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Self-report Mindfulness as a Mediator of Psychological Well-being in a Stress Reduction Intervention for Cancer Patients—A Randomized Study

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Abstract

Background There is increasing recognition of mindfulness and mindfulness training as a way to decrease stress and increase psychological functioning.

Purpose The aims of this study were to examine the effects of mindfulness stress reduction training on perceived stress and psychological well-being and to examine if changes in mindfulness mediate intervention effects on these outcomes. *Methods* Seventy women and one man with a previous cancer diagnosis (mean age 51.8 years, standard deviation= 9.86) were randomized into an intervention group or a waitlist control group. The intervention consisted of an 8-week mindfulness training course.

Results Compared to participants in the control group, participants in the mindfulness training group had significantly decreased perceived stress and posttraumatic avoidance symptoms and increased positive states of mind. Those who participated in the intervention reported a significant increase in scores on the five-facet mindfulness questionnaire (FFMQ) when compared to controls. The increase in FFMQ score mediated the effects of the

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J. T. Moskowitz Osher Center for Integrative Medicine, University of California, San Francisco, San Francisco, CA, USA intervention on perceived stress, posttraumatic avoidance symptoms, and positive states of mind.

Conclusions This study indicates that the improvements in psychological well-being resulting from mindfulness stress reduction training can potentially be explained by increased levels of mindfulness as measured with the FFMQ. The importance of these findings for future research in the field of mindfulness is discussed.

Keywords Mindfulness · Meditation · Stress reduction · Cancer · Depression · Perceived stress

Introduction

Mindfulness meditation as an intervention to promote stress reduction has become increasingly used over the last decade [1-9] and consistently shows promising beneficial effects on psychological well-being. Mindfulness or mindful awareness is derived from a Buddhist tradition and includes two major components [10]. The first important component of mindfulness concerns a self-regulation of awareness towards present mental states and processes. The second component concerns a nonevaluative openness and acceptance towards moment-to-moment experiences. Mindfulness can be trained by practicing various forms of meditation or through mental exercises [6]. The development of mindfulness is integrated in several structured training programs and therapies such as Mindfulness-Based Stress Reduction (MBSR; [6]), Mindfulness-Based Cognitive Therapy [11], Dialectical Behavior Therapy [12], and Acceptance and Commitment Therapy [13]. These programs and therapies have shown promising results in improving different psychological outcomes. In particular, mindfulness-based stress

reduction programs have shown a strong potential for changing peoples' experiences of stress-related complaints and increasing well-being [5, 7, 9, 10, 14–18].

The MBSR meditation course has been widely used in medical settings and has been shown to have potential to decrease stress and depression [2, 3, 5, 9, 15]. It has shown positive effects on quality of life and decreased stress symptoms in patients with varying cancer diagnoses [17-19]. Studies have also shown promising results of MBSR programs on sleep disturbances among cancer patients [5, 8]. A meta-analysis of the effects of MBSR on different patient groups gives support for the use of MBSR in reducing stress and enhancing quality of life, even though more welldesigned studies are needed [5, 20]. Many of the studies on the effects of MBSR programs have been exploratory in their design, used no or nonrandomized controls, and short followup periods. In addition, previous studies lack an adequate definition of the construct of mindfulness itself. Although it is central to all interventions, it is often neither operationalized nor evaluated for change in previous studies [5]. So far, very few studies have looked at the mediating effect of mindfulness on psychological outcomes [21, 22]. In this study, we clearly operationalize and measure mindfulness as it is currently conceptualized in the literature, which enables testing of the mediation of mindfulness on psychological outcomes. Most of the published studies of the effects of mindfulness meditation with cancer patients have been conducted in North America and only a few studies have used a randomized controlled design [20]. The current study uses a randomized controlled study design to extend findings regarding the effects of mindfulness training to a different cultural setting and uses a longer follow-up time than has been used in previous randomized trials. Furthermore, although posttraumatic stress symptoms are common among cancer patients [23], previous mindfulness studies have not examined this outcome.

This study aimed to examine the effects of a MBSR program, delivered in group sessions, among cancer patients. The effects of mindfulness training on the primary outcome of perceived stress and the secondary outcomes of depression, anxiety, posttraumatic stress symptoms, and positive states of mind were examined. To better understand the mechanisms through which mindfulness influences psychological wellbeing, a second aim was to examine if changes in mindfulness mediate intervention effects on these outcomes.

