0.71) were found for lower general anxiety and depression, better mental quality of life (psychological well-being), feeling in control of the pain, and higher pain acceptance. Small (nonsignificant) effect sizes were found for pain measures. There were no significant differences in the measures just after the intervention vs the 6-month follow-up.

Conclusion. A standardized mindfulness program (MBSR) contributes positively to pain management and can exert clinically relevant effects on several important dimensions in patients with long-lasting chronic pain.

Key Words. MBSR; Meditation; Pain Management; RCT; Pain Psychology; Mindfulness

Introduction

Three recent independent reviews of the effects of mindfulness meditation on chronic pain found that mindfulness meditation shows promise for improving chronic pain. However, all of the reviews stress that larger and better quality studies are needed to draw conclusions [1–3].

The review by Chiesa and Serretti [2] includes 10 controlled studies (6 randomized controlled trials [RCTs]) in which mindfulness-based stress reduction (MBSR) or "closely derived interventions" (mindfulness-based interventions [MBIs]) of a less specific nature were investigated. Most of the studies included patients with specific diagnoses, mainly fibromyalgia. The actual time spent on mindfulness meditation within the specific interventions was not noted in the review. The review concluded that there is not yet sufficient evidence to determine the

magnitude or the specific effects of MBI, recommended more standardized use of mindfulness, and highlighted the need for additional higher powered and better designed studies.

The review by Veehof and colleagues [1] includes 22 studies: 9 RCTs, 5 controlled studies, and 8 noncontrolled studies. The interventions were mixed: 15 studies used an MBSR program and 7 studies used an acceptance and commitment therapy (ACT)-based program. The details regarding the time spent performing mindfulness meditation in the studies are not presented in the review. The review concludes that the effects on pain intensity and depression are not superior to cognitive behavioral therapy. This review also stated the need for better studies.

The most recent review by Reiner and colleagues [3] includes 16 studies (8 controlled and 8 uncontrolled). This review reports more specific details about the actual interventions. Only 5 studies report using a standard MBSR intervention, while 7 used nonspecific "variants of MBSR," 2 used ACT, and 2 used "variants of ACT"; all 11 of these were considered MBIs. The authors suggested that MBIs decrease pain intensity both short and long term and note that further research is needed to clarify the unique advantages of mindfulness meditation.

These three reviews included studies that used various interventions that were "based on mindfulness meditation," but the reviews do not cite the actual time spent performing mindfulness meditation. The actual time spent meditating could vary quite a lot, for example, in the standard ACT programs [4], no time frames for mindfulness meditation were specified. Rather, it is primarily the "attitudes" of mindfulness that were worked with. The effects of the MBSR program itself are still in question in terms of treating the large group of patients with chronic nonspecific pain.

The MBSR program was designed to manage chronic pain [5], but the initial study by Kabat-Zinn in 1982 was uncontrolled. Over time, only one study with an RCT design seems to have investigated the use of the standardized well-described mindfulness meditation program in a group of patients with mixed chronic pain conditions. This study dates back to 1999 and includes a sample of only 15 intervention patients and 7 controls [6].

The aim of the present study was to conduct a standard RCT investigation of the effects of a mindfulness meditation program (MBSR) for patients with long-lasting, severe pain conditions of multiple origins in an ambulatory hospital setting.

Methods

Design

This was a randomized wait list controlled trial with a 6-month follow-up period. It included a pilot study, three wait list control groups, and three treatment groups. The study period was from February 2010 to November 2012. The treatment groups and wait list groups were time parallel. After the wait list period and measurements, the wait list participants received the treatment program.

The feasibility of the program and the usefulness of the measurement instruments were tested in a pilot study conducted in 2009 that included 11 participants. The measurement instruments used in the pilot study were more comprehensive than in the final study, and the participants participated in two qualitative group interviews, once during the course and again 6 months later. There were no quantitative measurements after 6 months. During the interviews, the pilot study participants all stated that they felt more alive and more energetic, and in the data analysis of the small sample, the SF36 vitality scale was the only SF36 scale reaching a significant level of change. The SF36 vitality scale was therefore chosen as the primary outcome measure for the current study, and was also used in a minimal relevant difference calculation of sample size.

Quantitative data from the pilot study are not included in this study.

