



ORIGINAL RESEARCH

Mindfulness-based intervention in cancer recovery: a pilot feasibility study in a Portuguese sample

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Abstract

Objectives: The aim of the present study was to assess, through a pilot randomised controlled trial, the feasibility and efficacy of a mindfulness-based intervention in oncology (MBIO) with Portuguese cancer patients, considering that such kind of interventions can be conditioned by cultural factors and that most studies have been carried out in countries with a different ethos.

Methods: A Portuguese version of an eight-week MBIO was delivered to 26 ambulatory cancer patients, aged between 46 and 64 years, attending two hospital centres in Portugal. Patients' health-related quality of life (QoL) and mindfulness processes were assessed before (T1), just after (T2), and 12 weeks following the programme (T3), with self-reported measures, using validated Portuguese versions of two scales: the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 and the Mindful Attention Awareness Scale.

Results: At T2, the attrition rate was null for the intervention group and 36% for the control group. Compared to controls and in reference to base-line (T1), participants in the intervention group had significantly ($p \leq 0.05$) improved (a) QoL function score at T2, and (b) QoL global health status, total score and symptom score at T3. Mindfulness approached a significant ($p = 0.12$) positive change at T2.

Conclusion: Overall, findings indicate that MBIOs may be feasible and effective in a Portuguese sample, opening up perspectives for larger scale studies, with more representative samples of the Portuguese population.

Keywords: Cancer; Oncology; Mindfulness; Mindfulness-Based Intervention; Quality of Life.

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Introduction

In the last 35 years, several programmes have been developed based on mindfulness, a key-concept in some ancient Eastern philosophies that can be defined as “the awareness that emerges through paying attention on purpose, in the present moment, and non-judgmentally to the unfolding of experience moment by moment” [1]. Such programmes have been applied in a wide range of conditions (stress, pain, depression, anxiety, relationship problems, psychosis, eating disorders, personality disorders, cancer), populations (children, adolescents, adults, couples) and settings (outpatient, inpatient, medical, mental health, prisons, workplace) [2]. The most investigated programmes are the Mindfulness-Based Stress Reduction (MBSR), initially used with chronic pain [3, 4] and the Mindfulness-Based Cognitive Therapy (MBCT), MBSR’s next-of-kin, initially developed for depression [5].

There is a considerable amount of published research and in the last five years the value of Mindfulness-Based Interventions (MBIs) has been systematically confirmed by meta-analyses. A comprehensive review of the effects of MBIs in a wide range of clinical and non-clinical populations, encompassing 209 studies and 12415 participants of both genders and diverse ages, was recently published [6]. In general, the studies reviewed showed that MBIs are effective in a variety of psychological problems, being especially effective for reducing anxiety, depression and stress. Effect size (ES) estimates (Hedge’s g) showed a value of $g = 0.53$ for controlled studies, which may be considered moderate (we follow Cohen [7], who suggested that $d = 0.2$ can be considered a ‘small’ ES, 0.5 represents a ‘medium’ ES size and 0.8 a ‘large’ ES). The attrition rate (16%) was smaller than usually obtained in cognitive and behavioural studies (22%), suggesting a higher commitment by MBIs participants [6].

Although most of the studies considered in that meta-analyses revealed a positive and strong correlation between mindfulness levels and clinical outcomes, some limitations should also be considered: mindfulness was measured only in 45% of the studies; little information has been provided about clinical moderators, namely the therapist’s training and experience in mindfulness; intervention duration and time length of home practice assignments were not consistently correlated with the efficacy of the MBIs, meaning that better efficacy predictors are needed.

Considering MBIs in Oncology (MBIOs), several studies have been dedicated to explore its effectiveness. MBIs cultivate useful skills for coping with a variety of difficulties—emotional distress, physical symptoms—and have been shown to be beneficial relative to common symptoms associated with cancer and its treatment, and therefore are likely to help cancer patients improving their psychosocial well-being [8]. In general, results point to the efficacy of MBIOs in several clinical outcomes, with small to medium ESs. Some studies concluded that it is through

increasing mindfulness that MBIOs increase psychological well-being [9-12]. Some of those studies report ESs ranging from 0.52 to 0.77.

Even if most of the studies regarding MBIOs reveal a significant positive correlation between mindfulness levels and clinical outcomes in cancer patients, several meta-analyses also highlight some critical points in the research: the need for more follow-up data to assess long-term effects [13, 14]; the shortage of information regarding cancer staging after the intervention, patients’ commitment to home assignments or details about the intervention like styles of implementation or therapists’ qualifications and experience with mindfulness [15]; several possible biases confounding efficacy results, namely expectancy bias, treatment length or study quality, although it was also highlighted that the effects are larger than could be expected from a psychological placebo, and are maintained after a median 12-week period [16]. From a clinical point of view limitations have been referred related with heterogeneity of cancer types, staging and status, insufficient information and reporting on treatments and no assessment of patients’ emotional engagement and adherence to the intervention [17].