Method

Study Sample and Recruitment

through cancer patient organizations. The study was open to patients with varying cancer diagnoses who were not undergoing current radiation or chemotherapy treatment. Patients interested in participation phoned the study coordinator and received more information about the study, the intervention, and what was required by participants. If eligible, the patients were randomized to either the intervention group or the waiting-list control group. Random selection of participants to either the intervention or control group was done consecutively using a random sequence of numbers indicating group assignment. Once a participant was recruited to the study, he/she was assigned a study number and was assigned to the intervention or control group according to the sequence of numbers. The sequence was produced through the SPSS software's random selection procedure [24]. Questionnaires were sent to the patients by mail directly after randomization and at 3 and 6 months after randomization, together with a prepaid return envelope. The waiting-list participants were scheduled to participate in the MBSR program after approximately 6 months. No blinding of group assignment was done. A power calculation was conducted to decide the adequate number of participants. The calculation was based on a similar study of cancer patients by Speca et al. showing an intervention effect with an effect size of 0.6 (Cohen's d) on symptoms of stress [18]. With an alpha at 0.05 and 80% power, we estimated a need to include 40 individuals in each study group. The study was approved by the Ethics Committee of the Karolinska Institute (No. 2007/48-31/2).

Intervention-MBSR Program

The intervention involved eight 2-h sessions and consisted of experiential and group exercises. The program was a modified version of the program developed by Jon Kabat-Zinn [6] and his colleagues at the Stress Reduction and Relaxation Clinic, Massachusetts Medical Center. The modified program followed the week-to-week curriculum of the original MBSR program, but no all-day retreat at the end of the program was included. The participants were not interviewed by the program instructor before the program, as was the case in the original program. During the intervention, the theoretical foundations of mindfulness regarding relaxation, meditation, and the body-mind connection were described. A variety of meditation, relaxation, and yoga exercises were practiced during group sessions and at home. Participants were encouraged to practice meditation 6 days a week at home using an instruction tape during the 8-week period. Training involved body scan meditation, sitting and walking meditation, and hatha yoga. The group process was focused on solving problems and challenges regarding successful meditation practice and the everyday application of mindfulness

and learning from each other's experiences. Each MBSR group had between eight and ten participants. The instructors for the present study were two clinical psychologists with training in cognitive behavioral therapy and previous experience and training in mindfulness meditation from workshops and retreats. Only one of the instructors had any formal education in leading MBSR programs. She had participated in an advanced 8-day MBSR training course for instructors at the Center for Mindfulness in Medicine, Health Care, and Society, University of Massachusetts Medical School and she lead three of the four programs for the intervention group. Both instructors had approximately 7 years of personal daily meditation experience each at the time the study was initiated. However, none of the instructors had previous experience of leading the 8-week mindfulness programs.

Measures

In addition to information regarding age, gender, type of cancer diagnosis, time of diagnosis, and current medication, a number of psychosocial measures were used at all assessments.

Five-Facet Mindfulness Questionnaire

The five-facet mindfulness questionnaire (FFMQ) is a selfreport measure of mindfulness. The instrument was developed by use of an exploratory factor analytic study of five independently developed mindfulness questionnaires. The analysis yielded five factors that appear to represent elements of mindfulness as it is currently conceptualized. The five facets are observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience [14]. A recent study of the construct validity of the FFMQ supported the possibility to assess mindfulness by means of self-report and showed a positive relationship between mindfulness and meditation experience [25]. In the current study, the Cronbach's alpha coefficient for the total mindfulness score was 0.93. The internal consistencies of the subscales were: observing, 0.83; describing, 0.95; acting with awareness, 0.90; nonjudging of inner experience, 0.89; and nonreactivity to inner experience, 0.83.

Perceived Stress Scale

The Perceived Stress Scale (PSS) is a ten-item scale measuring perception of stressful experiences during the past month [26]. The PSS has previously been used in several different populations. In the current study, the internal consistency was 0.83.

Hospital Anxiety and Depression Scale

The Hospital Anxiety and Depression Scale is a 14-item scale measuring anxiety and depression in nonpsychiatric populations and it has been frequently used within the health care setting [27]. It consists of two separate subscales measuring depression and anxiety over the past week. In the current study, the internal consistency was 0.86 for the anxiety scale and 0.79 for the depression scale.

Positive States of Mind

The Positive States of Mind (PSOM) is a six-item scale measuring different positive emotional and cognitive experiences [28, 29]. It assesses experiences of focused attention, productivity, responsible caretaking, restful repose, sharing, and sensuous nonsexual pleasure. In the current study, the internal consistency for the PSOM was 0.77.

