A brief mindfulness based intervention for increase in emotional well-being and quality of life in percutaneous coronary intervention (PCI) patients: the MindfulHeart randomized controlled trial

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A brief mindfulness based intervention for increase in emotional well-being and quality of life in percutaneous coronary intervention (PCI) patients: the MindfulHeart randomized controlled trial

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Abstract In this study effects of a brief mindfulness-based stress reduction intervention were examined in cardiac patients who had a percutaneous coronary intervention (PCI). One-hundred-and-fourteen patients (mean age 55 ± 7 years, 18 % women) were randomly assigned to a 4-session mindfulness group intervention or a minimal mindfulness self-help control group that received a booklet containing identical information. Compared to self-help, the group intervention showed larger increases in psychological and social quality of life ($p < .05$, partial $\eta^2 = .04$ and .05, respectively). For symptoms of anxiety and depression, and for perceived stress, this effect was evident only in patients younger than 60 years ($p < .01$, partial $\eta^2 = .10$ and .15, respectively). These effects were partially or fully mediated by increase in mindfulness. The brief group mindfulness intervention seems beneficial for cardiac PCI patients regarding general psychosocial quality of life, although for specific psychological symptoms, this intervention can be recommended only for nonelderly patients.

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Introduction

Although no clear consensus exists regarding the definition of mindfulness, most western scholars adopt the definition provided by Kabat-Zinn which includes paying attention to the present moment in an open and nonjudgmental way (Baer et al., 2006; Brown & Ryan, 2003; Kabat-Zinn, 1990). These characteristics putatively decrease psychological distress, as (1) attention is redirected from thinking about the past or future (e.g., rumination) to phenomena of the present moment, which (2) one approaches nonjudgmentally, i.e. accepts them just as they appear (Kabat-Zinn, 1990). Psychological interventions based on mindfulness have been developed and successfully applied in various patient groups to decrease emotional difficulties and enhance quality of life (Carlson et al., 2003; Nyklíček & Kuijpers, 2008; Roth & Robbins, 2004; Speca et al., 2000). Recent meta-analyses and systematic reviews have shown beneficial effects of mindfulness-based interventions on symptoms of anxiety and depression (Fjorback et al., 2011; Hofmann et al., 2010).

However, mindfulness based interventions to enhance psychological well-being and quality of life have rarely been applied in cardiac patients for an unknown reason. To the best of our knowledge, only the results of one pilot study have been published, suggesting favorable effects in this patient group as well (Tacon et al., 2003). Within the group of cardiac patients, those undergoing percutaneous coronary intervention (PCI) are of special interest. PCI is an invasive intervention performed for a life-threatening

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condition (occlusion or large risk of occlusion of a coronary artery) and as such is a stressful intervention. Because patients are well aware of this life-threatening nature of their condition, many cardiac patients undergoing PCI experience psychological distress and negative emotions (Denollet et al., 2006).

Therefore, the main aim of this investigation was to examine the relative effectiveness of a mindfulness based group intervention for these patients in the MindfulHeart randomized trial. Because mindfulness based interventions are generally delivered in a group format, the aim was to examine if this format indeed is superior to a minimal self-help format of identical contents. In addition, as little is known regarding potential influences on the effectiveness by basic demographic characteristics such as age, sex, and education (Crane & Williams, 2010; Nyklíček & Kuijpers, 2008), and no data are available regarding the effects of medical characteristics (i.e., indication for PCI and comorbidity), an additional aim was to examine these potential influences.

The hypothesis was that a group mindfulness based intervention would show larger beneficial effects on psychological symptoms and psychosocial aspects of quality of life compared to a minimal mindfulness self-help intervention. A priori hypotheses regarding differential effects by demographic or medical variables were not formulated because of a paucity of studies on this topic.

Methods

Participants

Consecutive patients who underwent a PCI procedure in the past month in the Catharina Hospital in Eindhoven, the Netherlands, were sent an invitation letter between February 2008 and May 2010 (N = 1690) for participation in the MindfulHeart trial. In the letter they were invited to participate in a stress reduction program based on coping with disturbing thoughts and feelings (becoming aware and letting go of them) and on becoming aware of and enjoying the present moment. Exclusion criteria were age above 70 years, current treatment for psychological complaints, serious physical (e.g., heart failure, cancer) or psychological (e.g., psychotic tendency, suicidal ideation) co-morbidity, past or present brain damage, insufficient mastery of the Dutch language, recent change in cardiovascular drugs, acute infection in the past 2 weeks, and use of anti-inflammatory medication except aspirin. The latter two criteria were employed because a part of the study aimed at examining effects on the immune system (data not reported here). The study was conducted according to the ethical standards declared in the Helsinki Declaration of 1975, as revised in 2000, approved by the Medical Ethics Committee of the Catharina Hospital at Eindhoven, The Netherlands, and registered in the Dutch Trial Registry (trial number NTR 3397: www.trialregister.nl).