Furthermore, it has been noted that most participants in the selected studies were highly educated Caucasians and that their attitudes towards the programme, like adherence or length of practice time, may have influenced their improvement in mental health [18]. In contrast, a study with multi-ethnic, low-income women revealed a very high attrition rate [19]. These studies raise the question of cultural factors conditioning the effectiveness of MBIOs.

The issue of cultural-specific factors is particularly important if we consider that MBIs have roots on Eastern spiritual (especially Buddhist) traditions and this will influence the perception of their usefulness in Western countries (the so-called ‘meaning effect’). Moreover, considering that MBIs have foundations in Eastern traditions, “concerns may arise that MBIs practices might be antithetical to Christian religious beliefs” [20]. Such cultural issue has been addressed in a study in USA, with Spanish- and English-speaking populations [21]. On the other hand, all the studies considered in all the reviewed meta-analyses were in English-speaking countries. In fact, most of the studies in MBIOs (and MBIs in general) were undertaken in North America and the UK, only a few in continental Europe and, to the best of our knowledge, none in Portugal. Currently, in clinicaltrials.gov there are no registered trials involving MBIs and cancer in (European or American) Latin countries [22]. A literature search in Google Scholar for words “mindfulness”, and “cancro”, “câncer” “cáncer” (respectively in European Portuguese, Brazilian Portuguese, and Spanish) provided only one original research paper, in a Spanish population [23], comparing the effectiveness of a MBSR intervention ($n=20$ patients) with a psycho-educational standard intervention in oncological patients ($n=17$), in a pre-post design. The outcome measures were anxiety, depression and health-related quality of life (QoL). Although

little can be inferred from just one study, the ES for QoL was $g = 0.52$, which is considerably higher than $g = 0.29$ obtained in another study [17]. Considering the lack of similar studies in Portugal and the significance of cultural specificities, the conclusion was clear regarding the need to assess the feasibility of MBIs in a country like Portugal, an European, Latin and predominantly Catholic society, with very little contact with Eastern cultures.

In sum, although the foregoing literature review points to the efficacy of MBIs and MBIOS, it also highlights some critical points in the research, including the issue of cultural-specific factors. These critical points were taken into consideration, as best as possible, in designing and carrying out this study, aimed to investigate, through a randomised controlled trial (RCT), the feasibility and acceptability of MBIOS in Portugal. Additionally, we wanted to assess the efficacy of the programme in promoting a higher QoL in Portuguese cancer patients.

We hypothesised that the mindfulness-based recovery programme, to be delivered as an adjunctive intervention, would be effective to improve the QoL of Portuguese cancer patients. Additionally we expected mindfulness and QoL to be positively correlated (i.e., an increase in mindfulness is associated with an improvement in QoL).

Methods

Participants and Procedures

Ambulatory cancer patients attending the two hospital centres of the county of Aveiro, Portugal, were eligible to participate. Participants were recruited by health professionals (physicians, psychiatrists, nurses clinical, psychologists and therapists) of those hospital centres. Of the 48 eligible patients referred to the study, a total of 26 patients participated in the study.

Given that information about cancer stages for this study sample was provided using different staging systems (namely TNM Classification of Malignant Tumours and the Roman Numeral system), or not provided at all for a considerable number of participants, that information is not included here.

Eligibility conditions to participate in the study were: 18 years or older, cancer diagnosis, ability and willingness to provide written informed consent to participate in the study. Exclusion criteria were: life expectancy of three months or less; currently receiving, or having received major surgery, radiotherapy, or any kind of antineoplastic therapy other than hormone therapy in the three months prior to admission; undergoing psychological or psychiatric treatment; previous participation in a MBSR or MBCT group; previously submitted to cognitive behavioural treatment; history of illicit drug or alcohol abuse within two years before admission; having received any investigational drug/device/therapy within 30 days prior to admission, or being scheduled to receive one during the course of the study; inappropriate for

study participation, in the judgment of the patient's physician or the main investigator.

Before completing the questionnaires for the first time, eligible patients were assigned a study number and then randomly distributed in a 1:1 ratio to do either the mindfulness-based programme (intervention group) or the control group, over a period of eight weeks. Only after having completed the questionnaires patients were told to which group (intervention or control) they had been allocated.

The control patients were in a waiting list; even though they could receive institutional psychological support if required (e.g. decompensation), none had received it during the course of the study.

Detailed demographic and clinical data for the intervention and control groups is presented in Table 1 where it is possible to observe a bias of gender (1 man and 25 women), age (46 to 64 years), and cancer type (more than half of the participants had breast cancer).

Both groups completed two questionnaires (described below) before the intervention (T1), at the end of the intervention phase (T2) and at the end of the 12-week follow-up period (T3). Data was collected between January and July 2014. The design diagram of this multicentre, feasibility, pilot randomised, controlled clinical study is in

Table 1. Participants' demographic and clinical data.