Impact of Event Scale—Revised

The Impact of Event Scale—Revised (IES-R) is a 22-item scale measuring common posttraumatic stress symptoms and the impact of stressful life events over the past week. It is a revision of the original IES consisting of two subscales measuring intrusive and avoidant symptoms [30]. The revised version has three subscales measuring intrusive thinking related to the traumatic event (IES-intrusion), avoidant behavior (IES-avoidance), and emotional arousal (IES-hyperarousal). In the current study, the internal consistency was 0.88 for IES-intrusion, 0.85 for IES-avoidance, and 0.80 for IES-hyperarousal.

Statistical Analysis

Baseline characteristics of the sample, stratified by experimental group, were examined to ensure that key variables were evenly distributed by randomization. An initial intention-to-treat analysis was conducted with missing data at follow-up imputed according to last-observation-carriedforward strategy. Additionally, a per-protocol analysis was conducted using the data for those who successfully completed both baseline and follow-up assessments. Missing data across questionnaire items ranged from 1.4% to 2.8%, and scale means were computed using the mean of available items for each participant. The most specific test of the hypothesis as a whole was the difference between groups on the contrast between baseline and follow-up. This was tested using multivariate repeated-measures analyses of covariance (MANCOVAs) with baseline and follow-up scores as dependent variables. Two analyses were performed: one with the psychological outcome variables (perceived stress,

depression, anxiety, positive states of mind, and posttraumatic stress symptoms) as dependent variables and one with mindfulness subscales (observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience) as dependent variables. Time, group (intervention vs. control), and education were entered as factors in the analyses, and age was entered as covariate. Cohen's d effect size was calculated based on the difference between the group means on baseline and follow-up change scores, and the denominator was based on the pooled standard deviation (SD) at baseline and follow-up adjusted for different sample sizes between groups [31].

To determine whether increases in mindfulness or the different facets of mindfulness were responsible for the changes, subsequent mediation analysis was conducted. When examining a meditational effect, the relationship between the independent variable and the dependent variable was decomposed into two causal paths. First, the direct effect of the intervention on different outcomes was calculated. Secondly, the mediating variable (i.e., change in mindfulness) was entered in the equation and, if the direct effect of intervention on outcome was significantly reduced or became nonsignificant, it was concluded that the relationship was mediated by the second variable. This procedure is described in greater detail by Baron and Kenny [32].

Results

Study Flow and Intervention Participation

Eighty-five patients agreed to participate in the study and were randomized to either mindfulness training or a waiting-list control group. All patients except one were women. The man was randomized to the control group. Fourteen patients dropped out of the study before returning the baseline assessment, seven individuals randomized to the intervention group and seven individuals randomized to the control group; see study flowchart in Fig. 1. Reasons to drop out were change of mind before first questionnaire was sent or problems finding a suitable time to participate in the intervention group. Among the remaining participants in the intervention group, eight completed all eight group sessions, seven individuals participated in seven sessions, eight in six sessions, two in five sessions, two in four sessions, three in three sessions, and two participants did not attend any of the sessions. Home practice of meditation during the program was assessed with a question included in the follow-up questionnaire regarding frequency of meditation practice during the program period. Sixty percent of the participants reported regular meditation practice during the study period, 28% reported a moderate amount of meditation, and 12% reported infrequent meditation practice.

Seven of the 32 participants (21.9%) in the intervention group did not return the 3-month follow-up questionnaire, and four participants in the control group (10.3%) did not return the follow-up questionnaires. Data for these participants were imputed using the last-observation-carriedforward method. There were no significant differences between dropout and the rest of the sample regarding age, education, or income and on differences in outcome measures at baseline (p > 0.10).

The current study is based on an intention-to-treat analysis of the results collected among the 71 patients recruited to the study (32 individuals in the intervention group and 39 individuals in the control group) that were randomized and also successfully filled out and returned the baseline questionnaire and an additional per-protocol analysis of the 60 patients (25 individuals in the intervention group and 35 individuals in the control group) that were randomized and also successfully filled out and returned both baseline and 3-month follow-up questionnaires. In the sample of 71 patients, 54 had breast cancer, ten had gynecological cancer, five had lymphatic cancer, one had pancreatic cancer, and one had cancer in the neck. Ten patients had received their diagnosis within the last year, 39 patients between 1 and 2 years ago, and 22 patients had been diagnosed with cancer more than 2 years ago. The analysis in this paper used the baseline and 3-month followup measurements. There were no adverse events or side effects reported.

