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PAPER

Mindfulness-based stress reduction added to care as usual for lung cancer patients and/or their partners: A multicentre randomized controlled trial

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Abstract

Objective: Lung cancer patients report among the highest distress rates of all cancer patients. Partners report similar distress rates. The present study examined the effectiveness of additional mindfulness-based stress reduction (care as usual [CAU] + MBSR) versus solely CAU to reduce psychological distress in lung cancer patients and/or their partners.

Methods: We performed a multicentre, parallel-group, randomized controlled trial. Mindfulness-based stress reduction is an 8-week group-based intervention, including mindfulness practice and teachings on stress. Care as usual included anticancer treatment, medical consultations, and supportive care. The primary outcome was psychological distress. Secondary outcomes included quality of life, caregiver burden, relationship satisfaction, mindfulness skills, self-compassion, rumination, and posttraumatic stress symptoms. Outcomes were assessed at baseline, post-intervention, and 3-month follow-up. Linear mixed modeling was conducted on an intention-to-treat sample. Moderation (gender, disease stage, baseline distress, participation with/without partner) and mediation analyses were performed.

Results: A total of 31 patients and 21 partners were randomized to CAU + MBSR and 32 patients and 23 partners to CAU. After CAU + MBSR patients reported significantly less psychological distress (p = .008, d = .69) than after CAU. Baseline distress moderated outcome: those with more distress benefitted most from MBSR. Additionally, after CAU + MBSR patients showed more improvements in quality of life, mindfulness skills, self-compassion, and rumination than after CAU. In partners, no differences were found between groups.

Conclusion: Our findings suggest that psychological distress in lung cancer patients can be effectively treated with MBSR. No effect was found in partners, possibly because they were more focused on patients' well-being rather than their own.

KEYWORDS

caregivers, lung cancer, mindfulness-based stress reduction, oncology, partners, psychological distress, psychosocial intervention, quality of life, randomized controlled trial

1 | INTRODUCTION

Lung cancer is the leading cause of death by cancer worldwide and ranks number 5 of most burdensome diseases in western countries.[1] Lung cancer patients report among the highest rates of psychological distress (43-58%) of all cancer patients.[2] Partners report similar rates of distress.[3] In addition, patients and partners seem to mutually affect one another, such that distress or well-being in patients affects those in partners, and vice versa.[4] This suggests that both patients and partners should be included when treating distress in (lung) cancer. Possibly because of the poor prognosis and fast deterioration of physical

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health, limited research has been conducted in lung cancer on how to reduce patients' and partners' distress.[5]

There are multiple treatments that have been found effective in reducing psychological distress in cancer patients. Cognitive behavioral therapy, for example, focuses on challenging dysfunctional thoughts to change them into more realistic/helpful ones.[6] However, as one of the major challenges of lung cancer is to emotionally come to terms with the existence of the cancer rather than challenging it, experiential approaches, which emphasize acceptance, allowing emotions, and letting them take their natural course, might be more helpful.[7] Mindfulness-based stress reduction (MBSR) is a group-based training in which participants practice mindfulness and receive teaching on stress. Mindfulness is defined as paying attention to present moment experiences in a nonjudgmental way.[7] Several meta-analyses in cancer patients showed that compared to care as usual (CAU), mindfulness-based interventions (MBIs) are effective in improving psychological distress with moderate effect sizes.[8] Randomized controlled trials (RCT) also demonstrated MBIs effectiveness on fatigue, pain, and quality of life.[9-11]

Although MBIs seem effective in cancer patients, the generalizability of these findings is limited because the vast majority of study participants so far were women, had breast cancer and were curatively treated.[8] Hardly any evidence is available on the effectiveness of MBIs in lung cancer patients.[12,13] In addition, only 3 nonrandomized studies on MBIs for cancer patients included partners.[13-15]

The aim of this study was to examine the effectiveness of MBSR added to CAU compared to CAU alone to reduce psychological distress in patients with lung cancer and/or their partners. Secondary outcomes included quality of life, caregiver burden, relationship satisfaction, mindfulness skills, self-compassion, rumination, and post-traumatic stress symptoms. Additionally, we examined potential moderating effects of gender, disease stage, baseline distress levels, and participation with/without partner. We also explored the potential mediating role of mindfulness skills, self-compassion, rumination, and post-traumatic stress symptoms.