Participants

Participants were referred to our specialized pain center by physicians and were recruited to the study as described below. All patients were diagnosed with chronic pain by trained physicians who specialized in treating pain. All of the pain conditions were serious and long-lasting. The patients were treated at the pain clinic prior to enrollment in the study for a mean of 19.21 (standard deviation [SD] 11.6) months. All patients received standard treatment at the pain clinic before, during, and after the intervention. As standard treatment, each patient was seen at the clinic at 6- to 12-week intervals or less often in some cases. During a routine visit, the patient was asked by a staff member if he or she would be interested in participating in a study that looked at the effects of meditation on chronic pain. If the patient was interested, a written invitation to an informational meeting conducted by the MBSR mindfulness meditation teacher and the study organizers was issued. The invitation also provided some information about the meditation program. Patients who were invited to the meeting all had been treated for some time at the pain clinic, which meant that their pain medication had been adjusted and was set, that treatment was in a more stable phase, and that the clinical routines were predictable. Patients with unstable clinical situations such as pharmaceutical treatments that continued to change and patients with obvious mental disabilities such as severe cognitive problems or emotional turmoil were not invited. Patients with very poor Danish language skills were also not invited. There were no non-invitations (exclusions) based on the type of pain or on physical abilities.

At the informational meeting, the interested patients were told about the intervention schedule, which involved

course meetings. They were told that if they participated, they would have to spend 45 minutes every day in meditation during the 8-week course period, complete the appropriate questionnaires in a timely manner, and supply detailed information about their reasons for leaving the course if they did so. Every patient who was able to meet these obligations was considered to be eligible for study participation.

Patients could inform pain center staff about their participation and status in the study if they wanted to, but the staff was not informed in a formal way about which patients were participating in the study.

Randomization

The three informational meetings were organized and timed so that approximately 40 patients would sign up for the mindfulness course. The invitation letter informed the invitees that they would be randomized to either a treatment group or to a wait list group. At the end of the informational meeting, the patients were asked to decide whether they wished to participate on the given premises. The randomization procedure was a "simple randomization" that has been reported as working well in large groups [7]; this procedure was performed openly. The patients themselves drew small red or white pieces of paper that were concealed in envelopes. The colors indicated either the wait list or the treatment condition. The process of randomization and the assignment of patients to groups were performed by the study organizers (authors).

Control (Wait List) Condition

Patients assigned to the wait list received treatment at the pain center as usual. This included going to scheduled meetings with physicians, nurses, psychologists, or social workers. The wait list period lasted between 2 and 2.5 months. After this period, the patients were assigned to the MBSR program, and program and measurements were performed exactly as in the treatment group.

Intervention

Frequency and Setting

Participants were seen at weekly group meetings: Eight meetings were 3-hour sessions, and one meeting was 4.5 hours. A follow-up session was conducted 2 months after the last session. The study was based at the multidisciplinary pain center in Rigshospitalet, Copenhagen, which is a Danish state hospital. The sessions were held in a building owned by the hospital and located near the pain center. The room was big enough to allow everybody to sit or lie down and was fully accessible to wheelchairs.

The three treatment groups included 22, 16, and 17 participants at the beginning of treatment. The sessions were conducted mainly by a fully trained and highly experienced MBSR instructor with a strong background in meditation. This teacher had completed a training and certification process with Jon Kabat-Zinn and colleagues at the Center for Mindfulness in Medicine, Health Care and Society at the University of Massachusetts in the United States. Some small parts of the sessions were conducted by a fellow MBSR teacher under close supervision by the main teacher to ensure treatment integrity. The second teacher was less experienced and uncertified but had been fully trained at the Mindfullife Institute in Denmark.

The mindfulness instructors had no relationship or contact with the patients other than at the mindfulness course.

Program Techniques and Protocol

The mindfulness program was closely based on the standard MBSR protocol [8]. Participants were taught to meditate daily for 45 minutes at home following instructions on a CD and were instructed to keep a diary.

During the pilot project, a few adjustments of the MBSR program were necessary to accommodate the patients, some of whom were quite disabled due to chronic pain. The following changes were made: The 2.5-hour MBSR sessions were extended to 3 hours in order to include a 20-minute break at which water and fruit was served and giving disabled participants the possibility to go to the restroom without missing much of the session. The additional 10 minutes of actual "teaching time" also allowed for repetition of didactical points.

The seventh so-called "all-day-session" was reduced to 4.5 hours from the standard 7.5 hours and included a 45-minute break with sandwiches, fruit, and water instead of the standard 60-minute break. Reductions were applied in both the mindful movements training and the trainings in walking meditation. Also, the "Hasty-Walking" intervention was omitted. Furthermore, this session was held on a regular program day rather than as an extra session in addition to the weekly sessions. The reason was logistic; the pain center was not staffed on the weekends.

The physical exercise part of the instruction (i.e., yoga) had to be modified to accommodate the physical abilities of the specific study group. Patients had to participate in more than 60% of the meetings (i.e., attend at least six of the nine meetings) to be included in the study.

Measurements

Baseline Measurements

Baseline demographic and health data were collected from the medical records of the patients. These included age, sex, duration of pain, duration of opioid treatment, work and relationship status, formal education, and pain location(s).