A power analysis indicated that for an estimated effect size of Cohen's $d = .5$ (Hofmann et al., 2010), a power of .80, alpha of .05, five predictors and two measurement points, two groups of 53 participants would be needed. Of patients who expressed potential interest in participation (N = 397, 23.5 %), 273 (68.8 %) were excluded because of (1) exclusion criteria (mainly age >70 and comorbidities: N = 202) or (2) declination to participate (N = 71). Thus, 114 patients (20 women; mean age 55.8 ± 7.3 years) were randomized into one of the two groups (see Fig. 1 for participants' flow).

Procedure

Patients were approached per written invitation within 1–4 weeks after their PCI procedure. When patients returned an expression of interest, they were contacted by telephone to discuss exclusion criteria. When patients did not meet exclusion criteria and still were interested to participate, they were randomized into one of the two groups by a master's student of psychology as part of data collection for his master's thesis. Subsequently, participants received questionnaires and an informed consent form, which after completion were returned in a postage free envelope to the department of Medical Psychology of the Catharina Hospital in Eindhoven. In addition, participants received either an invitation for the first group session or the self-help booklet. Six weeks later, all participants again received questionnaires to complete.

Intervention

The applied group (6–8 patients) intervention is a brief mindfulness training, which is loosely based on the Mindfulness-Based Stress Reduction (MBSR) program, as developed by Kabat-Zinn (1990). The adjusted program in this study was less intensive, including only 3 weekly 90–120 min meetings and an additional evaluation session 2 weeks later. The three sessions consisted of (1) psycho-education regarding the role of behavior, bodily sensations, emotions, and thoughts in psychological distress, (2) psycho-education regarding the role of mindfulness and non-judgmental acceptance of one's bodily sensations, thoughts, feelings, and behavior in stress reduction, (3) mindfulness practices (mindfulness of bodily sensations, emotions, and thoughts) in an upright sitting position (the standard lying body scan and mindful yoga were not included), and (4) discussion of one's experiences while doing the practices during the sessions and at home. Participants were asked to practice daily for 30 min. The

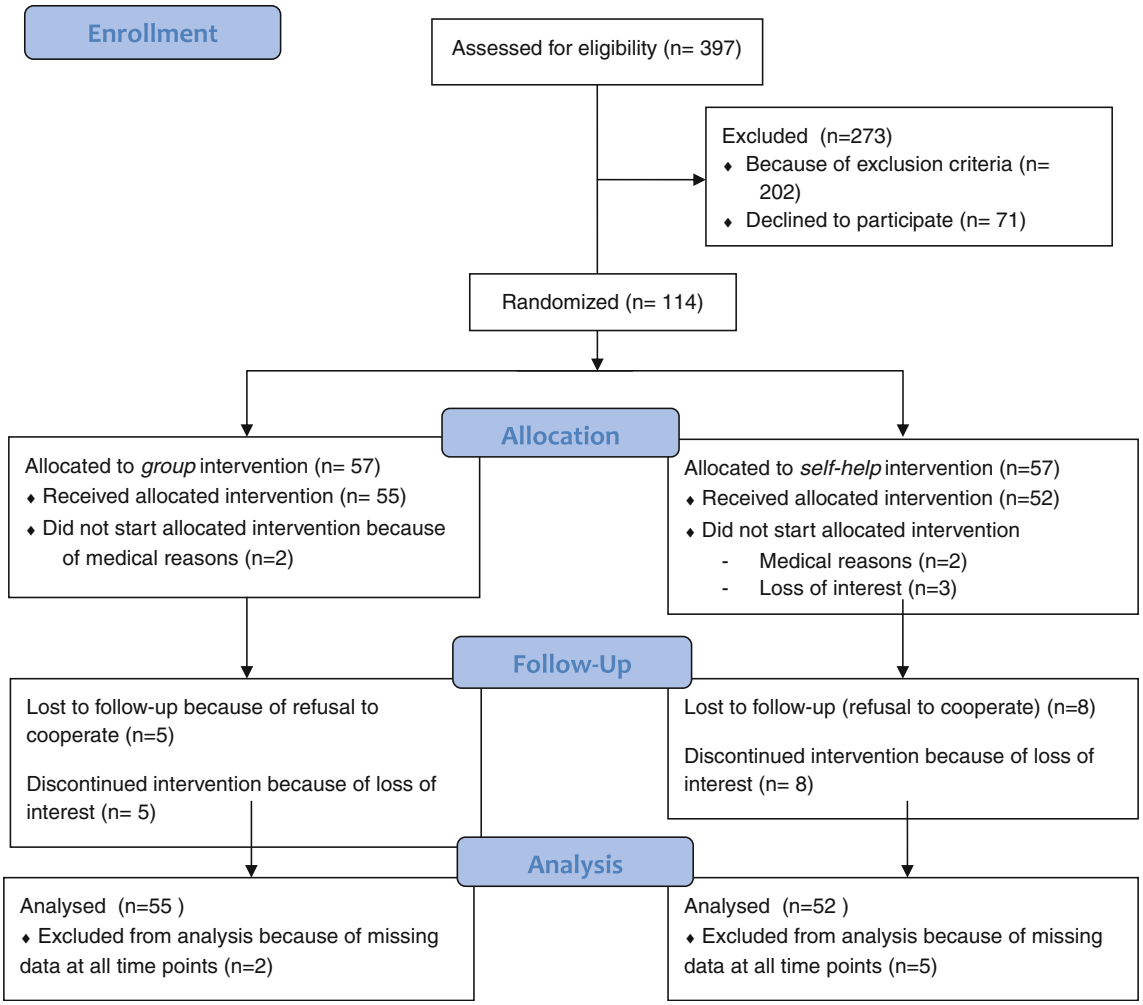

Fig. 1 Flow chart of study participants

groups were trained by a certified clinical psychologist having personal experience with mindfulness/vipassana meditation since 2000 and extended experience with supervising mindfulness based interventions since 2005.