Characteristic	Intervention	Control
Sex		
Female	11	14
Male	1	0
Age		
Mean(SD), years	53.8(8.1)	56.6(7.5)
Cancer type		
Breast	7	8
Colon/gastrointestinal	3	3
Other	2	3
Relationship status		
Married/living with partner	11	10
Single, divorced or separated	1	3
Employment status		
Full-time	4	5
Unemployed	1	
Retired	7	9
Education		
Primary school	1	4
Secondary school	2	4
High school graduate	5	2
College/technical degree	1	-
Master/postgraduate degree	2	4
Average years of education(SD)	11.5(3.8)	10.5(5.0)

Figure 1 and the flow chart of patients' disposition along the study is presented in **Figure 2**.

Patients did not pay neither were paid for their participation. Before signing an informed consent, all participants were briefed about the study's purpose and features, namely that it involves mindfulness meditation, which has Buddhist roots, but that the program has a scientific and totally secular approach. After the study completion, the control group was given the chance to do the same programme as the intervention group.

This MPIO study was supervised by Bangor University (BU), UK, and has been approved by the ethics committee of BU, after approval by the ethics committees and administration boards of the hospital centres.

Main Outcome Measures

Socio-demographic characteristics and health-related information were assessed by several questions related with age, education, marital status, employment status, and cancer type.

The well-being of cancer patients, assumed as a multi-dimensional construct (QoL), was measured in the present study with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC QLQ-C30) [24], an instrument widely used in the oncology field. QLQ-C30 consists of 30 items distributed by 6 functioning subscales (physical, role, cognitive, emotional, social, and global quality of life), three symptom subscales (fatigue, pain, nausea/vomiting), and six single items about common symptoms (dyspnoea, sleep disturbance, appetite loss, constipation, diarrhoea and financial problems). All subscales presented Cronbach's $\alpha \geq 0.70$ with the exception of role function (0.52). For the purpose of this study, a Portuguese validated version of EORTC QLQ-C30 was used [25]. All subscales of the Portuguese version presented Cronbach's $\alpha \geq 0.70$, with the exception of cognitive function (0.57).

Recently, a total score of QLQ-C30 was proposed [26], which was found to discriminate between patients and con-

trols better than the QLQ-C30 global quality of life scale, being also very reliable (Cronbach's $\alpha = 0.94$ for cancer patients, and 0.95 for the general population). Moreover, the same authors proposed two other score calculations: the function score (simple mean of the 15 items belonging to the five function scales), and the symptom score (simple mean of the thirteen items belonging to symptom scales). Both scales presented Cronbach's α levels > 0.87 for both patients and controls.

To measure mindfulness processes, the Mindful Attention Awareness Scale (MAAS) questionnaire [27] was used. It assesses the general ability of a person to be attentive to and aware of the present moment, in daily life. It has only 15 items, and so it takes a short time to complete. It has been validated for oncology; a Cronbach's $\alpha = 0.94$ was found for both the cancer patients and the general population [28]. For the purpose of this study, a Portuguese validated version of MAAS [29] was used.

To assess compliance regarding home practice assignments, patients in the intervention group were asked to keep a daily record of the time and duration of their formal and informal practices, both during the intervention and the 12-week follow-up.

A prerequisite to evaluate the effectiveness of a programme in improving the well-being of cancer patients is the willingness of a sufficient number of these to participate in this study—in other words, the feasibility of the study. Feasibility can be evaluated through: (a) the fraction of the patients eligible and referred to the study who have signed the informed consent forms; (b) the fraction of the latter who have completed the study protocol [30].

Intervention Details

The mindfulness-based programme delivered to cancer patients in recovery is a Portuguese adaptation, prepared and taught by the first author, of T. Bartley's programme Mindfulness-Based Cognitive Therapy for Cancer [31]. Bartley has supervised the programme administration.