2 | METHODS

2.1 | Study design

Following CONSORT guidelines,[16] we conducted a multicentre, parallel-group, RCT comparing CAU + MBSR with CAU. The trial protocol has been published previously[17] and received approval by the local medical ethics committee (CMO Arnhem-Nijmegen, 2011-519).

2.2 | Participants

The study population consisted of patients and/or partners of patients presenting with cytologically or histologically proven nonsmall cell or small cell lung cancer. Patients in the curative "and" palliative stage were included, with stage being based on the intent of the anticancer treatment. To facilitate patients and partners, they could decide how they wanted to participate, such that patients and partners were invited to participate together, but both were welcome to participate alone if preferred. Depending on whether the patient had a life partner who was willing to participate, "partners" could be the life partner or another close relative/friend. Exclusion criteria for patients and partners were <18 years of age, insufficient understanding of Dutch language, former MBI participation, current participation in other psychosocial programme, current weekly treatment by psychologist/psychiatrist, physical impairments (ie, hospitalization, life expectancy shorter than study period), or cognitive impairments (ie, Mini-Mental State Examination <26)[18] hampering participation.

Patients and/or partners were recruited at the Radboud University Medical Centre Nijmegen, Canisius-Wilhelmina Hospital Nijmegen, Rijnstate Hospital Arnhem, Jeroen Bosch Hospital 's-Hertogenbosch, Elkerliek Hospital Helmond, Pantein Hospital Boxmeer by the nurse practitioner via telephone, invitation letter, or face-to-face. Interested patients and/or partners were invited for a research interview, in which eligibility criteria were checked, further explanation about the study was provided, and written informed consent was obtained.

2.3 | Randomization

Participants were randomly allocated to CAU + MBSR or CAU (ratio 1:1) via a randomization website specifically designed for this study. When participating together, partners received the same treatment allocation as patients. Randomization was stratified by hospital and minimized by disease stage (curative versus palliative), baseline distress level (anxiety or depression subscale of Hospital Anxiety and Depression Scale [HADS] ≥8), current versus no anticancer treatment (chemotherapy/radiotherapy), and participation (together versus patient or partner alone). A nurse practitioner enrolled participants in the trial, the researcher performed randomization, after which, the nurse practitioner informed the participants.

2.4 | Mindfulness-based stress reduction

The intervention was based on the original 8-week MBSR programme, consisting of eight 2.5-hour weekly sessions and one 6-hour silent day, including daily 45-minute home practice.[7] Mindfulness exercises, such as body scan, gentle yoga, sitting, and walking meditation were practiced. Participants received teachings on stress and grief and were invited to share their experiences. For more details, see study protocol.[17] Three formally trained MBSR teachers fulfilling the advanced criteria of the Center for Mindfulness of the University of Massachusetts Medical School ran 9 MBSR groups in total with on average 9 participants per group (consisting of both study participants and patients with other cancer types). Teachers maintained daily meditation practice and received regular peer supervision. Two experienced MBSR teachers/assessors, of which one was independent of the trial, rated 2 videotaped sessions for each teacher with the MBI Teaching Assessment Criteria (MBI:TAC).[19] They discussed the ratings and made an overall judgment of teacher competence and programme adherence. One teacher was rated at beginner level and left the trial after 2 courses. The other 2 teachers were rated as proficient. The different teachers did not affect outcomes in patients and partners.

2.5 | Care as usual

In both groups, CAU consisted of anticancer treatment (ie, surgery, chemotherapy, radiotherapy), medical consultations, and supportive care, including psychosocial care (eg, visits to psychiatrist/psychologist, participation in psychosocial programme). After participation, CAU participants were invited to MSBR.

2.6 | Outcome

The primary outcome for patients and partners was the total HADS score, a 14-item questionnaire developed to assess psychological distress in patients with somatic conditions.[20] It includes an anxiety and depression subscale and shows good psychometric properties in the general medical population, including oncology patients.[21] In the present study, internal consistency was .90 in patients and .89 in partners.