The self-help intervention consisted of a booklet based on the group training and was written by the same clinical psychologist. The psychoeducation and exercises were identical to the information given in the group intervention, thus controlling for the content of the psycho-education and exercise part of the group intervention, but lacking the attention and support from the trainer and the group. The participants who received the self-help booklet were asked to thoroughly read the theory and to practice the exercises daily as indicated.

Measures

Demographic and medical information

Socio-demographic information included age, gender, marital status, and education. Self-reported psychological health variables included history of psychological care and use of psychotropic medication. Clinical cardiac variables included number of arteries affected, date of diagnosis of ischemic heart disease, history of myocardial infarction, medication, indication for PCI—acute versus planned—, and comorbidity, which were obtained from patients' medical records.

Psychological well-being

The Symptoms of Anxiety-Depression index (SAD-4) (Denollet, 2006) was developed as a Dutch screening method for mixed and interrelated symptoms of depression and anxiety in post-myocardial infarction patients. The questionnaire contains two questions concerning depression (feeling blue and hopeless) and two concerning anxiety (feeling tense and restless), which are scored on 5-point Likert scales. Items load on one factor, and item-total correlations between .61 and .76 and Cronbach's α of .86 indicate a good internal consistency, while the validity is also supported (Denollet, 2006).

The Perceived Stress Scale (PSS) (Cohen et al., 1983) assesses the degree to which participants appraise their lives as being stressful. It has 14 items scored on 5-point Likert scales of which 7 are reversed scored. The internal consistency is adequate of both the original (Cronbach's $\alpha = .75–.86$) and the Dutch version (Nyklíček & Kuijpers, 2008) and a test–retest reliability of .85 has been reported. The construct validity has been established (Cohen et al., 1983; Cohen et al., 1993).

Vitality was assessed using the positive affect subscale of the Dutch Global Mood Scale (GMS), which consists of 10 items scored on 5-point Likert scales (Denollet, 1993). It assesses mainly states of energy and self-confidence. Adequate Cronbach's α (>.90), test–retest reliability ($r = .55$), and convergent and discriminant validity have been demonstrated (Denollet, 1993).

Quality of life

The World Health Organization Quality of Life-Bref questionnaire was used to assess generic quality of life (WHOQOL Group, 1998). The WHOQoL-Bref consists of 26 items assessing contentment in four domains of quality of life: physical health, psychological health, social relationships, and environment. It has been reported to show satisfactory internal consistency of the domains (Cronbach's α ranging from .66 for the social domain to .82 for physical health). It also has adequate test–retest reliability and discriminant validity (WHOQOL Group, 1998). In this study, the environment subscale was not used as it was considered less relevant to the present research questions.

The Seattle Angina Questionnaire (SAQ) (Spertus et al., 1995) was used to obtain health-related quality of life. This questionnaire assesses 11 questions in 5 domains: physical limitation, angina stability, angina frequency, treatment satisfaction and disease perception. The items have a 5 or 6 point response scale. Cronbach's α is calculated for four domains: physical limitation (.89), angina frequency (.87), treatment satisfaction (.77) and disease perception (.66). The content, construct and criterion validity have been demonstrated (Dougherty et al., 1998).

Mindfulness

Mindfulness was assessed using the short form of the Freiburg Mindfulness Inventory (FMI-s) (Walach et al., 2006). This 14-item questionnaire with 4-point Likert scales measures general mindfulness. It is sensitive to change and has a Cronbach's α of .86 in its original version and .79 in the Dutch version (Klaassen et al., 2012). The construct validity has been found to be adequate (Walach et al., 2006).

Practice time

In both groups compliance with performing mindfulness exercises at home was registered through a compliance form on which participants were requested to record daily how long they practiced that day (in minutes).