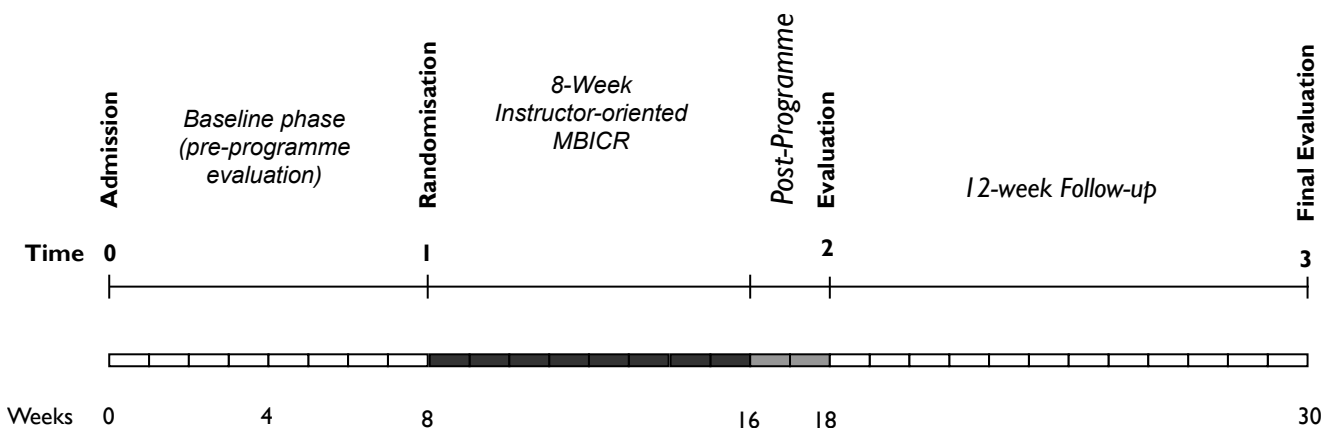


Figure 1. Study diagram.

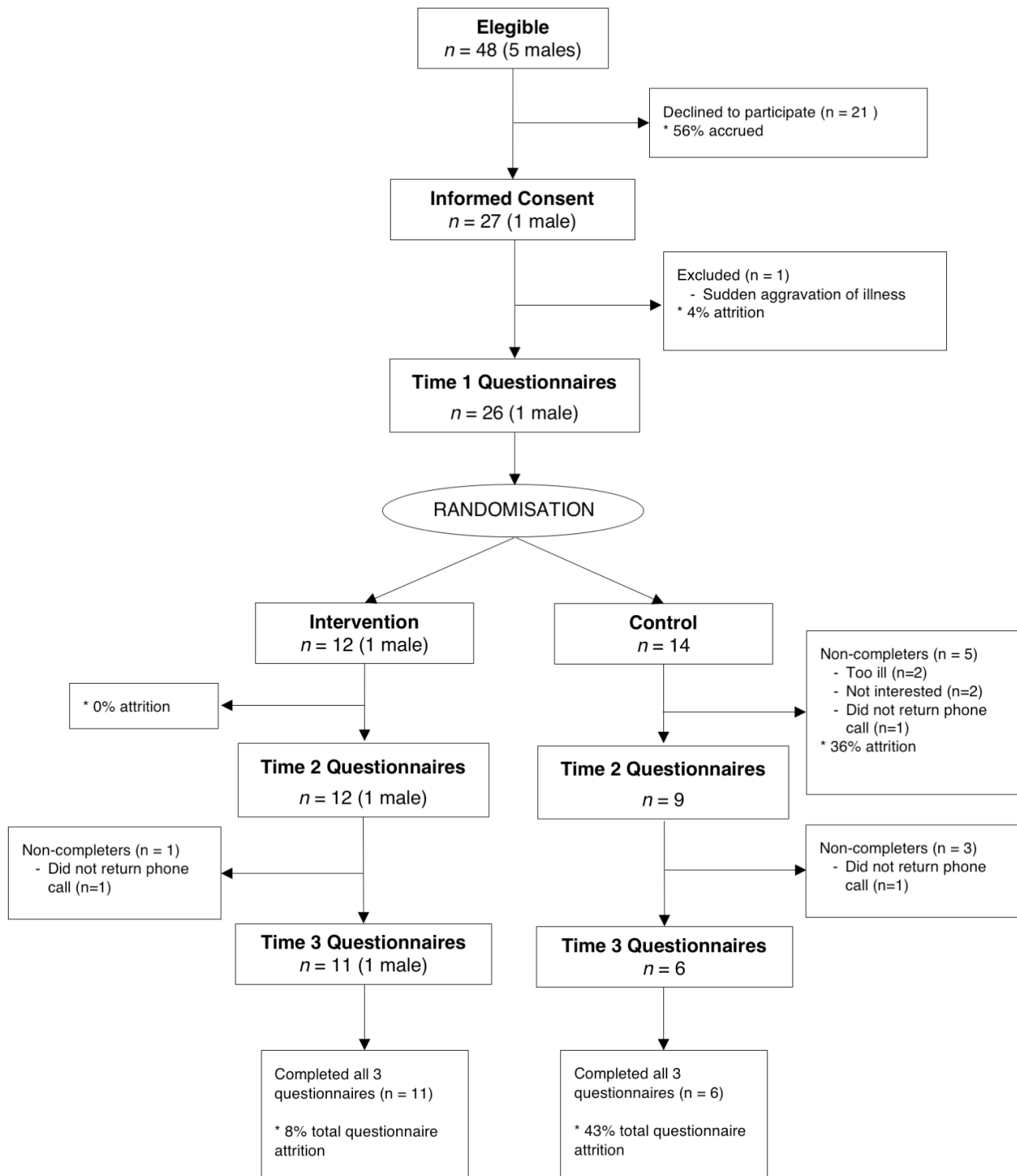


Figure 2. Flow chart of patients' disposition along the study.