Outcome Measurements and Time Schedule

The data set comprised the six questionnaires listed below, which were distributed at three time points: 1) at

the informational meeting (baseline data); 2) before the first session for the wait list groups and after the last ordinary treatment for the treated groups; and 3) 6 months after the last session (6-month follow-up data). All questionnaires were distributed and collected by the investigators (authors). The questionnaires were mostly distributed by hand before and after meetings and sessions and were usually also collected this way. The exceptions were the wait list baseline questionnaires and the follow-up questionnaires, all of which were distributed and collected by postal mail. All questionnaires were completed by the patients at home.

Pain Measures

Pain was measured with two instruments: the Brief Pain Inventory, comprising visual analog scales (VASs) ranging from 1 to 10. Patients were asked to indicate the worst, the least, and the average pain within the last 24 hours and their current level of pain [9]. The four scales are summarized in an average score (1–10), with higher scores indicating more pain. This scale is widely recommended as a main pain measurement [10] and has been validated and found to be reliable in Scandinavian languages [11].

The SF36 is a standardized, well-validated, multidimensional questionnaire that measures health, level of function, and well-being for eight dimensions [12]. It has been validated and found to be reliable in Danish [13]. The bodily pain dimension scale of the SF36 questionnaire has one question about pain within the last 4 weeks and one question about the practical impact of pain. The scores are transformed to a score ranging from 0 to 100, with a higher score indicating less pain.

Physical Function

The SF36 physical function scale is the most extensive one of the SF36. It includes 10 questions about different kinds of physical limitations. The transformed score ranges from 0 to 100, with a higher score indicating fewer physical limitations.

Mental Function

The Hospital Anxiety and Depression Scale is a 14-item screening instrument for anxiety and depression in nonpsychiatric patients [14] that has been validated and found reliable for the Danish general population [15] and for patients with chronic pain [16,17]. The range is from 0 to 21 for both anxiety and depression, with higher scores indicating more anxiety and depression.

The SF36 vitality scale comprises four questions. The transformed scaled score ranges from 0 to 100, with a higher score indicating greater vitality.

"Catastrophic thinking" is a subscale of the Coping Strategies Questionnaire (CSQ), which was developed in 1981 and originally comprised seven scales, each with six questions [18]. The scale has been validated and found reliable in Scandinavia (Sweden) [19], and norms are found for patients with pain [20]. The catastrophic thinking subscale is the most robust scale [21]. This subscale comprises six questions, with scores ranging from 0 to 36. Higher scores indicate more catastrophic thinking.

"Control over pain" and "minimizing pain" are two single questions about pain in the CSQ, with higher scores indicating better coping with pain.

The SF36 psychological well-being scale comprises five questions. The transformed scaled score ranges from 0 to 100, with a higher score indicating greater psychological well-being.

Pain Acceptance

The Chronic Pain Acceptance Questionnaire is a 20-item, VAS score-based instrument for measuring pain acceptance. It results in three summed scores: engagement in activity (in spite of pain), pain willingness, and total pain acceptance score. The instrument has been validated and found to be reliable in six languages, including Swedish (Scandinavia) [22–24]. The range for the sub-scores is 0 to 60, and the total score ranges from 0 to 120. A higher score indicates greater pain acceptance.

Quality of Life

The SF36 summary measures of physical health and mental health are usually referred to as quality of life scales. The scales sum up all 36 questions of the SF36 and the transformed scales. The transformed scaled score ranges from 0 to 100, with a higher score indicating a higher quality of life.

Statistical Analysis

Sample Size

The main outcome measure was the "vitality" dimension of the SF36. Notably, the SF36 is a much tested, well-validated questionnaire that is used internationally and which is highly recommended. In the pilot study preceding this investigation (N = 11), the computations showed SD = 16.5, and with parameters set for an estimated clinically relevant difference >12%, $P < 0.05$, and a power of 80%. The MIREDIF computation showed that we needed a minimum of 30 patients for the control group and for the treatment group. We predicted that an estimated 65% of participants would complete the entire program (participation in at least 60% of the sessions and completion of questionnaires at the 6-month follow-up).

Data Analysis

Descriptive statistics for the two groups were generated and the groups were compared using the chi-square test and the independent sample *t*-test for dichotomous and

continuous variables, respectively. Completed questionnaires were all included in the database and analysis.

For the main analysis, an intention-to-treat analysis was performed, using the "last value carried forward" method of imputing values for missing or non-complete questionnaires. In case of incomplete baseline data, data were imputed by carrying first value backward.

On the main outcome variable, nine questionnaires were missing or incomplete in the control group and five in the treatment group. A data imputation based on probabilities from multiple socio-demographic data was also tested; linear regression of the main outcome variable and all socio-demographic data was performed for analysis of systematic associations. None were found, indicating no systematic differences between completers and non-completers.