Descriptive Analyses and Randomization Check

The sample consisted of 70 women and one man, the mean age was 51.8 years (SD=9.86), 39 of the participants (54.9%) had at least a bachelor degree, 30 participants (42.3%) had full-time or part-time employment, and 44 (62.0%) had a household income of 30,000 Swedish kronor or more. Twenty-three participants (32.4%) used antidepressants. There were no significant differences between the intervention and control group concerning age (t=-0.33, df=69, p>0.10), education (χ^2 = 0.57, df=1, p>0.10), work status ($\chi^2=0.06$, df=1, p>0.10), household income ($\chi^2 = 0.88$, df = 1, p > 0.10), or use of antidepressants ($\chi^2=2.94$, df=1, p=0.09). In addition, no differences were found in any of the psychological outcome variables-perceived stress, depression, anxiety, positive states of mind, posttraumatic stress symptoms, or mindfulness (all p > 0.10)—indicating that the randomization was successful.

Bivariate correlations between the psychological outcome variables from the baseline measurement are pre-

Fig. 1 Flowchart describing study recruitment and dropout



sented in Table 1. In these analyses, data from the whole sample (n=71) was used. All variables were significantly correlated with the highest correlation found between perceived stress and anxiety (r=0.72, p<0.001).

Change in Psychological Distress and Positive States of Mind

The MANCOVA analysis with baseline and follow-up on psychological outcomes perceived stress, depression, anxiety, positive states of mind (reversely coded), and posttraumatic stress symptoms (IES-intrusion, IESavoidance, and IES-hyperarousal) showed a significant time×group (intervention vs. control) interaction ($F_{7.60}$ = 2.27, p=0.040, partial $\eta^2=0.21$), indicating that the intervention group reported a larger reduction of psychological distress and increase in positive states of mind than the control group. There was no significant main effect of time or group, and none of the potential confounding variables showed significant effects. Results from the univariate tests as well as mean values, change scores, and effect size for the differences in change between intervention and control group on the psychological outcome variables are presented in Table 2. The univariate tests showed that there were significant group×time interactions for perceived stress $(F_{1,66}=8.79, p=0.004, \text{ partial } \eta^2=0.12)$, positive states of mind $(F_{1,66}=5.40, p=0.023, \text{ partial } \eta^2=0.08)$, and IES- avoidance ($F_{1,66}$ =6.61, p=0.012, partial η^2 =0.09). The intervention group experienced a larger reduction in perceived stress and IES-avoidance and a larger increase in positive states of mind.

The subsequent per-protocol analysis with the 60 participants that filled out and returned both baseline and follow-up assessments also showed a significant time×group (intervention vs. control) interaction ($F_{7,49}=2.95$, p=0.0012) with a larger effect size (partial $\eta^2=0.30$). The univariate tests again showed significant group×time interactions for perceived stress ($F_{1,55}=10.47$, p=0.002, partial $\eta^2=0.16$, $d_{diff}=0.87$), positive states of mind ($F_{1,55}=9.22$, p=0.004, partial $\eta^2=$ 0.14, $d_{diff}=0.66$), and IES-avoidance ($F_{1,55}=8.43$, p=0.005, partial $\eta^2=0.13$, $d_{diff}=0.53$). In addition, there was a significant group×time interaction for IES-hyperarousal ($F_{1,55}=4.42$, p=0.040, partial $\eta^2=0.07$, $d_{diff}=0.46$). Overall, the effect sizes were larger in the per-protocol analysis.

Change in Mindfulness

The MANCOVA analysis with baseline and follow-up on FFMQ subscales—observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience—showed a significant effect for the time×group (intervention vs. control) interaction ($F_{5,62}$ =3.45, p=0.008, partial η^2 =0.22), indicating that the intervention group reported a larger increase in FFMQ

| | Perceived stress | Depression | Anxiety | Positive states of mind | IES-intrusion | IES-avoidance | IES-hyperarousal |
|-------------------------------|------------------|------------|---------|-------------------------|---------------|---------------|------------------|
| Perceived stress | - | 0.56** | 0.72** | -0.51** | 0.44** | 0.41* | 0.56** |
| Depression | | - | 0.59** | -0.68** | 0.35* | 0.40* | 0.47** |
| Anxiety | | | _ | -0.51** | 0.55** | 0.51** | 0.64** |
| Positive states of mind | | | | _ | -0.33* | -0.37* | -0.40* |
| Posttraumatic stress symptoms | | | | | | | |
| IES-intrusion | | | | | _ | 0.60** | 0.71** |
| IES-avoidance | | | | | | _ | 0.61** |
| IES-hyperarousal | | | | | | | - |

Table 1 Bivariate correlation between psychological outcome variables on baseline measures using data for the total sample (n=71)