The intervention programme consisted of 8 weekly group meetings and home exercises. Each group session, lasting 2–2.5 hours, was comprised of 6 patients. In each session, the exercises to do at home were explained, followed by discussions and problem-solving activities regarding personal practice. Assigned practices included: daily practice of exercises taught during group sessions; journaling for self-monitoring (self-recording of patient's

cognitive appraisal of stressful experiences); practice of mini-meditations (from simple brief pauses for awareness, to a few minutes' breathing spaces) throughout each day. During group sessions, participants were led through exercises that underpin the exploration of: stress-inducing patterns; connections between emotion and cognition, and between breathing patterns and emotional responses; propensity to view thought contents as inherent features of

the self; and cognitive distortions. Poems and stories were read in every session, to help with the “orthogonal rotation in perspective” [32]. The programme also included a day-long (5-6 hours) group session spent in silence, where loving-kindness meditation was taught.

In the last session of the programme, participants were asked to complete anonymously an assessment form that consisted of four questions regarding the 8 week’s course (“What has been most meaningful to you?”, “What was most difficult or challenging?”, “Is there anything you would have liked to be different?”, “Is there anything you would like us to know?”), plus a space for further comment.

Participants received a workbook [33] and audio instructions to support home practice. Special care was dedicated to the choice of suitable Portuguese idiomatic expressions, poetry and stories. On the other hand, given that, at the time when this study was carried out, most health professionals were not acquainted with MBIs, the first author has taught MBSR courses to professionals (doctors, nurses, psychologists and therapists) who provided care to cancer patients at the hospital centres where the study took place, prior to the beginning of this study. The health professionals who have attended those courses were asked to refer cancer patients to this study, thus knowing by direct experience what they were recommending to their patients.

Data Analyses

QoL was assessed by the aggregated scores (total, function, and symptom) of the EORTC QLQ-C30 questionnaire. Mindfulness was assessed by the total score in MAAS. The results of each measurement (at T1, T2 and T3) that are used in this work are the effect sizes (Cohen's *d*). Bivariate correlations based on all participants were computed between change in mindfulness and in QoL scores, considering pre- and post-intervention.

Given that the design is Independent-Groups Pretest-Posttest, a mixed ANOVA analysis was performed, with T1 and T2 or T3 as Within-Subjects Variables and Group as Between-Subjects Factor. The *F* statistic relative to “time*group” was converted into a *d*-value using the following expression [34]:

$$d \equiv \sqrt{F \times \left(\frac{1}{n_1} + \frac{1}{n_2} \right) \times \frac{n_1 + n_2}{n_1 + n_2 - 2}}.$$

In this analysis, only participants that have answered a given item both at T1 and T2 or T3 were included.

MAAS scores were obtained by simply summing the items scores. Computing QLQ-C30 scores is less straightforward since the Likert-type scales do not have the same width for all items; in addition, for all but the two global QoL items, higher scores mean lower QoL. So, following Ref. [26] and the questionnaire manual [35], item scores were reversed (except the two belonging to the global health status scale) and converted to a 0–100 range. Then the five function scales, the total score, the function score

and the symptom score are computed as, respectively, the average scores of the thirty QLQ-C30 items, the fifteen items belonging to function scales, and the thirteen items related to symptom scales.

Data analysis was conducted using IBM SPSS®, v.20.

Results

Feasibility

From the 48 eligible patients there was an accrual of 56%. No drop out at the end of the programme in the intervention group was observed. Compliance as regards class attendance was over 80%, Questionnaires were completed all three times by 92% of participants in the intervention group (attrition of 8%) and 43% in the control group (Figure 2).

Regarding the programme acceptability, the course assessment form in the last group session provided additional information. For many participants the most meaningful aspect had to do with looking at themselves with more kindness. On the other hand, even though they deemed as challenging or difficult the discipline of daily practice, many would have liked the course to be longer. Finally, a frequent suggestion was that this kind of programme should go on. Furthermore, when the intervention and control groups gathered together in order to complete the T2 questionnaires (after the course was over), several members of the intervention group recommended the programme to the control group.

Intervention Outcomes

With the number of participants enrolled, this study can detect [36] medium ESs ($d = 0.5$), if type-I error $\alpha = 0.05$ and two-tailed is assumed, with a statistical power $P = 0.2$; or, for $\alpha = 0.05$, two tailed, $P = 0.75$, and 24 participants, this study can only detect ESs of $d = 1.1$

Sample characteristics at baseline

A comparison of the intervention and control groups at baseline (time point T1) in terms of the main outcome variables is presented in Table 2, where the absolute values of ESs are shown. Results revealed significant differences between the two groups for MAAS, and for two function scales and six symptom items from QLQ-C30.