Statistical analysis

Data analyses were conducted using the IBM Statistical Package for the Social Sciences (SPSS) version 19.0. The groups were compared on baseline variables using Chi square and independent sample t tests. In the case of missing values, logistic regression analyses were performed to examine if measured variables could predict missingness, which would be interpreted as missingness at random, warranting multiple imputation of the missing data. In such a case, multiple imputation is best practice, because it reduces bias as a result of for instance attrition in the case it is related to outcome. If attrition and outcome are predicted by measured variables, which are not necessarily included in the substantive analyses, imputation based on these variables reduces bias (Graham, 2009; Sterne et al., 2009; Van Buuren & Groothuis-Oudshoorn, 2011). In this case, because some variables are categorical of nature, the Predictive Mean Matching is method is used. Because this method imputes predicted values of a set of individuals with comparable characteristics to those individuals who have missing values on a variable, there is no need to specify an explicit model for the distribution of missing values and its main advantages are: (a) only realistic values are used, (b) it is less vulnerable to model misspecifications (Van Buuren & Groothuis-Oudshoorn, 2011). Fifteen iterations producing 15 imputations were performed using all available variables in the model as it is recommended to use as much information as available (Sterne et al., 2009). To be clear, most of these auxiliary variables are not used in the analyses testing the hypotheses. To examine if our multiple imputation method had large effects on the outcomes, sensitivity analyses were also performed based on participants with complete data.

Repeated measures Multivariate Analysis of Variance (MANOVA) was planned to examine differences in changes over time between groups regarding groups of related variables: psychological well-being and quality of life formed the two sets of analyses. Variables that showed significant associations with change in the dependent variables would be included as covariates in repeated measures MANCOVAs. Potential moderating effects by age, education, and indication for PCI and comorbidity were examined by introducing them as additional covariates or, in the case of dichotomous variables, as fixed

factors. Sex was not used as such, because of a limited number of female participants in the study. Because the SPSS (M)ANCOVA procedure does not provide pooled estimates for the analyses based on multiple imputation data sets, the pooled statistics are obtained from equivalent linear regression analyses using the same variables (yielding t-statistics instead of F-statistics).

Bivariate correlations based on all patients were computed between simple change scores of the outcome variables and of mindfulness scores between pre- and post-intervention. Based on the approach of Baron and Kenny (Baron & Kenny, 1986), first conditions were tested to determine if mediation analyses are relevant, such as correlations between the independent, dependent, and mediator variables. If these conditions were met, a nonparametric bootstrap procedure for mediation effects with 5,000 resamples (Preacher & Hayes, 2004) was used to test the indirect effects of mediation statistically. This procedure is recommended above standard Sobel testing as the latter is highly sensitive to the frequently occurring violation of normality of the distribution of the product term of indirect effects (Preacher & Hayes, 2004).

Results

Participants flow

Randomization of the 114 individuals resulted in a group training condition and a self-help condition both containing 57 patients. Two patients who were randomized into the group training and five patients randomized into the self-help condition declined participation before completion of baseline questionnaires due to medical reasons (three acute PCI and one ammonia) or loss of interest (three patients in the self-help condition) (see Fig. 1 for flow chart of participants).

Five out of 55 remaining participants (9 %) in the group training dropped out of the intervention, mainly because of loss of interest and did not complete questionnaires at follow-up. In the self-help group, eight of the 52 participants (15 %) did not complete the intervention and had missing questionnaire data at 8-week follow-up, the difference between groups not being significant (χ^2 (1) = 0.99, $p > .10$).

First, a logistic regression analysis was performed to examine potential predictors of missingness to examine the desirability to apply multiple imputation procedures for missing values. These analyses included demographic, medical, and baseline psychological variables, and the study condition. Having not completed questionnaires at T2 was (nearly) significantly predicted by being in the self-help group ($p = .08$), having more stents ($p = .008$), and higher cardiac treatment satisfaction ($p = .07$). Together these variables accounted for 90 % correctly classified individuals and explained between 19 % (Cox & Snell R^2) and 38 % (Nagelkerke R^2) of the variance, implying that this form of missingness may be regarded as missingness at random and may be best imputed by multiple imputation methods (Sterne et al., 2009). All missing values were imputed using multiple imputation (see "Statistical Analysis"), resulting in complete data of 107 participants (55 group condition, 52 self-help) in all analyses.

Baseline characteristics and randomization check

All participants were Caucasian, of which 88 (82 %) were men. Mean age was 55.8 years (SD = 7.2; range 37–69 years). Thirty-nine participants (36 %) had relatively high education (completed high professional education or college/university), 71 (66 %) were married or living together with a partner, 32 (30 %) were referred for PCI because of an acute condition, 67 (63 %) received a drug eluting stent, 89 (83 %) were on beta-blocking medication, whereas only 14 (13 %) were on psychotropics (mainly antidepressants) (Table 1). The groups were not different on almost all demographic, medical, psychological well-being, mindfulness, and quality of life variables ($p > .10$), except for indication for PCI (which was an acute condition in 23 participants in the group condition vs. 9 in the self-help condition; χ^2 (1) = 6.54, $p = .01$), and perceived stress (being higher in the group condition; t (105) = 2.06, $p = .04$; see Table 2 for means and SD). A tendency was found for the group condition to score higher on symptoms of anxiety and depression at baseline compared to the self-help condition (t (105) = 1.84, $p = .07$).

Because of these baseline differences, instead of repeated measures analyses, ANCOVAs were performed using difference scores between pre and post intervention values of psychological well-being and quality of life variables which were used as dependent variables and baseline values as covariates. Such a procedure using change scores has been shown to provide both a reliable and unbiased estimate of true change (Rogosa, 1988), while permitting control for baseline differences. Pooled estimates were derived from equivalent linear regression analyses.