Data from the pilot study are not included the data set. All basic calculations were performed using SPSS 19 software (SPSS, Inc., Chicago, IL, USA) with standard settings. The main independent variable was the patient group. Changes in the control group were defined as the values on the baseline questionnaires minus values at the starting point for the course (which was approximately 9–10 weeks later). Changes in the treatment group were defined as differences between the baseline measures and end-of-course measures, which were obtained immediately or no more than 2 weeks after the course ended. Changes in follow-up were defined as differences between baseline measures and the 6-month measures. Changes in scores were determined separately for the groups, and effect sizes of differences were computed from the means and SDs using the dedicated facility at http://www.uccs.edu/~lbecker/, reported as Cohen's d. *P* values for differences between the intervention and control groups were tested using the SPSS independent sample *t*-test.

Continuous variables were assessed for normality using the Kolmogorov–Smirnov test and by inspection of the frequency plots (histogram) and Q–Q plots. To minimize inflation of significance from the many variables, $P = 0.05$ was determined as the significance level only for the primary outcome variable and consider $P = 0.01$ as significance level for the secondary, more explorative variables.

Ethics

At the time the project started, questionnaire-based investigations in which no human biological materials were included were all approved by the Committees on Biomedical Research Ethics for the capital region of Denmark.

Results

Baseline Characteristics

The baseline socio-demographic and health data of the study participants are shown in Table 1. Statistical comparisons between the treated group (N = 54) and the wait list group (N = 55) revealed one important statistically significant difference ($P = 0.02$), namely that the duration of pain was 4 years longer in the wait list group (11.8 years) than in the treatment group (7.8 years). Although not significant, there was also an age difference of 2.3 years between the groups, with subjects in the wait list group being older. There was a significant difference in the number of patients reporting pain in the thorax; however, so few subjects reported pain in the thorax (4 vs 16) that this may have been a type 1 error.

Comparing all treated participants in both groups after 6 months to the dropout group, two significant differences were noted: The average age in the dropout group was nearly 8 years younger than in the treated groups (42.1 vs 49.8 years, $P = 0.01$) and 72% of subjects in the studied groups were married/coupled vs 46% in the dropout group ($P = 0.02$). The difference in the average working hours was nearly, but not quite, significant (26.6 hours/week for the studied group vs 16.9 for the dropout group, $P = 0.054$). A difference in reporting cervical pain was also seen ($P = 0.04$).

Adherence

Eleven subjects dropped out of the intervention groups and eight dropped out of the wait list groups, resulting in an overall completion rate of 82% (90 of 109) during the investigation period. In the intervention groups, three had conflicting work obligations, two did not have the energy for meeting every week, one had a negative impression of the course, four dropped out for unknown reasons, and one was excluded due to insufficient participation (attending <60% of the sessions). In the wait list groups, eight people declined to participate in the MBSR program. When the wait list group completed the course, the completion rate was 79% (37 of 47), similar to the completion rate of the treated group (also 80%, 43 of 54). Participants dropped out most often after the first few sessions. Attendance at the sessions was 87%. The final sizes of the three treatment groups and the three wait list treatment groups were between 13 and 18 patients completing the program.

At the 6-month follow-up, three participants from the intervention group did not complete the questionnaires. In the wait list group that completed the course, this number was four. The reasons are unknown (Figure 1).

Dropout and Non-Completion

The associations between the main outcome measure and socio-demographic characteristics were assessed using linear regression. There were no significant associations found, indicating that possible socio-demographic differences between completers and non-completers likely had minimal influence on the findings. Of special interest were the three variables with significant differences between dropouts and completers, which were analyzed separately. All relationships were small: duration