Intervention effects

The ESs (*d*) for MAAS scale and QLQ-C30 subscales, comparing the time point immediately after intervention with baseline, are presented in Table 3. Comparison between the 12-week follow-up time point and baseline for the two scales is presented in Table 4 (see Figures 3 and 4 for plots).

Although MAAS change scores were not significant in either assessments, they revealed a nearly significant ($p = 0.12$) increase in the pre-post comparison.

Only three variables had significant *d*-values in the pre-post intervention (Table 3). Cognitive function has increased; constipation problems have improved after the

Table 2. Comparison of control and intervention groups at baseline (T1).

	Control group			Intervention group			<i>F</i>	<i>df</i>	<i>p</i>	<i>d</i>
	<i>n</i>	Mean	SD	<i>n</i>	Mean	SD				
MAAS	14	56.07	15.68	12	52.92	13.03	4.43	24	0.01	0.83
QLQ-C30										
Global health status	11	61.54	16.78	11	59.85	21.67	0.82	20	0.42	0.39
Physical Function	14	75.00	13.84	12	73.89	16.20	0.53	24	0.60	0.29
Role Function	14	82.29	22.81	12	83.33	24.62	0.30	24	0.77	0.21
Emotional Function	11	71.79	23.68	11	62.12	24.82	21.22	20	0.01	1.96
Cognitive Function	11	69.23	28.38	11	60.61	27.41	14.67	20	0.01	1.63
Social Function	11	79.49	20.23	11	78.79	25.92	0.12	20	0.91	0.15
Fatigue	11	66.67	16.34	11	68.69	24.75	1.09	20	0.29	0.45
Nausea /vomiting	14	97.92	6.05	12	88.89	22.84	38.30	24	0.00	2.43
Pain	14	72.92	22.10	12	75.00	27.98	1.13	24	0.27	0.42
Dyspnoea	14	93.75	14.19	12	97.22	9.62	6.44	24	0.01	1.00
Insomnia	14	75.00	31.64	12	61.11	44.57	33.18	24	0.01	2.27
Appetite loss	14	91.67	27.51	12	91.67	15.08	0.00	24	1.01	0.00
Constipation	10	91.67	10.54	11	81.82	22.92	29.79	19	0.01	2.38
Diarrhoea	14	77.08	43.71	12	91.67	28.87	37.23	24	0.01	2.40
Financial problems	14	77.08	41.71	12	58.33	47.41	51.25	24	0.01	2.82

n = number of participants. SD = standard deviation. *F* = *F*-function. *df* = degrees of freedom. *p* = *p*-value (two-tailed). |*d*| = absolute *d*-values.

Bold type *d*-values are significant to $p \leq 0.05$.