Secondary outcomes for patients included quality of life (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Global Quality of Life subscale[22]), for partners caregiver burden (Self-Perceived Pressure from Informal Care[23]), for patients and partners relationship satisfaction (Investment Model Scale-Satisfaction subscale[24]), mindfulness skills (Five Facet Mindfulness Questionnaire[25]), self-compassion (Self-Compassion Scale[26]), rumination (Ruminative Response Scale-Brooding subscale[27]), and post-traumatic stress symptoms (Impact of Event Scale[28]). All questionnaires showed acceptable to excellent internal consistency (.70-.93) in patients and partners. Assessments took place at baseline (T0), post intervention (T1), and 3-month post T1 (T2). See study protocol for further details.[17] Information about patients' frequency and nature of health care use during the intervention period was collected via monthly self-reported health care diaries. Questions included visits to health care professionals and participation in psychosocial programmes.

2.7 | Statistical analyses

We used GPower to first calculate the sample size needed for an independent samples *t* test. The power analysis was corrected for clustering using the factor $(1 + (n\text{-}1)^{*}\text{ICC})$[29] and corrected for repeated measurements and baseline distress using the factor $((1 + \rho)/2\text{-}\rho_0^2)$.[30] We also took account of a 20% dropout rate, resulting in a required number of 110 patients and 110 partners to detect a medium-sized difference (0.5) with 80% power and alpha ≤.05. As the recruitment rate was slower than anticipated, we extended the recruitment period from 2 to 3.5 years resulting in a sample of 63 patients and 44 partners.

Data of patients and partners were analyzed separately. All analyses were conducted using (1) intention-to-treat (ITT; ie, all cases with T0 and either T1 and/or T2 scores) and (2) per-protocol (PP) samples (ie, cases with ≥4 MBSR sessions in CAU + MBSR and no MBSR participation in CAU). Using linear mixed models, the T1 and T2 scores that were nested within individuals were compared between groups. We controlled for the T0 score and a priori specified variables, ie, stratification and minimization variables.[31] When no group × time interaction was found, the interaction term was dropped from the analysis for the respecting outcome variable. As the random effects for MBSR groups were negligible, analyses were conducted without group as random effect. Cohen's *d* effect size was based on the difference between pooled group means (T1 and T2) divided by the pooled baseline standard deviation. Sensitivity analyses based on last observation carried forward (LOCF) and complete cases (CC; ie, completed T0, T1, and T2) were performed. Moderation was examined by adding the potential predictor and its interaction with group to the model. The following predictors were used: gender, disease stage (curative/palliative), baseline psychological distress, and participation with/without partner. Mediation analyses were performed on PP sample, using the multiple mediation model by Preacher & Hayes.[32] We examined whether T0 to T1 change in potential mediators (mindfulness skills, self-compassion, rumination, and post-traumatic stress symptoms) mediated T0 to T2 change in psychological distress.

3 | RESULTS IN PATIENTS

3.1 | Study sample

Between February 2012 and April 2015, 410 patients were assessed for eligibility. Of the 359 eligible patients, 63 patients (18%) participated (Figure 1). Participating patients were younger (M = 58.7; SD = 7.9) than those refusing (M = 63.6; SD = 12.9, p = .030), but they did not differ in gender. Forty-one patients (65%) participated with a partner. There were no baseline differences between CAU + MBSR and CAU patients (Table 1), with the exception that CAU + MBSR patients reported a shorter time since diagnosis (p = .036) and more often received anticancer treatment during the intervention period (p = .039; Table 1) than CAU patients. On the basis of the cutoff level of our screening study (HADS ≥15),[33] 22 patients (35%) reported clinically heightened distress at baseline. Health care diaries, which were completed by 46 (75%) patients, indicated that visits to health care professionals and participation in psychosocial programmes did not differ between CAU + MBSR and CAU (Table S1).

There were no baseline characteristic differences between patients who completed MBSR (n = 20; 65%) and those who dropped out MBSR (n = 11; 35%). The average time between filling out T0 and T1 was 3.5 months (SD = 1.1) and T1 and T2 was 3.1 months (SD = 0.8). Missing data at T1 and T2 assessment were equally distributed between CAU + MBSR and CAU. Patients not completing T1 and/or T2 assessment were more often in the palliative disease stage (71%) than patients completing both assessments (36%, p = .007). Six patients (10%) died during the study period.