Manipulation check

A repeated measures MANOVA on self-reported mindfulness including sex, age, and education as covariates revealed only one significant effect: a Time by Group interaction, which was significant in all 15 imputations (pooled t (101) = 2.62, $p = .009$, partial $\eta^2 = .08$). Post-hoc analyses in both conditions in isolation revealed

Table 1 Baseline characteristics of the sample: means (standard deviations) or numbers (percentages)

	Mindfulness group (N = 55)	Mindfulness self-help (N = 52)	*t*- or χ^2-value
Age	55.4 (7.3)	56.3 (7.3)	–0.62
Female	10 (18 %)	9 (17 %)	0.01
Partner	32 (58 %)	39 (75 %)	2.68
High education	20 (36 %)	19 (37 %)	1.25
Acute PCI	23 (42 %)	9 (17 %)	6.54*
Psychological help	9 (16 %)	5 (10 %)	0.56
Comorbidity	16 (29 %)	22 (42 %)	1.50
Drug eluting stent	31 (56 %)	33 (63 %)	0.96
Number of stents	1.55 (1.12)	1.41 (0.83)	0.70
Beta-blockers	43 (78 %)	46 (89 %)	1.35
Antihypertensives excl. Betablockers	7 (13 %)	4 (8 %)	0.29
Anticoagulants	53 (96 %)	52 (100 %)	0.45
Nitrates	16 (29 %)	24 (46 %)	2.64
NSAIDs	48 (87 %)	44 (85 %)	0.01
Psychotropics	6 (11 %)	8 (15 %)	0.16

High education = Completed high professional education or college/university (vs. all other); *PCI* percutaneous coronary intervention, *NSAIDs* non-steroid anti-inflammatory drugs; * $p < .05$

increase in mindfulness only in the group condition (pooled t (51) = 2.78, p = .008, partial η^2 = .13) (Table 2).

Psychological well-being

In addition to baseline values of the outcome variables, age, educational level, and comorbidity were used as covariates or additional factors in the analyses, because they showed associations with some outcomes. Indication for PCI was not included, because it was not associated with change in any outcome variable. In addition, to examine potential moderating effects by age, education (completed high professional education or college/university vs. not), and comorbidity (yes/no), interaction effects between these factors and group were included in a further analysis. Because of too few women, interactions with sex were not included.

In the analysis on perceived stress, main effect of Time (intercept) was highly significant (pooled t (102) = 4.24, $p < .001$; partial η^2 = .15), showing decreasing stress across groups (Table 2). Baseline values of perceived stress were significantly predictive of decrease from pre to post-intervention (pooled t (102) = 3.10, p = .002; unstandardized B = .31, 95 % CI = .11–.51). In addition, a trend appeared for younger age being associated with larger decrease (pooled t (102) = 1.73, p = .085; B = −.17, 95 % CI = −.36 to .02). There was no effect of Group ($p > .10$). A sensitivity analysis based on complete cases revealed similar effects (Table 2).

However, in the analyses including interactions, a significant Group by Age interaction appeared (pooled t (101) = −2.66, p = .008; partial η^2 = .07); only in the group condition age was inversely related to decreases over time (B = −.13, 95 % CI = −.23 to −.03). To examine this effect more closely and facilitate interpretation, age was dichotomized into younger (below 60 years) and older (60 and over) age groups (this division rendered categories of comparable size). A post-hoc analysis per age group revealed a Group main effect only in the younger group (pooled t (60) = 2.63, p = .009; partial η^2 = .10) showing larger decreases in the group condition compared to self-help in patients below 60 years of age (B = 4.04, 95 % CI = 1.02–7.06) (Fig. 2).

Similar results were obtained for symptoms of anxiety and depression. A significant main effect of Time (pooled t (102) = 3.46, $p < .01$; partial η^2 = .11) showed decreasing symptoms across groups (Table 2). Baseline symptoms were a significant predictor of change (pooled t (102) = 6.45, $p < .001$), showing that larger baseline values were associated with larger decreases from pre to post intervention (B = 0.48, 95 % CI = .33–.63) across conditions. The main effect of Group was marginally significant (pooled t (102) = 1.80, p = .072; partial

Table 2 Means (and standard errors) of original data of psychological well-being and mindfulness at pre- and post-intervention for the group and self-help conditions

	Mindfulness group (N = 50–55)		Mindfulness self-help (N = 44–52)		*F*-/*t*-values time	*F*-/*t*-values group
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment		
Perceived stress	22.89 (0.96)	18.44 (1.11)	20.47 (0.97)	18.42 (1.12)	19.65***/4.24***	2.28/1.34
Anxiety and depression	4.03 (0.49)	2.42 (0.41)	3.01 (0.49)	2.80 (0.42)	9.55**/3.46**	4.04*/1.80#
Vitality	19.42 (1.01)	23.05 (1.03)	20.74 (1.04)	22.52 (1.05)	11.87**/3.61***	1.09/0.95
Mindfulness	36.17 (1.09)	38.63 (1.05)	38.09 (1.17)	37.42 (1.12)	2.96#/1.22	9.33**/2.62**