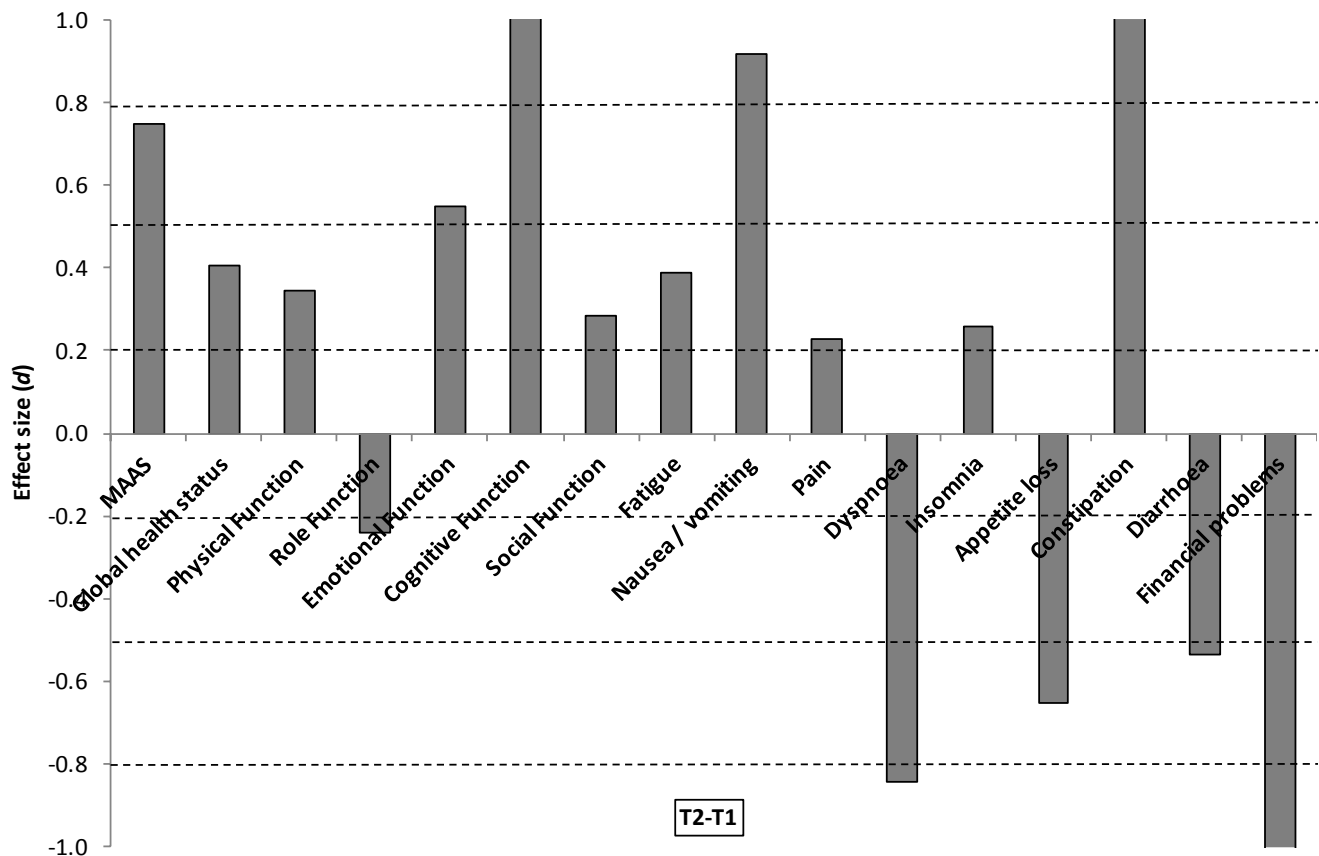


Figure 3. Effect sizes (*d*) for MAAS scale and QLQ-C30 scales and items: post-intervention vs. baseline. Horizontal dashed lines indicate Cohen's benchmarks for effect sizes.

Table 3. Effect sizes (Cohen's d) for mindfulness and quality of life, comparing immediate post-intervention with baseline (T1).

	Time point	Control group			Intervention group			F	df	p	d
		n	Mean	SD	n	Mean	SD				
MAAS	T1	9	62.22	11.88	12	52.92	13.03	2.61	19	0.12	0.75
	T2	9	65.56	13.10	12	63.67	11.93				
QLQ-C30											
Global health status	T1	7	71.43	13.49	8	60.42	25.49	0.53	13	0.48	0.40
	T2	7	71.43	13.49	8	65.63	21.56				
Physical Function	T1	9	79.26	18.09	9	79.26	14.31	0.47	16	0.50	0.34
	T2	9	81.48	31.67	9	88.89	14.43				
Role Function	T1	8	79.17	23.15	9	87.04	27.36	0.22	15	0.65	-0.24
	T2	8	81.25	16.52	9	81.48	17.57				
Emotional Function	T1	14	52.38	37.76	10	55.00	33.84	1.62	22	0.22	0.55
	T2	14	44.05	40.88	10	68.33	26.29				
Cognitive Function	T1	14	55.95	36.75	10	55.00	31.48	5.40	22	0.03	1.00
	T2	14	40.48	43.22	10	73.33	29.61				
Social Function	T1	14	59.52	36.81	10	76.67	34.43	0.43	22	0.52	0.28
	T2	14	52.38	47.53	10	80.00	31.23				
Fatigue	T1	14	50.80	31.04	10	62.22	34.03	0.80	22	0.38	0.39
	T2	14	38.89	37.43	10	63.34	27.74				
Nausea/ vomiting	T1	8	97.92	5.89	9	87.04	26.06	3.15	15	0.10	0.92
	T2	8	93.75	17.68	9	94.44	11.78				
Pain	T1	8	75.00	29.55	9	72.22	31.18	0.20	15	0.66	0.23
	T2	8	77.08	30.78	9	79.63	21.69				
Dyspnoea	T1	8	91.67	15.43	9	96.30	11.11	2.65	15	0.13	-0.84
	T2	8	100.00	0.00	9	96.30	11.11				
Insomnia	T1	7	90.48	16.26	7	85.71	26.23	0.20	12	0.66	0.26
	T2	7	80.95	17.82	7	80.95	26.23				
Appetite loss	T1	8	83.33	35.63	9	88.89	16.67	1.59	15	0.23	-0.65
	T2	8	100.00	0.00	9	88.89	16.67				
Constipation	T1	8	95.83	11.78	8	75.00	23.57	5.73	14	0.03	1.28
	T2	8	95.83	11.78	8	100.00	0.00				
Diarrhoea	T1	8	91.67	23.57	8	100.00	0.00	1.00	14	0.33	-0.53
	T2	8	95.83	11.78	8	100.00	0.00				
Financial problems	T1	8	95.83	11.78	5	100.00	0.00	4.50	11	0.06	-1.31
	T2	8	100.00	0.00	5	86.67	18.26				

SD = standard deviation; F = F statistic; df = degrees of freedom; p = p-value (two-tailed); Bold type d-values are significant to $p \leq 0.05$.

intervention, contrarily to financial problems. All three parameters revealed large changes.