Table 1 Characteristics of the study participants

	Waiting List Group at Baseline (N = 55)	Meditation Group at Baseline (N = 54)	*P* Value (Waiting List Group vs Meditation Group)	Waiting List Group and Meditation Group at the 6-Month Follow-Up (N = 72)	Dropouts (N = 22)	*P* Value (6 Months vs Dropouts)
Age: mean (SD)*	48.84 (12.20)	46.52 (12.42)	0.33	49.83 (12.23)	42.14 (10.85)	0.01
Range	22–76	19–75		19–76	24–65	
Sex: male % (N)	13 (7)	17 (9)	0.56	15 (11)	9 (2)	0.46
Duration of pain in years, mean (SD)*	11.82 (11.09)	7.83 (5.52)	0.02	10.63 (9.56)	7.41 (6.43)	0.14
Range	1–57	1–28		1–57	1–27	
Opioid use in years, mean (SD)*	5.69 (5.88)	4.13 (4.32)	0.13	5.53 (5.71)	3.62 (3.98)	0.16
Range	0–37	0–20		0–37	0–11	
Months in clinic before mindfulness	19.53 (11.82)	18.89 (11.29)	0.77	18.86 (11.40)	19.82 (11.78)	0.73
Work status: yes, % (N)	36 (29)	39 (21)	0.56	38 (27)	36 (8)	0.19
Hours, mean (SD)*	24.94 (12.28)	22.60 (11.45)	0.60	26.59 (11.12)	16.88 (13.2)	0.05
Pain location:						
Head, % (N)	13 (7)	17 (9)	0.56	11 (8)	18 (4)	0.38
Cervical, % (N)	22 (12)	32 (17)	0.25	31 (22)	9 (2)	0.04
Shoulder, arms, % (N)	40 (22)	37 (20)	0.75	39 (28)	27 (6)	0.32
Thorax, % (N)	7 (4)	30 (16)	0.003	22 (16)	9 (2)	0.17
Abdominal, % (N)	11 (6)	11 (6)	0.97	13 (9)	5 (1)	0.29
Low back, % (N)	64 (35)	48 (26)	0.10	51 (37)	59 (13)	0.53
Legs, % (N)	55 (30)	50 (27)	0.64	49 (35)	59 (13)	0.39
Pelvis, % (N)	13 (7)	13 (7)	0.97	10 (7)	18 (4)	0.28
Anal/genital, % (N)	4 (2)	9 (5)	0.23	4 (3)	14 (3)	0.11
Married/coupled status, % (N)	64 (35)	67 (36)	0.74	72 (52)	46 (10)	0.02
School ≥12 years, % (N)	59 (30)	46 (25)	0.20	44 (32)	36 (8)	0.65
Formal education, yes % (N)	87 (48)	85 (46)	0.58	85 (61)	91 (20)	0.61
Income ≥Danish average of 250,000 DKR/person, % (N)	76 (32)	56 (30)	0.51	60 (43)	50 (11)	0.24

* *P* value determined using the Student's *t*-test; otherwise, *P* value determined using the chi-square test.
Formal education: professional training beyond school.
DKR = Danish Krone; SD = standard deviation.

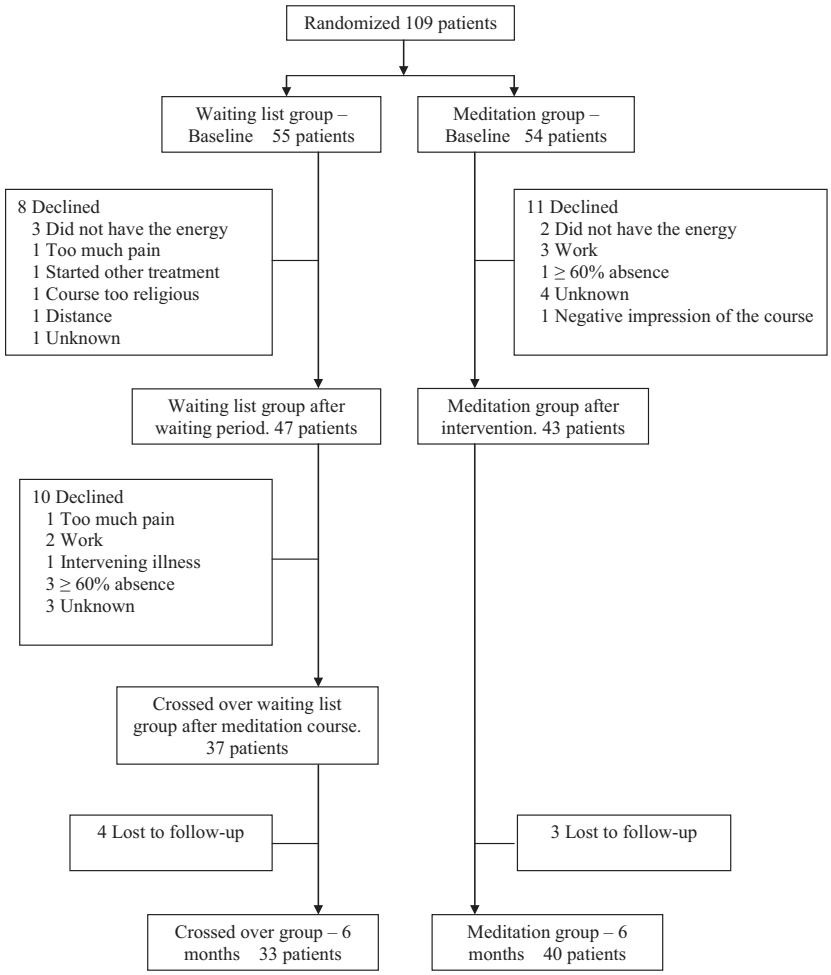

Figure 1 Flow diagram of study subjects.

of pain: Pearson –0.08 ($P = 0.50$); age: Pearson 0.12 ($P = 0.29$); and married/coupled: *t*-test ($P = 0.21$).

Harm

The patients were asked to report reasons for discontinuing participation in the course. In addition, there was passive surveillance of adverse effects [25]. As a result, we know that at least two of the participants experienced temporary strong feelings of anger toward their pain condition and at least two patients experienced greater anxiety.