3.2 | Effectiveness

Intention-to-treat analyses revealed that patients in CAU + MBSR showed significantly less psychological distress at post-intervention and follow-up than those in CAU (p = .008, d = .69; Table 2). Examining the HADS subscales, CAU + MBSR patients reported less anxiety (Mean difference of 2.78, p = .007, d = .62) and less depressive symptoms (Mean difference of −2.55, p = .027, d = .69) than CAU patients. Additionally, we found significant improvement in 4 of 6 secondary outcomes: quality of life (p = .047, d = .60), mindfulness skills (p = .001, d = .84), self-compassion (p = .009, d = .80), and rumination (p = .018, d = .67; Table 2). We also found a trend showing improvement in post-traumatic stress symptoms (p = .051, d = .37). Per protocol analyses

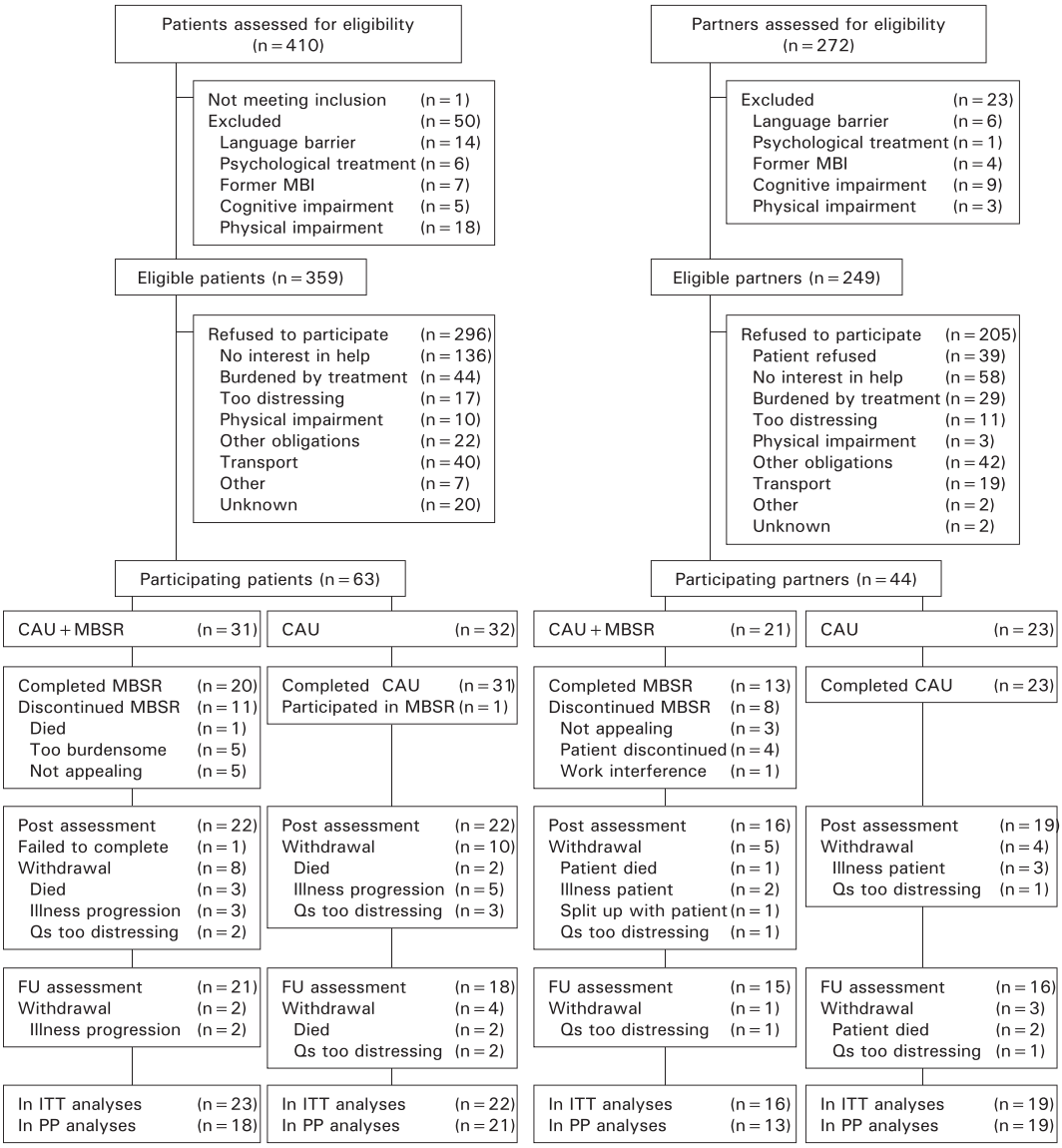

FIGURE 1 CONSORT flow diagram

(n = 39) and sensitivity analysis based on LOCF (n = 63) and CC (n = 38) did not reveal any differences in direction or significance for the outcomes. Only PP and CC analysis on quality of life were exceptions, showing no significant difference between groups.

3.3 | Moderation

Baseline distress predicted the difference in psychological distress between CAU + MBSR and CAU (p = .023; Figure S1). With each additional unit of baseline distress, the difference between CAU + MBSR and CAU increased with 0.52 (95% CI, 0.08, 0.96). Gender, disease stage, and participation with/without partner did "not" moderate the intervention effect.

3.4 | Mediation

The process measures that significantly improved after MBSR (mindfulness skills, self-compassion, and rumination) were selected for mediation analysis. Bootstrapping the indirect effect of intervention on psychological distress via the potential mediators showed no significant effects (as the confidence intervals contained 0), indicating that baseline to post-intervention changes in mindfulness skills (95% CI, −.15, .09), self-compassion (95% CI, −.23, .04), and rumination (95% CI, −.19, .08) did not mediate the follow-up effect on psychological distress.