* $p < .05$; ** $p < .01$; *** $p < .001$, # $.05 < p < .10$; *F* values represent values based on complete cases (N = 94), *t* values are pooled statistics based on 15 imputations of missing data (N = 107). Tests are ANCOVAs on change scores adjusted for baseline scores of the outcome, age, education, and comorbidity (or equivalent linear regression analyses)

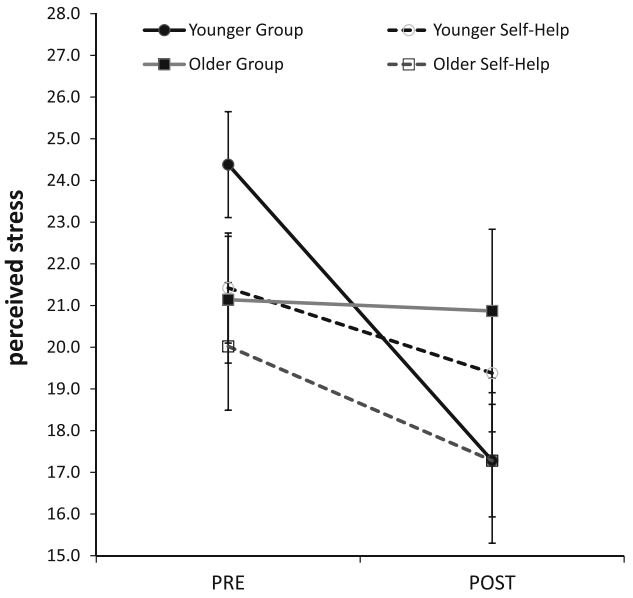

Fig. 2 Change in perceived stress from pre- to post-intervention for the mindfulness group condition versus mindfulness self-help control condition stratified by age (younger = younger than 60 years; older = 60 years and older): means and standard errors of the original complete cases data

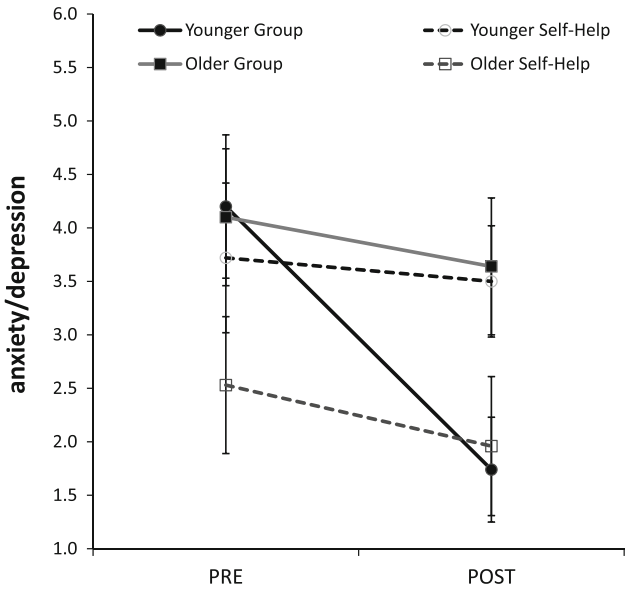

Fig. 3 Change in symptoms of anxiety and depression from pre- to post-intervention for the mindfulness group condition versus mindfulness self-help control condition stratified by age (younger = younger than 60 years; older = 60 years and older): means and standard errors of the original complete cases data

$\eta^2 = .03$). The trend indicated a larger tendency for decreased symptoms in the group condition. In a sensitivity analysis based on complete cases, this effect reached the conventional level of significance (Table 2).

In the analysis including interaction affects, two significant interaction effects with Group were present: Group by baseline SAD (pooled t (101) = 2.55, $p = .013$; partial $\eta^2 = .07$; only in the group condition baseline SAD was associated with larger decreases over time: B = 0.64, 95 % CI = .47–.81) and Group by Age (pooled t (101) = −2.99, $p = .003$; partial $\eta^2 = .09$; only in the group condition age was inversely related to decreases over time: B = −.03, 95 % CI = −.01 to −.05). Post-hoc analyses per age group revealed a significant Group main effect in the younger group only (pooled t (60) = 3.32, $p = .001$; partial $\eta^2 = .15$); similar to perceived stress, larger decreases in symptoms were evident in the group condition compared to the self-help group (B = 1.94, 95 % CI = 0.79–3.09) (Fig. 3).

For vitality, a main effect of Time appeared (pooled t (102) = 3.61, $p = .001$; partial $\eta^2 = .11$), indicating increase in vitality across groups (Table 2). Baseline vitality was a significant predictor of change (pooled t (60) = −5.07, $p < .001$): lower baseline values were associated with larger increase (B = −.50, 95 % CI = −.69 to −.30). Effect of Group was not significant ($p > .10$) and no interaction effects were present.