Post-Intervention Outcomes

Table 2 compares the changes in the scores of the intervention and control groups at baseline and after the 8-week program/waiting period. Comparing mean changes in the groups, the main outcome variable SF36 vitality was significant after the intervention (level $P \leq 0.05$). Lower level of anxiety, greater ability to control pain, greater readiness to engage in activities despite pain (pain acceptance), and a better mental quality of life (level $P \leq 0.01$) were also significant.

At 6 months after the intervention, none of the scores were significantly different from the scores measured just after treatment ended in a paired sample *t*-test. After 6 months, the following scores had changed in a more positive direction: pain measures, the depression scale, and all pain acceptance measures.

To understand the nature of change in pain better, we analyzed the two questions concerning pain in the SF36 separately. One question is about the level of pain, the other is about the impact of pain on everyday life. In the treatment group, the level of pain did not change significantly at any time, whereas the score for the question about the impact of pain on everyday life was significantly improved between baseline (raw score mean 2.07 [SD 0.89]) and after the course (mean 2.57 [SD 1.13]), $P = 0.01$, and improved further after 6 months (mean 2.71 [SD 1.18], $P < 0.01$).

Completion of the Mindfulness Course by the Wait List Group

After the wait list condition, all participants were offered the full MBSR program in three separate

Table 2 Comparisons of outcome measures in the meditation group vs the waiting list control group at baseline, after intervention, and at the 6-month follow-up: intention-to-treat analysis

Outcome Measure	Group[†]	Baseline Mean ± SD	After Intervention Mean ± SD	Effect Size (Cohen's d)[‡]	*P* Value	6-Month Follow-Up (Meditation Group Only) Mean ± SD[§]
Primary outcome						
SF36, vitality dimension	Meditation	28.3 ± 22.0	36.8 ± 24.4	0.39	0.04	34.8 ± 26.6*
	Control	26.9 ± 20.5	27.8 ± 20.2			
Pain						
BPI, average score	Meditation	19.0 ± 6.6	18.8 ± 5.9	0.25	0.17	18.0 ± 6.6
	Control	19.2 ± 5.2	17.9 ± 5.6			
SF36 pain scale	Meditation	24.3 ± 16.2	28.5 ± 18.1	0.21	0.26	30.1 ± 20.7*
	Control	23.7 ± 12.9	25.1 ± 15.5			
Physical functioning						
SF36 physical function scale	Meditation	45.4 ± 23.8	48.3 ± 25.8	–0.05	0.78	48.1 ± 24.9*
	Control	45.2 ± 20.6	48.6 ± 21.3			
Mental functioning						
HADS, anxiety	Meditation	9.3 ± 4.5	8.1 ± 4.4	0.50	0.01	8.3 ± 4.8
	Control	9.1 ± 4.4	9.4 ± 4.5			
HADS, depression	Meditation	7.1 ± 4.5	5.9 ± 4.3	0.37	0.05	5.5 ± 4.1*
	Control	7.6 ± 4.7	7.6 ± 4.8			
Catastrophic thinking	Meditation	16.6 ± 7.3	14.7 ± 7.9	0.20	0.28	14.9 ± 7.6
	Control	18.6 ± 7.9	18.1 ± 8.6			
Control over pain	Meditation	2.3 ± 1.3	2.9 ± 1.3	0.55	<0.01	2.8 ± 1.4*
	Control	2.5 ± 1.2	2.4 ± 1.1			
Minimizing pain	Meditation	2.3 ± 1.2	2.6 ± 1.3	0.19	0.30	2.4 ± 1.3
	Control	2.3 ± 1.2	2.4 ± 1.0			
SF36 psychological well-being scale	Meditation	57.0 ± 20.7	63.3 ± 20.5	0.43	0.02	62.6 ± 21.3
	Control	52.1 ± 17.3	52.5 ± 19.0			
Pain acceptance						
Engagement activity	Meditation	28.3 ± 12.0	32.3 ± 11.5	0.71	<0.01	33.0 ± 13.1*
	Control	29.4 ± 10.8	28.8 ± 10.9			
Pain willingness	Meditation	19.8 ± 8.2	22.0 ± 9.1	0.34	0.07	28.4 ± 9.6*
	Control	18.7 ± 8.0	18.6 ± 7.1			
Pain acceptance, total score	Meditation	48.21 ± 16.6	54.2 ± 18.1	0.60	<0.01	56.0 ± 20.9*
	Control	48.0 ± 16.2	47.2 ± 15.3			
Health-related quality of life						
SF36 physical health composite	Meditation	28.3 ± 7.1	30.1 ± 8.8	0.10	0.61	30.3 ± 8.7*
	Control	28.9 ± 6.5	30.1 ± 7.8			
SF36 mental health composite	Meditation	41.3 ± 13.2	45.5 ± 12.9	0.48	0.01	44.7 ± 13.5
	Control	39.5 ± 12.3	38.7 ± 12.7			