*p<0.01, **p<0.001

subscales than the control group. There was no significant main effect of time or group, and none of the potential confounding variables showed significant effects. Results from the univariate tests as well as mean values, change scores, and effect size for the differences in change between intervention and control group on the FFMQ subscales are presented in Table 3. The univariate tests showed that there were significant group×time interactions for all subscales: observing ($F_{1,66}=7.64$, p=0.007, partial $\eta^2 = 0.10$), describing ($F_{1.66} = 8.39$, p = 0.005, partial $\eta^2 = 0.11$), acting with awareness ($F_{1,66} = 4.73$, p = 0.033, partial $\eta^2 = 0.07$), nonjudging of inner experience ($F_{1,66} =$ 5.97, p=0.017, partial $\eta^2=0.08$), and nonreactivity to inner experience ($F_{1,66}=10.39$, p=0.002, partial $\eta^2=$ 0.14). The intervention group experienced a larger increase in all FFMO subscales.

The subsequent per-protocol analysis with the 60 participants that filled out and returned both baseline and follow-up assessments also showed a significant effect for the time×group (intervention vs. control) interaction ($F_{5,51}$ =4.99, p=0.001) with larger effect size (partial η^2 =0.33). The univariate tests again showed significant group×time interactions for observing ($F_{1,55}$ =9.41, p=0.003, partial η^2 =0.15, d_{diff} =0.63), describing ($F_{1,55}$ =8.35, p=0.005, partial η^2 =0.13, d_{diff} =0.42), acting with awareness ($F_{1,55}$ =6.44, p=0.014, partial η^2 =0.10, d_{diff} =0.47), nonjudging of inner experience ($F_{1,55}$ =8.24, p=0.006, partial η^2 =0.13, d_{diff} =0.55), and nonreactivity to inner experience ($F_{1,55}$ =16.18, p=0.001, partial η^2 =0.23, d_{diff} =0.75). Overall, the effect sizes were larger in the per-protocol analysis.

To examine the association between change in mindfulness as measured with the FFMQ and the outcome

| | Mindf | ulness | interve | ntion | Wait-l | ist cor | ıtrol | | Chang | e scor | es | | | | |
|-------------------------------|-------|--------|---------|-------|--------|---------|-------|------|---------|--------|--------|------|-------------------|--------------|------------------------------------|
| | Pre | | Post | | Pre | | Post | | Interve | ention | Contro | ol | Interve | ntion effect | Effect size |
| | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | F _{1,66} | p value | $d_{\mathrm{diff}}{}^{\mathrm{a}}$ |
| Perceived stress | 22.56 | 6.20 | 16.91 | 6.83 | 20.74 | 5.45 | 18.88 | 6.27 | -5.66 | 6.71 | -1.86 | 5.70 | 8.79 | 0.004 | 0.63 |
| Depression | 6.41 | 4.46 | 4.67 | 4.23 | 7.18 | 3.55 | 6.49 | 3.30 | -1.74 | 3.01 | -0.69 | 2.78 | 2.91 | 0.093 | 0.28 |
| Anxiety | 10.53 | 4.70 | 8.26 | 4.46 | 10.44 | 4.59 | 9.29 | 3.97 | -2.27 | 3.82 | -1.15 | 3.09 | 2.68 | 0.107 | 0.26 |
| Positive states of mind | 18.97 | 3.68 | 22.03 | 4.31 | 18.90 | 3.70 | 20.03 | 4.06 | 3.06 | 3.76 | 1.13 | 3.31 | 5.40 | 0.023 | 0.50 |
| Posttraumatic stress symptoms | | | | | | | | | | | | | | | |
| IES-intrusion | 13.28 | 7.07 | 11.27 | 6.42 | 15.05 | 6.72 | 13.49 | 6.92 | -2.01 | 3.94 | -1.56 | 5.08 | 0.18 | 0.68 | 0.07 |
| IES-avoidance | 10.55 | 6.79 | 7.43 | 6.97 | 11.77 | 7.51 | 11.56 | 7.31 | -3.12 | 4.49 | -0.21 | 4.98 | 6.61 | 0.012 | 0.41 |
| IES-hyperarousal | 9.50 | 5.51 | 6.28 | 5.24 | 10.85 | 5.52 | 9.36 | 5.40 | -3.22 | 3.68 | -1.49 | 4.24 | 3.43 | 0.069 | 0.33 |

Table 2 Means and SDs of psychological outcome variables at baseline and 3-month follow-up for the intervention and control group

^a The effect size was calculated based on the difference between the group means on baseline and follow-up change scores, and the denominator was based on the pooled SD at baseline and follow-up adjusted for different sample sizes between groups