Quality of life

Because more than 50 % of patients indicated to experience no pain on the Seattle Angina Questionnaire at both measurement times, the analyzed subscales of this measure involved only Physical Limitations and Disease Perception. Because age and partner status showed associations with change in some quality of life parameters, they were included in the analyses. In addition, interaction effects between age and partner status with group were included to investigate potential moderating effects.

In the analysis on increase in psychological quality of life, a main effect of Time was significant (pooled t (102) = 2.27, $p = .03$; partial $\eta^2 = .05$), showing overall increase in scores. Baseline values of psychological quality of life predicted change (pooled t (102) = −4.62, $p < .001$; B = −.40, 95 % CI = −.57 to −.23), showing that smaller baseline values were associated with larger increases from pre to post intervention. The main effect of Group was also significant (pooled t (102) = −2.02, $p = .044$; partial $\eta^2 = .04$), reflecting a larger increase in the group condition compared to self-help (Table 3, also for results based on complete cases). No interaction effects with Group were present.

For social quality of life, main effect of Time was not significant (pooled t (102) = 1.64, $p = .11$; partial $\eta^2 = .02$). Baseline scores were a significant predictor (pooled t (102) = −3.58, $p < .001$; B = −0.31, 95 % CI = −0.48 to −0.14), as well as the effect of Group (pooled t (102) = −2.29, $p = .022$; partial $\eta^2 = .05$) in

Table 3 Means (and standard errors) of original data of quality of life variables at pre- and post-intervention for the group and self-help conditions

	Mindfulness group (N = 55)		Mindfulness self-help (N = 52)		*F*-/*t*-values time	*F*-/*t*-values group
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment		
Physical QoL	13.46 (0.37)	14.49 (0.40)	14.36 (0.42)	15.16 (0.45)	1.75/1.67#	0.34/0.17
Psychological QoL	14.27 (0.32)	15.14 (0.31)	14.89 (0.36)	15.02 (0.35)	3.87#/2.27*	4.81*/−2.02*
Social QoL	14.86 (0.39)	15.51 (0.40)	14.99 (0.44)	14.69 (0.45)	1.91/1.64	5.03*/−2.29*
Physical limitations	69.44 (2.85)	80.69 (2.46)	68.19 (3.18)	80.81 (2.74)	6.18**/3.76***	0.16/0.27
Disease perception	52.44 (3.18)	70.36 (2.70)	54.31 (3.55)	68.99 (3.02)	2.78#/1.33	0.53/0.73

* $p < .05$; ** $p < .01$; *** $p < .001$; # $.05 < p < .10$; *QoL* quality of life; *F* values represent values based on complete cases (N = 94), *t* values are pooled statistics based on 15 imputations of missing data (N = 107). Tests are ANCOVAs on change scores adjusted for baseline scores of the outcome, age, and partner status (or equivalent linear regression analyses)

the same direction as for psychological quality of life (Table 3, also for results based on complete cases).

For the other three, more medically oriented, quality of life subscales, the effect of Time was significant for Physical Limitations (pooled t (102) = 3.76, $p < .001$; partial $\eta^2 = .12$), marginally significant for physical Quality of life (pooled t (102) = 1.67, $p = .097$; partial $\eta^2 = .03$), and not significant for Disease Perception (pooled t (102) = 1.33, $p = .19$; partial $\eta^2 = .02$), showing an increase in quality of life for the (marginally) significant dimensions. The respective baseline values were significant predictors of increase for all three dimensions (pooled t (102) = −3.20, $p = .001$; B = −.25, 95 % CI = −.41 to −.10 for physical quality of life, pooled t (102) = −4.71, $p < .001$; B = −.43, 95 % CI = −.61 to −.25 for Physical Limitations, and pooled t (102) = −6.62, $p < .001$; B = −.51, 95 % CI = −.66 to −.36 for Disease Perception): the lower the baseline values, the larger the increase. However, Group was not significant in these medically oriented dimensions of quality of life (all $p > .10$), which was also the case in the analysis based on complete cases (Table 3).

The role formal home practice and self-reported mindfulness

The groups appeared to differ in home practice time with the participants in the group condition on average having totally practiced 366 ± 304 min, whereas the self-help group practiced 175 ± 231 min (F (1, 81) = 6.36, $p = .014$, partial $\eta^2 = .07$).

Across conditions, no associations were found between amount of weekly formal home practice and changes in outcome variables ($p > .10$), except increase in social quality of life ($r = .25, p = .027$). This correlation appeared to be significant in the group condition ($r = .33$, $p = .03$), but not the self-help condition ($r = -.02$, $p > .10$). Within groups no other correlations appeared ($p > .10$).

Because the groups differed regarding increase in self-reported mindfulness, it was examined if this increase may have mediated the differences between the groups found on symptoms of anxiety and depression, perceived stress, and psychological and social quality of life. A first condition for potential mediation is correlation between change in mindfulness and change in these outcome variables.