* Marks significance level <0.01 between baseline and 6 months for the meditation group in a paired sample *t*-test.
[†] Group sizes: Meditation group, N = 54. Waiting list control group, N = 55.
[‡] Effect size d = Mt – Mc/σpooled. Mt = mean change in the score of the treatment group; Mc = mean change in the score of the control group; σpooled = $\sqrt{(\sigma t^2 + \sigma c^2/2)}$; σt = standard deviation of the change in the score of the treatment group; σc = standard deviation of the change in the score of the control group.
[§] No significant difference ($P < 0.05$) between the 8-week and 6-month scores with a paired sample *t*-test.
BPI = Brief Pain Inventory; HADS = Hospital Anxiety and Depression Scale; SD = standard deviation.

courses conducted just after the waiting period. The same measures were used as in the treatment condition. The baseline, after course, and 6-month scores for this group are shown in Table 3.

The main changes confirmed the findings from the between-group comparisons. Lasting significant changes were found for vitality, better coping with pain, better pain acceptance, and better mental health quality of life, as seen in Table 3.

Table 3 Outcomes for the waiting list control group before and after completing the mindfulness meditation (MBSR) program and at the 6-month follow-up: intention to treat, paired sample *t*-test analysis

Outcome Measure	Baseline Mean ± SD	After Intervention Mean ± SD	6-Month Follow Up	*P* Value Baseline to 8 Weeks	*P* Value Baseline to 6 Months
Primary outcome					
SF36, vitality dimension	27.8 ± 20.2	34.9 ± 21.8	32.5 ± 20.8	<0.01	0.02
Pain					
BPI, average score	17.9 ± 5.6	18.2 ± 5.1	17.5 ± 6.1	0.50	0.49
SF36 pain scale	25-1 ± 14.9	28.8 ± 15.5	30.6 ± 17.6	0.01	<0.01
Physical function					
SF36 physical function scale	48.6 ± 21.3	50.3 ± 20.9	53.4 ± 20.9	0.20	0.02
Mental function					
HADS, anxiety	9.6 ± 4.5	8.4 ± 4.0	8.6 ± 4.6	<0.01	0.09
HADS, depression	7.6 ± 4.8	6.3 ± 4.6	6.8 ± 5.0	<0.01	0.03
Catastrophic thinking	18.1 ± 8.6	16.7 ± 8.9	15.7 ± 9.1	0.05	<0.01
Control over pain	2.4 ± 1.1	2.7 ± 0.9	2.9 ± 1.2	0.01	<0.01
Minimizing pain	2.4 ± 1.0	2.6 ± 1.1	2.8 ± 1.3	0.03	<0.01
SF36 psychological well-being scale	52.5 ± 19.0	59.6 ± 20.6	55.5 ± 21.6	<0.01	0.13
Pain acceptance					
Engagement activity	28.8 ± 10.9	31.3 ± 11.4	31.1 ± 11.6	<0.01	0.05
Pain willingness	18.6 ± 7.0	20.6 ± 6.8	21.0 ± 7.3	<0.01	<0.01
Pain acceptance, total score	47.2 ± 15.3	51.7 ± 16.5	51.9 ± 17.5	<0.01	0.01
Health-related quality of life					
SF36 physical health composite	30.1 ± 7.8	30.0 ± 7.5	32.1 ± 8.2	0.81	0.01
SF36 mental health composite	38.7 ± 12.7	43.1 ± 14.0	41.4 ± 13.9	<0.01	0.09

N = 55.
BPI = Brief Pain Inventory; HADS = Hospital Anxiety and Depression Scale; MBSR = mindfulness-based stress reduction; SD = standard deviation.

Analysis of Completers

Statistical analysis of only those intervention participants who completed the program was also done on all variables. The analysis did not vary from the intention-to-treat analysis in structure, but as expected the effect sizes were generally higher.

Discussion

This study showed that mindfulness meditation, which was modeled on the MBSR protocol [8], had significant effects on the lives of patients with long-term chronic pain compared with a wait list group. The chosen primary outcome of this study, the vitality dimension of the SF36 instrument, showed significant positive effects in the hypothesized direction after the treatment program. There was a medium effect size immediately after treatment and a minor, nonsignificant decrease at the 6-month follow-up. The change could be classified as a "clinically important difference" according to standard comparisons using the SF36 instrument [25–27].