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| | Mindful | ness inter | vention | | Wait-list | control | | | Change | scores | | | | | |
|------------------------------------|---------|------------|---------|------|-----------|---------|-------|------|-----------|--------|---------|------|------------|----------------|------------------------|
| | Pre | | Post | | Pre | | Post | | Intervent | tion | Control | | Interventi | on effect | Effect size |
| FFMQ subscales | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | $F_{1,66}$ | <i>p</i> value | $d_{ m diff}{}^{ m a}$ |
| Observing | 28.92 | 6.14 | 31.80 | 5.09 | 27.23 | 5.92 | 27.03 | 5.55 | 2.89 | 4.88 | -0.21 | 4.24 | 7.64 | 0.007 | 0.56 |
| Describing | 27.93 | 7.44 | 29.44 | 7.66 | 28.06 | 7.70 | 26.77 | 8.21 | 1.51 | 4.30 | -1.29 | 3.96 | 8.39 | 0.005 | 0.37 |
| Act with awareness | 24.03 | 6.44 | 27.69 | 6.16 | 20.67 | 6.64 | 22.15 | 6.46 | 3.66 | 4.63 | 1.49 | 4.33 | 4.73 | 0.033 | 0.34 |
| Nonjudgment of inner experiences | 24.78 | 7.77 | 29.78 | 7.16 | 23.97 | 7.58 | 26.00 | 7.50 | 5.00 | 6.62 | 2.03 | 4.97 | 5.97 | 0.017 | 0.40 |
| Nonreactivity to inner experiences | 17.79 | 4.95 | 22.06 | 4.11 | 17.72 | 4.85 | 19.41 | 5.14 | 4.28 | 3.64 | 1.68 | 3.40 | 10.39 | 0.002 | 0.55 |

follow-up adjusted for different sample sizes between groups

variables, the correlations between change in total FFMO scores from baseline to 3-month follow-up and the change score of the different outcome variables were examined. In these analyses, data from the whole sample was used (n=71). Change in FFMO score was significantly correlated with change in perceived stress (r=-0.57, p<0.001), depression (r=-0.43, p<0.001), anxiety (r=-0.39, p<0.001)p < 0.01), positive states of mind (r=0.56, p < 0.001), IESavoidance (r=-0.51, p<0.001), and IES-hyperarousal (r=-0.35, p<0.01). The differences between different FFMQ subscales and change in the different outcome variables were also examined. The results are presented in Table 4. An increase in the FFMQ subscale observing was only correlated with an increase in positive states of mind, and the subscale nonreactivity was the only scale associated with change in all outcome variables. Change in IESintrusion was only correlated with change in FFMQ subscale nonreactivity.

The Effect of FFMQ as a Mediator

Analyses were also done to examine mindfulness, as measured with the FFMQ, as a mediator using a series of regression models as suggested by Baron and Kenny [32]. First, the effect of the intervention on the mediator was examined using change in total FFMQ score as dependent variable and group (i.e., intervention vs. control) as independent variable. Group significantly influenced increase in total FFMQ score (β =0.43, p< 0.001). Secondly, the effect of group on psychological outcomes was examined. As the MANCOVA analysis presented above had demonstrated a larger decrease in perceived stress and IES-avoidance and a larger increase in positive states of mind in the intervention group, these were the variables included in the test of mediation. The intervention effect on each of the variables was examined using ANCOVA procedures with 3-month follow-up as outcome variable and adding the baseline measure as a covariate. This procedure takes into account baseline levels of the outcome measure and gives a more accurate test of intervention effect. Significant intervention effects were found for perceived stress ($\beta = -0.23$, p < 0.05), positive states of mind (β =0.23, p<0.05), and IESavoidance (β =-0.22, p<0.01), showing significantly larger changes for the intervention group. Thirdly, change in the total FFMQ score was entered in each of these models to investigate the mediation effect. The effect of the intervention on perceived stress, positive states of mind, and IES-avoidance were mediated by the level of mindfulness. This is shown by substantial reductions in the relationship between group and the outcomes when FFMQ was entered into the equation. The mediation is illustrated in Fig. 2.