4 | RESULTS IN PARTNERS

4.1 | Study sample

Of the 410 patients assessed for eligibility, 79 did not have a partner; of 37, it was unknown; and of 22 patients, the partner had not been assessed, leaving 272 partners to be assessed for eligibility (Figure 1). Of the 249 eligible partners, 44 (18%) participated. Three partners (7%) participated without a patient. Partners were either the life partner (n = 38), ex-partner (n = 1), relative (n = 3), or friend (n = 2). There were no baseline differences between partners in CAU + MBSR and CAU (Table 1). On the basis of the cutoff level of our screening study (HADS ≥15),[33] 19 partners (43%) reported clinically heightened distress at baseline.

TABLE 1 Baseline characteristics of patients and partners

	Patients			Partners		
	CAU + MBSR (*n* = 31)	CAU (*n* = 32)	*P*	CAU + MBSR (*n* = 21)	CAU (*n* = 23)	*P*
Demographic characteristics, *n* (%)[a]						
Age, *M* (*SD*)[b]	60.6 (6.8)	57.0 (8.5)	.072	60.8 (8.2)	56.6 (10.4)	.152
Gender, males			.374			.967
Females	18 (58)	15 (47)		12 (57)	13 (47)	
Males	13 (42)	17 (53)		9 (43)	10 (53)	
Marital status			.758			.387
Married/living together	27 (87)	27 (84)		20 (95)	21 (91)	
Alone/divorced/widowed	4 (13)	5 (16)		1 (5)	2 (9)	
Education level[c]			.906			.319
Low	11 (36)	13 (41)		3 (14)	5 (22)	
Intermediate	11 (36)	10 (31)		9 (43)	13 (57)	
High	9 (29)	9 (28)		9 (43)	5 (22)	
Currently employed	12 (38)	12 (39)	.921	12 (57)	9 (39)	.232
Clinical characteristics, *n* (%)[a]						
Tumor Type[d]			.511			
Nonsmall cell	28 (90)	26 (81)				
Small cell	2 (7)	5 (16)				
Mesothelioma	1 (3)	1 (3)				
Disease stage			.379			
Curative	14 (45)	18 (56)				
Palliative	17 (55)	14 (44)				
TNM stage			.981			
I	5 (16)	5 (16)				
II	3 (10)	3 (9)				
III	13 (42)	15 (19)				
IV	10 (32)	9 (28)				
Months since diagnosis, *M* (*SD*)[b]	4.8 (4.5)	9.3 (10.8)	.036			
Current treatment			.039			
Chemotherapy	15 (48)	6 (19)				
Radiotherapy	1 (3)	0 (0)				
Chemo- and radiotherapy	0 (0)	1 (3)				

Abbreviations: CAU, care as usual; MBSR, mindfulness-based stress reduction.