However, there were higher significant effect sizes in areas other than vitality, especially in the areas of pain acceptance (i.e., in engaging in activities in spite of pain), being in control of pain, and in general anxiety in the treatment group compared with the wait list group. Medium effect sizes were found for mental health quality of life, including psychological well-being and lower depressive symptoms. Small effect sizes that did not reach statistical significance were found for the pain measures. After 6 months, there were nonsignificant changes in both directions. It is noteworthy that both pain scales showed less pain at the 6-month follow-up. This study adds to previous studies that showed the possible benefits of MSBR in pain in several ways. Three review studies [1–3] reported small to moderate effects sizes for MBIs. Several recent RCTs were conducted that used the MBSR protocol to investigate issues that are closely related to chronic pain conditions, such as studies of functional diseases. Treating fibromyalgia with MBSR, Schmidt et al. [28] found only small effects on quality of life, depression, pain, anxiety, and somatic complaints. Fjorback et al. treated functional disorders with MBSR [29] and found no effect on physical health measures but did find faster improvement in terms of quality of life. Weak or small to moderate effects of MBSR were found in two meta-analyses of somatoform conditions (fibromyalgia) [30,31], and a recent meta-analysis of studies of more general chronic conditions found only small to moderate effects of MBSR on depression, anxiety, and psychological distress [32,33].

According to the socio-demographic data (Table 1), the wait list group had chronic pain significantly longer than the treatment group (4 years more on average) and, on average, they were also 2 years older. Thus, this group might represent a more chronic and troubled group than the intervention group, and it can be considered a result in itself that even subjects with very long-standing pain are still able to benefit from a mindfulness program.

It seems evident from previous studies as well as from the present study that mindfulness does not change measures of physical functioning, that the effects on pain levels are small, and that change is slow. When we study patients with pain, at first it seems obvious that the main outcome should be related to changes in a pain measure. However, we suggest that this be rethought. People with long-lasting pain have often learned to ignore pain in order to function normally. This habit is challenged by MBSR meditation procedures that involve paying increased attention to the body and to the pain. By acknowledging the pain and relating to it in a different way, the patients bring more consciousness to the actual pain condition. Mindfulness is not targeted at minimizing pain but rather at changing the relationship with pain. Thus, the findings of small and slow changes in pain levels in response to treatment make sense from this perspective. Anecdotally, we note that some patients experimented with using less pain medication during the program.

The intervention in this study, mindfulness meditation, involves complex human learning and human interactions. It is not a pill [34]. It may be a misconception that research in meditation is most meaningful when there is an assumption that MBSR can be used at the same dose and manner for everyone as "one size fits all." The meditation process, the personal engagement, and the time spent in actual meditation are very personal and not everybody will be motivated in the same way just because they are in pain. Meditation is very often accompanied by the process of learning to access a personal "inner space." For some, this process is an exciting discovery and exploration; for others, it is a constant battle that in itself is painful. When taken seriously, meditation might not suit every patient or affect every patient in the same way. In addition, when meditation is taken seriously, it involves a change in daily time schedules and therefore changes in lifestyle, which patients must be motivated to undergo.

The review article by Chiesa and Serretti [2] argues that the next research direction is to investigate which effects of meditation are specific and which are nonspecific. The next logical research question could also be: Which patients benefit most from mindfulness meditation? We suggest that the next step is to investigate "what works for whom" to refine the process to target the most suitable patients, i.e., those most likely to respond to a specific MBSR intervention.

This study tried to follow the methodology used by Morone et al. [35] in a similar, but smaller study of elders with low back pain, in order to make direct comparisons possible. When we had to use methodology that differed from the methodology in that study, we tried to follow the rationale of ecological validity [36], i.e., we tried to make the RCT experiment mirror the everyday conditions in a multifaceted pain clinic as much as possible. For these reasons, as well as after reflecting on the nature of the mindfulness intervention, it could be argued to present per protocol (completers analysis) computations instead of the standard intention-to-treat analysis. No major differences were found between the two data handling methods, and the intention-to-treat has the advantage of making immediate comparisons possible regarding other published results in the area. During the study, all patients received treatment as usual. This might have influenced results in several cases in which, for example, patients changed their medication. In addition, social or emotional issues may have changed or been resolved during the study period, and this may have influenced outcome measures. We did not measure or record such events and changes, which is a methodological weakness. We considered the average treatment period of 1.5 years in the pain clinic before the study period as an indication that treatment as usual did not include planned or major changes in treatment strategies. However, such changes may have occurred. Mindfulness meditation is a clinically complex treatment that must show ecological validity and feasibility in a clinical hospital setting if mindfulness is to be a realistic, positive alternative to usual treatment.

There are limitations to the study: first of all, the amount of dropouts and not completed questionnaires. We have tried to address this problem as reasonably as we could, but it still represents a problem for the interpretation of the results. Furthermore, the study design does not take into account the possible natural processes of greater motivation for those staying on the wait list and the probability of natural nonspecific improvements during the follow-up period. The differences concerning age, duration of pain, and married/coupled status between the treatment and the wait list groups may also have influenced the results in favor of the treatment group.

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