| | ΔFFMQ | ΔObserving | ΔDescribing | ΔNonjudging of inner experience | ΔNonreactivity to inner experience | ∆Acting with awareness |
|----------------------------------|----------|------------|-------------|---------------------------------|------------------------------------|------------------------|
| ΔPerceived stress | -0.57*** | -0.22 | -0.40*** | -0.40*** | -0.59*** | -0.39*** |
| ΔDepression | -0.43*** | -0.17 | -0.24* | -0.31** | -0.44*** | -0.34** |
| ΔAnxiety | -0.39*** | -0.08 | -0.37** | -0.27* | -0.36** | -0.30* |
| Δ Positive states of mind | 0.56*** | 0.40*** | 0.40*** | 0.37** | 0.44*** | 0.32** |
| Posttraumatic stress symptoms | | | | | | |
| Δ IES-intrusion | -0.20 | -0.04 | -0.16 | -0.11 | -0.32** | -0.11 |
| ∆IES-avoidance | -0.51*** | -0.15 | -0.37** | -0.45*** | -0.41*** | -0.35** |
| ΔIES -hyperarousal | -0.35** | -0.08 | -0.23 | -0.18 | -0.40*** | -0.37** |
| | | | | | | |

Table 4 Correlations between change in FFMQ subscales between baseline and follow-up and change in psychological outcomes (in these analyses, data from the whole sample was used; n=71)

*p<0.05, **p<0.01, ***p<0.001

Discussion

There is a growing interest in the effect of different mindfulness-based treatments and stress reduction techniques. However, the mechanisms through which training of mindfulness skills or abilities might decrease stress and increase well-being needs to be better understood. In this study, the patients who were randomized to the intervention showed a greater decrease in perceived stress, posttraumatic stress symptoms, and increased positive states of mind than the control group. Reduction of psychological distress and stress symptoms as a result of mindfulness interventions for cancer patients have been reported previously in a few randomized studies [18, 19] and some nonrandomized studies [2–4, 17, 33]. Our findings are in line with these results and give support to the use of mindfulness interventions to reduce psychological distress among cancer patients. In addition, the present work extends previous findings in that it is one of the few studies of these effects outside of North America and thus gives support for the use of this type of intervention in other cultural contexts. The study replicates the positive findings of mindfulness interventions on perceived stress symptoms previously reported, but it also expands our knowledge by reporting on reductions in posttraumatic avoidance symptoms and increases in positive states of mind. Positive emotional



Fig. 2 Beta coefficients for the pathways showing the mediational effect of change in FFMQ score on perceived stress, IES-avoidance, and positive states of mind at 3-month follow-up adjusted for baseline values (*p < 0.001)

states and positive affect have recently received increased attention in the research literature. It has been suggested that positive affect is not just the flip side of negative affective states. Rather, there is increasing support for the idea that positive mood and negative mood are related but distinct constructs [34, 35]. Emerging evidence is also showing that positive affect seems to have a stronger association with health outcomes and mortality than negative affect [36-40]. There are several hypothetical pathways through which positive affect might be connected to health outcomes. One possible mechanism for the effect of positive affect is through improved health behaviors and more adaptive coping, and there are studies indicating that positive affective states are associated with greater attention to and processing of health-relevant information. According to the broaden-and-build theory, positive affect plays an important role in presenting a wider variety of thought and action alternatives and further enforces people's general resources [34]. The development of interventions that increases positive affect among individuals under stressful conditions are, therefore, of interest.

Furthermore, this study examined the mediating effect of mindfulness on psychological outcomes which, to our knowledge, has only been demonstrated in a couple of previous randomized studies of college students and individuals in the general population [21, 22]. To examine mediation, we used a recently developed scale to measure mindfulness as it is currently conceptualized, the FFMQ [14]. In our study, the intervention group showed a larger increase in FFMO score than the control group. The 8-week training program in mindfulness seemed to increase all five different subscales of the FFMQ or different mindfulness skills. When we further analyzed the mediational effect of the FFMQ on the psychological outcomes, we found that the change in FFMO score mediated the relationship between intervention participation and the psychological outcomes at 3-month follow-up. The results strongly suggest that mindfulness interventions influence psychological well-being through increased mindfulness. This is in line with previous studies [21, 22]. Even though all different FFMQ subscales increased significantly more among the patients in the intervention group, not all subscales were related to the outcome variables. In particular, the observing subscale seemed only to influence positive states of mind, and none of the negative emotional outcomes. This indicates that being more observant of emotion and sensations might be important for overall wellbeing, but not for reducing psychological distress. Another interesting finding is that the mindfulness training influenced avoidant behavior but not intrusive thoughts, even though these symptoms often occur simultaneously. This might result from the fact that mindfulness training is not focused at diminishing or taking away unpleasant thoughts

or emotions, but rather at accepting thoughts and sensations without avoiding them, and through that process, decreasing the influence of these thoughts on the rest of the person's life.