Although in the self-help group no significant correlation was obtained (all $p > .10$), in the group condition increase in mindfulness correlated significantly with decrease in perceived stress (pooled $r = .31$, $p = .03$), decrease in symptoms of anxiety and depression (pooled $r = .44$, $p = .001$), and increase in psychological quality of life (pooled $r = .35$, $p = .02$), but not social quality of life (pooled $r = .11$, $p = .45$). Hence, for the three first mentioned variables mediation analyses were performed using the bootstrapping procedure. Increase in mindfulness fully mediated the difference between the groups regarding decrease in symptoms of anxiety and depression in the subsample younger than 60 years old (coefficient of indirect effect = 0.95, 95 % CI = 0.14–1.99) and increase in psychological quality of life in the whole sample (coefficient of indirect effect = 0.34, 95 % CI = 0.10–0.67). For perceived stress in the younger subsample the mediation effect was partial: although the coefficient of indirect effect was not significant (coefficient = 1.65, 95 % CI = −0.25 to 3.62), the effect of group in the original analysis testing effects on perceived stress became nonsignificant when adjusted for change in mindfulness (from the original pooled t (60) = 2.63, $p = .009$ to pooled t (59) = 1.64, $p = .10$).

Discussion

The present study aimed at examining the effects of a mindfulness based group intervention compared to a minimal self-help mindfulness control group regarding psychological well-being and quality of life. In addition, potentially moderating effects of age, education, and comorbidity were examined.

Regarding psychological well-being, the mindfulness group intervention was superior to the minimal self-help control intervention, but only in patients younger than 60 years of age. The group mindfulness intervention reduced perceived stress and symptoms of anxiety and depression more strongly than the control group in the relatively younger subsample, the effect size of the difference between groups being medium to large. This effect was not anticipated as to the best of our knowledge differential age effects have not been reported or examined systematically before. This effect does not seem to be due to differences in education, because education did not show significant moderating effects. Also differential regression to the mean effects do not seem to offer an explanation, because baseline perceived stress and symptoms of anxiety and depression were not significantly higher in any condition in younger versus older participants. One may speculate that because mindfulness probably requires a certain openness to taking new perspectives (Kabat-Zinn, 1990), which older patients may be less able to do (Na & Duckitt, 2003), this may have dampened the potential for obtaining effects in these older patients. However, beneficial effects on more general psychological and social aspects of quality of life were obtained in this study, although smaller in effect size. An alternative speculation may involve the possibility that for older participants, the association between specific psychological symptoms of distress and the broader satisfaction with psychological and social domains of quality of life is less strong than among younger people. This may enhance the possibility of increase in more general satisfaction, despite no change in symptoms in this group. This possibility deserves further investigation.

With respect to aspects of quality of life that relate more strongly to physical and medical dimensions, no differential effects between the groups were found. Because the mindfulness intervention focuses on psychosocial quality of life, effects on these dimensions were not anticipated.

The often found main effect of time showing favorable changes across groups is difficult to interpret without another, inactive, control group. Either the minimal self-help intervention also is effective for those dimensions or the changes rather reflect more general phenomena such as regression to the mean or spontaneous recovery. Therefore, these effects are not considered as important in this study.

Changes in mindfulness statistically fully mediated the differences between groups regarding symptoms of anxiety and depression and psychological quality of life, while the mediation effect on perceived stress was partial. This suggests that increase in mindfulness as a result of the intervention may have been the main working ingredient resulting in the beneficial psychological effects found. However, to be able to establish the causality of this effect, repeated assessments of both mindfulness and psychological well-being over time during the intervention, using analyses including temporal precedence of mindfulness relative to psychological well-being are necessary in future studies. The amount of practice was different between groups, suggesting that the group format is superior to self-help in motivating patients to practice at home. Nevertheless, home practice was not associated with changes in outcomes, except for the social aspect of quality of life. This finding is in line with the inconsistencies found in the literature concerning the role of practice time (Carlson et al., 2003; Carmody & Baer, 2008; Jain et al., 2007; Nyklíček & Kuijpers, 2008; Shapiro et al., 2003). Perhaps, the effect of the amount of practice is only noticeable when it is recorded not only using a fairly accurate method (Nyklíček & Kuijpers, 2008), such as in the present study, but also during an intervention with a longer duration than the present one.

Limitations

The following limitations of the present study are acknowledged. The lack of a passive control group prevents conclusions regarding effectiveness of the minimal self-help intervention. In addition, in light of the self-help nature of the control group, comparisons between groups were not controlled for general effects such as differences in the amount of attention and support received. Future studies should include an attention/support control group to the design. Furthermore, the group intervention had a format deviant from the standard MBSR intervention, mainly having a substantially shorter duration. This may have attenuated the effects. In addition, randomization was not completely successful as some pre-intervention differences between groups were evident. This was largely dealt with by including baseline values as covariates in the analyses. Another limitation is the low number of participating women, which prevented the examination of possible moderating effects of sex. In addition, this may limit the generalizability of the present results to female patients.

Clinical implications

The present results indicate that a brief group mindfulness intervention may be applied to post PCI patients younger than 60 years with the aim to decrease their levels of psychological symptoms of distress. For older patients these effects are not found, but the intervention may be useful to older patients as well if the aim is to enhance general satisfaction with psychological and social aspects of one's life.

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