[a]χ^2test.

[b]Independent Samples *t* test.

[c]Low, primary/lower secondary education; intermediate, upper secondary education; high, higher vocational training/university.

[d]Despite inclusion criterion of nonsmall and small cell lung cancer, 2 mesothelioma patients participated. Given these patients met the other eligibility criteria, we chose to retain them in the analyses.

There were no baseline characteristic differences between completers (*n* = 13; 62%) and noncompleters of MBSR (*n* = 8; 38%). The average time between filling out T0 and T1 was 3.2 months (*SD* = 0.7) and T1 and T2 was 3.3 months (*SD* = 0.9). Missing data at T1 and T2 assessment were equally distributed between CAU + MBSR and CAU. Partners who completed both assessments were more often life partners (93%) than those not completing T1 and/or T2 (69%, *p* = .032).

4.2 | Effectiveness

Intention-to-treat analyses did not show any differences at post-intervention and follow-up between CAU + MBSR and CAU partners in psychological distress or any secondary outcome (Table 3). We did find a trend that relationship satisfaction decreased after CAU + MBSR compared to CAU (*p* = .055, *d* = .63). Per protocol analyses (*n* = 32) and sensitivity analysis based on CC (*n* = 31) and LOCF (*n* = 44) resulted in similar findings.

4.3 | Moderation

Neither gender nor distress levels or participation with/without patient moderated intervention outcome.

4.4 | Mediation

No mediation analyses were conducted because no significant effects on either outcome or potential mediator variables were found.

TABLE 2 Intention-to-treat analyses on all outcomes in patients

	Baseline		Post-Treatment		3-Month Follow-Up				
	MBSR (*n* = 31) *M* (*SD*)	CAU (*n* = 32) *M* (*SD*)	MBSR (*n* = 22) *M* (*SD*)	CAU (*n* = 22) *M* (*SD*)	MBSR (*n* = 21) *M* (*SD*)	CAU (*n* = 18) *M* (*SD*)	Group Difference *M* (95% CI)[a]	*P*[b]	*d* (95% CI)
Primary outcome									
HADS	11.97 (6.97)	12.94 (8.05)	10.03 (6.84)	13.10 (9.51)	8.29 (5.19)	13.89 (10.41)	-5.19 (-8.94; -1.43)	.008	.69 (.18; 1.19)
Secondary outcomes									
QLQ-C30-GHS	63.71 (18.83)	56.73 (22.30)	68.65 (18.62)	56.75 (25.50)	69.05 (17.71)	56.48 (20.12)	12.38 (0.20; 24.56)	.047	.60 (.08; 1.09)
IMS-S	6.84 (1.21)	6.42 (1.41)	6.82 (1.16)	6.51 (1.91)	6.86 (1.09)	6.35 (2.09)	0.07 (-0.49; 0.62)	.806	.05 (.00; .55)
FFMQ	130.64 (14.58)	134.10 (18.50)	135.63 (21.48)	131.20 (24.58)	143.84 (19.41)	132.44 (23.27)	13.94 (5.77; 22.11)	.001	.84 (.32; 1.34)
SCS	104.58 (20.52)	102.84 (17.31)	119.48 (21.11)	105.00 (19.17)	118.30 (20.30)	105.17 (23.83)	15.08 (4.00; 26.16)	.009	.80 (.28; 1.30)
RRS-Br	9.90 (3.19)	8.94 (2.56)	8.19 (3.01)	9.24 (3.33)	7.78 (2.65)	8.83 (4.23)	-1.94 (-3.52; -0.36)	.018	.67 (.15; 1.17)
IES	26.45 (19.04)	27.35 (19.95)	19.24 (15.42)	24.14 (17.80)	16.66 (16.56)	22.49 (17.58)	-7.10 (-14.24; 0.05)	.051	.37 (.00; .86)