There are several possible pathways through which mindfulness might influence psychological functioning [1]. Being mindful may lead to a view of thoughts and feelings as being transient, allowing the individual to view cognitions as "just thoughts" and affects as "just feelings." This perspective may lead to less automatic thought patterns and rumination and can lead to more effective affect regulation and reduced reactivity to unpleasant states. Mindfulness also involves an acceptance of being with what is as opposed to having the need to alter present unpleasant states and striving towards future, more pleasant goals. This focus on being content with the present situation without constantly striving towards future possible states might in itself generate a greater sense of well-being and happiness that is not conditional on experience. Mindfulness might also promote physical and mental health through the promotion of relaxation and reduction of experiences of heightened physiological stress reactivity. In this study, all five subscales of mindfulness were increased among the participants in the intervention group, and change in all five subscales of mindfulness was related to outcomes. However, nonreactivity to inner experiences and acting with awareness were the subscales most consistently related to positive psychological outcomes. It is possible that the skills of observing and describing thoughts, sensations, and emotions are necessary in the process of being nonreactive to them and acting with awareness without being overwhelmed by them, but being observant might not influence positive psychological functioning as much in itself. Change in the subscale of nonjudgment of inner experiences was most strongly related to cancer-related posttraumatic avoidance symptoms. This seems reasonable as the ability to experience emotions and cognitions related to the cancer diagnosis without valuing these thoughts as good or bad and having a more accepting attitude towards them might reduce the need to avoid such thoughts and feelings.

While this study shows very promising results, there are several limitations. First, the fact that we studied a specific population limits the possibility to generalize the findings to different illness groups or others experiencing stress. The participants were also self-selected which might have generated a group of highly motivated participants. Another potential limitation is the wait-list control design. It is unclear what part of the intervention is actually influencing outcomes and a study design using an active placebo intervention would give stronger support for the specific effects of the mindfulness intervention. A further limitation was that there was no systematic collection of information regarding program fidelity. In this study, we replaced missing values at follow-up with measures at baseline. assuming unaltered values for study dropouts. This strategy of data imputation is not without limitations, as it generally is a conservative strategy resulting in diminishing intervention effects. However, it has been recommended as the preferable strategy for data imputation in trials using two groups with nearly the same sample sizes [41]. This study also suffers from the limitations associated with self-report. This is especially true for the measurement of mindfulness, and there are some controversies regarding the use of questionnaires in assessing mindfulness. Difficulties reported in the measurement of mindfulness include unclear definition of mindfulness, lack of knowledge among questionnaire constructors of Buddhist thinking, and differences in semantic understanding of concepts and questionnaire items with varying mindfulness experience [42]. It is likely that participants in the intervention group were more inclined to report higher levels of mindfulness than the control group due to social desirability, wishful thinking, or better understanding of the concepts behind the questions used to measure mindfulness. Patients with and without mindfulness training are likely to interpret the meaning of questionnaire items in very different ways. It is unclear, however, in what direction a better understanding of the underlying concepts or the interpretation of the questions would influence the reporting. It is possible that a better understanding of mindfulness brings more insight into one's own mindlessness or it might develop one's ability to correctly report it. Furthermore, there is a possibility that the mindfulness intervention group subjects are biased in their reporting at follow-up, reporting higher levels of those qualities that they were supposed to have developed during the program.

In this study, we did not find a significant effect of the mindfulness training on depression and anxiety and slightly lower effect sizes than has been reported in some previous observational studies [20]. This might be a result of the fact that the mindfulness instructors used in our study had limited experience of leading MBSR programs and no certified training. There is currently no formal education for MBSR instructors in Sweden and only few trained instructors. Nevertheless, the intervention showed significant effects on several of the psychological outcomes and the overall effect size (average d=0.35) in this study is very similar to the effect size for mental health outcomes presented for randomized controlled studies in a recent meta-analysis on the effect of MBSR for cancer patients (d=0.37; [20]).

Despite these limitations, the present study gives an indication that the improvements in psychological wellbeing resulting from mindfulness stress reduction training can be explained by increased levels of mindfulness as measured with FFMQ. This supports the use of mindfulness stress reduction training to increase well-being among cancer patients and suggests a causal pathway in which the mindfulness training influences positive outcomes. The study also gives support for the use of the FFMQ in the measurement of mindfulness as it shows that the scale is both sensitive to change over time and to the development of mindfulness, as promoted by a MBSR program. Future research should focus on understanding which specific elements of the mindfulness training influence particular subdimensions of mindfulness and psychological outcomes. Studies among patients with specific cancer diagnoses at particular times after diagnosis might clarify when and for whom mindfulness interventions are the most efficient.

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