Abbreviations: FFMQ, Five Facet Mindfulness Questionnaire; HADS, Hospital Anxiety and Depression Scale; IES, Impact of Event Scale; IMS-S, Investment Model Scale-Satisfaction subscale; QLQ-C30-GHS, Quality of Life Questionnaire Cancer-Global Health Status subscale; RRS-BR, Ruminative Response Scale-Brooding subscale; SCS, Self-Compassion Scale.

[a]Group difference is the pooled score of post-intervention and follow-up in MBSR compared to the pooled score of post-intervention and follow-up in CAU, controlling for baseline symptom levels.

[b]Based on mean group difference.

TABLE 3 Intention-to-treat analyses on all outcomes in partners

	Baseline		Post-Treatment		3-Month Follow-Up				
	MBSR (*n* = 21) *M* (*SD*)	CAU (*n* = 23) *M* (*SD*)	MBSR (*n* = 16) *M* (*SD*)	CAU (*n* = 19) *M* (*SD*)	MBSR (*n* = 15) *M* (*SD*)	CAU (*n* = 16) *M* (*SD*)	Group Difference *M* (95% CI)[a]	*P*[b]	*d* (95% CI)
Primary outcome									
HADS	13.81 (6.76)	14.74 (7.43)	13.88 (7.78)	13.42 (6.98)	12.73 (7.55)	11.69 (6.52)	-0.85 (-4.84; 3.13)	.661	.12 (.00; .71)
Secondary outcomes									
SPPIC	23.81 (5.37)	22.95 (4.85)	22.87 (4.63)	23.95 (5.43)	21.79 (6.00)	22.44 (3.74)	-0.78 (-3.86; 2.30)	.607	.15 (.00; .74)
IMS-S	6.13 (1.29)	6.21 (1.18)	6.11 (1.31)	6.63 (1.32)	6.54 (1.05)	6.90 (1.00)	-0.77 (-1.56; 0.02)	.055	.63 (.01; 1.23)
FFMQ	131.86 (15.28)	127.38 (17.68)	132.21 (16.32)	133.44 (15.53)	132.55 (16.07)	133.44 (15.53)	0.58 (-6.25; 7.41)	.861	.04 (.00; .63)
SCS	107.48 (14.07)	103.39 (20.13)	109.13 (16.28)	105.22 (24.07)	108.69 (17.53)	105.13 (18.02)	3.74 (-5.27; 12.74)	.397	.21 (.00; .80)
RRS-Br	8.71 (2.15)	9.48 (3.00)	8.50 (2.13)	9.00 (2.47)	8.60 (1.68)	8.69 (1.92)	-0.54 (-1.78; 0.70)	.373	.21 (.00; .79)
IES	29.19 (12.55)	27.15 (13.65)	28.57 (12.73)	23.79 (18.52)	20.71 (14.70)	25.25 (16.37)	-3.55 (-13.07; 5.97)	.450	.27 (.00; .86)

Abbreviations: FFMQ, Five Facet Mindfulness Questionnaire; HADS, Hospital Anxiety and Depression Scale; IES, Impact of Event Scale; IMS-S, Investment Model Scale-Satisfaction subscale; RRS-BR, Ruminative Response Scale-Brooding subscale; SCS, Self-Compassion Scale; SPPIC, Self-Perceived Pressure due to Informal Care.

[a]Group difference is the pooled score of post-intervention and follow-up in MBSR compared to the pooled score of post-intervention and follow-up in CAU, controlling for baseline symptom levels.

[b]Based on mean group difference.

5 | DISCUSSION

This is the first identified RCT examining MBSR in addition to CAU in lung cancer patients and/or their partners. In patients, CAU + MBSR resulted in significant improvements in psychological distress, quality of life, mindfulness skills, self-compassion, and rumination up until 3-month follow-up. They also tended to improve on psychological stress symptoms. Our findings correspond with former RCTs demonstrating the beneficial impact of MBIs in patients with other cancer types, mainly breast cancer.[8] In line with previous research, baseline distress levels moderated outcome.[34] More distressed patients benefitted more than those less distressed. Change in mindfulness skills, self-compassion, and rumination did not appear to mediate the effect of MBSR on psychological distress at follow-up. However, statistical power was limited, and future studies should explore this further. In contrast with our pilot study,[13] in partners, MBSR did not affect psychological distress or any other outcome measure. Other pilot studies showed mixed findings, with partners reporting no improvement[15] or less mood disturbance and stress after MBI participations.[14]

5.1 | Study limitations

An important limitation of the current trial is the small sample size as a result of difficulties with enrolment. Merely 18% of all eligible patients and partners participated. The main reason for refusing participation was that patients and partners thought they did not need psychosocial support. Other patients felt too burdened by their physical symptoms or anticancer treatment to participate. Some, however, refused participation because they found talking about the cancer too distressing. These people might actually benefit most from MBSR, as becoming aware of fears and worries might help participants to acknowledge rather than avoid thoughts and feelings, which can facilitate coping.[7] In addition to low enrolment, about a third of patients and partners dropped out the intervention. Moreover, in both conditions, patients and partners dropped out the study resulting in missing data (25-29%). Previous psychosocial studies in lung cancer reported similar dropout rates,[35] mostly due to physical impairments caused by either illness progression or anticancer treatment.

5.2 | Clinical implications

The fact that patients who did participate benefitted from the intervention, stresses the importance of reaching those for whom MBSR might be beneficial. It might be helpful if psychosocial interventions such as MBSR would be better integrated in regular cancer care. Screening for psychological distress might be a first step to make both professionals and patients aware of patients' psychosocial needs. Given the cancer and mental health stigma, it might be important to support physicians to discuss MBSR with their patients, particularly with those who may not be ready for therapy. Offering mindfulness training to physicians themselves, enabling them to offer short-term techniques to patients, or offering open introductory workshops to all who might be interested might be interesting options for this. In addition to the classical face-to-face format, individual, online, or blended care versions of MBSR could be developed to facilitate patients with poor functioning to participate.

Mindfulness-based stress reduction participation did not affect patients' relationship satisfaction. Patients scored high on relationship satisfaction at baseline, leaving little room for improvement. Because patients are very sick and depend on the care of their partner, patients might be reluctant to report dissatisfaction about their relationship. Interestingly, partners did not seem to benefit from MBSR, and in contrast with previous studies,[36] their relationship satisfaction even tended to increase more after CAU than after CAU + MBSR, possibly because partners assume the role of caregiver. Caregivers are often more concerned about the patients' well-being than about their own issues.[37] During MBSR, partners may feel conflicted when they are invited to pay attention to themselves and focus on their own needs,[37] preventing them from fully benefitting[13] and leaving less space for their relationship satisfaction to develop. Moreover, partners might be reluctant to discuss their fears to protect the patient. The MBSR programme is not tailored to the specific problems that caregivers experience, such as balancing self-care with care for the patient or preparing for a future without their partner.[38] In terms of possible solutions, one might consider addressing these specific problems of caregivers during MBSR and offer separate courses to partners, or use a format with partly combined and partly separate sessions.

Our cross-sectional dyadic study in couples facing lung cancer suggested that mindfulness skills and self-compassion go beyond the individual and may impact couple functioning.[39] Without dyadic analyses, potential associations between patients and partners remain obscured. Unfortunately, the current sample size of couples was too small to conduct dyadic analyses. Future research should apply dyadic analyses on couples participating in MBSR to examine how change in one's own and one's partner processes affect one's outcome.[40]

In conclusion, this RCT confirmed the effectiveness of MBSR in lung cancer patients on a range of psychological outcomes, especially in distressed patients. Partners, however, did not seem to benefit from MBSR. More research is needed on what lung cancer patients and partners experience as facilitators and barriers of participation to help researchers/clinicians to make effective psychosocial intervention more accessible.

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CONFLICT OF INTEREST

The authors have declared no conflict of interest.

ETHICAL APPROVAL

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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SUPPORTING INFORMATION

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