After the 12-week follow-up, five variables presented significant d-values: global health, emotional, cognitive and social functions, and fatigue (Table 4). Changes were all superior to 0.8, so they may be considered large.

The ESs relative to total score, function score and symptom score are shown in Tables 5 and 6, respectively for the post-intervention and follow-up compared to baseline (see Figure 5 for the corresponding plot).

From all the QLQ-C30 aggregated scores, only function score was significant at the post-intervention. Conversely, at the end of the follow-up function score was the only not significant. In either comparison, all the significant changes were quite large (≥ 1.1).

Given the limited number of variables with statistically significant changes, and most importantly the fact that mindfulness was not one of them, mediation effects were not examined.

Table 4. Effect sizes (Cohen's d) for mindfulness and quality of life, comparing 12-week follow-up with baseline.

	Time point	Control group			Intervention group			F	df	p	d
		n	Mean	SD	n	Mean	SD				
MAAS	T1	6	59.33	12.60	10	49.70	10.56	3.52	14	0.83	1.04
	T3	6	57.67	15.46	10	62.20	12.99				
QLQ-C30											
Global health status	T1	5	71.67	13.94	9	60.18	12.34	4.64	12	0.05	1.30
	T3	5	31.67	12.36	9	34.26	12.80				
Physical Function	T1	5	77.33	20.33	11	72.73	16.45	0.40	14	0.54	0.37
	T3	5	74.67	17.25	11	76.97	28.81				
Role Function	T1	5	80.00	29.82	11	81.82	25.23	0.01	14	0.91	0.07
	T3	5	86.67	18.26	11	81.82	29.30				
Emotional Function	T1	14	52.38	37.76	12	55.55	31.45	5.13	24	0.03	0.93
	T3	14	28.57	40.39	12	59.72	31.35				
Cognitive Function	T1	14	55.95	36.75	12	56.94	29.69	4.73	22	0.04	0.89
	T3	14	28.57	42.58	12	61.11	35.77				
Social Function	T1	14	59.52	36.81	12	72.22	33.59	4.10	24	0.05	0.83
	T3	14	29.76	42.46	12	76.39	37.91				
Fatigue	T1	14	50.80	31.04	12	62.97	30.83	6.27	24	0.02	1.03
	T3	14	23.02	32.75	12	66.67	33.83				
Nausea/ vomiting	T1	5	96.67	7.46	10	98.33	5.27	0.26	13	0.62	-0.30
	T3	5	100.00	0.00	10	100.00	0.00				
Pain	T1	6	77.78	27.22	10	83.33	15.71	0.59	14	0.45	0.43
	T3	6	72.22	37.51	10	88.33	15.81				
Dyspnoea	T1	5	93.33	14.91	10	96.67	10.54	2.17	13	0.17	-0.87
	T3	5	100.00	0.00	10	96.67	10.54				
Insomnia	T1	5	86.67	18.26	8	79.17	30.54	0.28	11	0.61	0.33
	T3	5	80.00	18.26	8	79.17	24.80				
Appetite loss	T1	5	93.33	14.91	10	96.67	10.54	2.29	13	0.15	0.89
	T3	5	86.67	18.26	10	100.00	0.00				
Constipation	T1	5	100.00	0.00	10	83.33	23.57	0.00	13	1.00	0.00
	T3	5	100.00	0.00	10	83.33	23.57				
Diarrhoea	T1	6	88.89	27.22	10	100.00	0.00	0.02	14	0.90	-0.07
	T3	6	83.33	40.82	10	96.67	10.54				
Financial problems	T1	6	94.45	13.61	8	87.50	24.80	1.26	12	0.28	0.66
	T3	6	79.17	40.05	8	90.63	12.94				

SD = standard deviation; F = F statistic; df = degrees of freedom; p = p-value (two-tailed); Bold type d-values are significant to $p \leq 0.05$.

Discussion

The primary interest of this work was to study, through a RCT, the feasibility and acceptability of the first (to the best of our knowledge) mindfulness-based programme for Portuguese cancer patients. Another goal was to assess the efficacy of the programme in promoting a higher QoL.

The fact that 56% of screened patients were enrolled in the study can be considered relevant, given that most

of them didn't know what mindfulness is about. That rate is similar to the 42% reported for a RCT with a modified MBSR [37]. The number of patients enrolled is similar to what has been reported in other pilot feasibility MBI studies [38-42].

While no targets for attrition rates had been defined at the outset, a 10-15% rate is often observed in this kind of studies [11, 43-46]. In the present study, the attrition rate for the intervention group may therefore be consid-

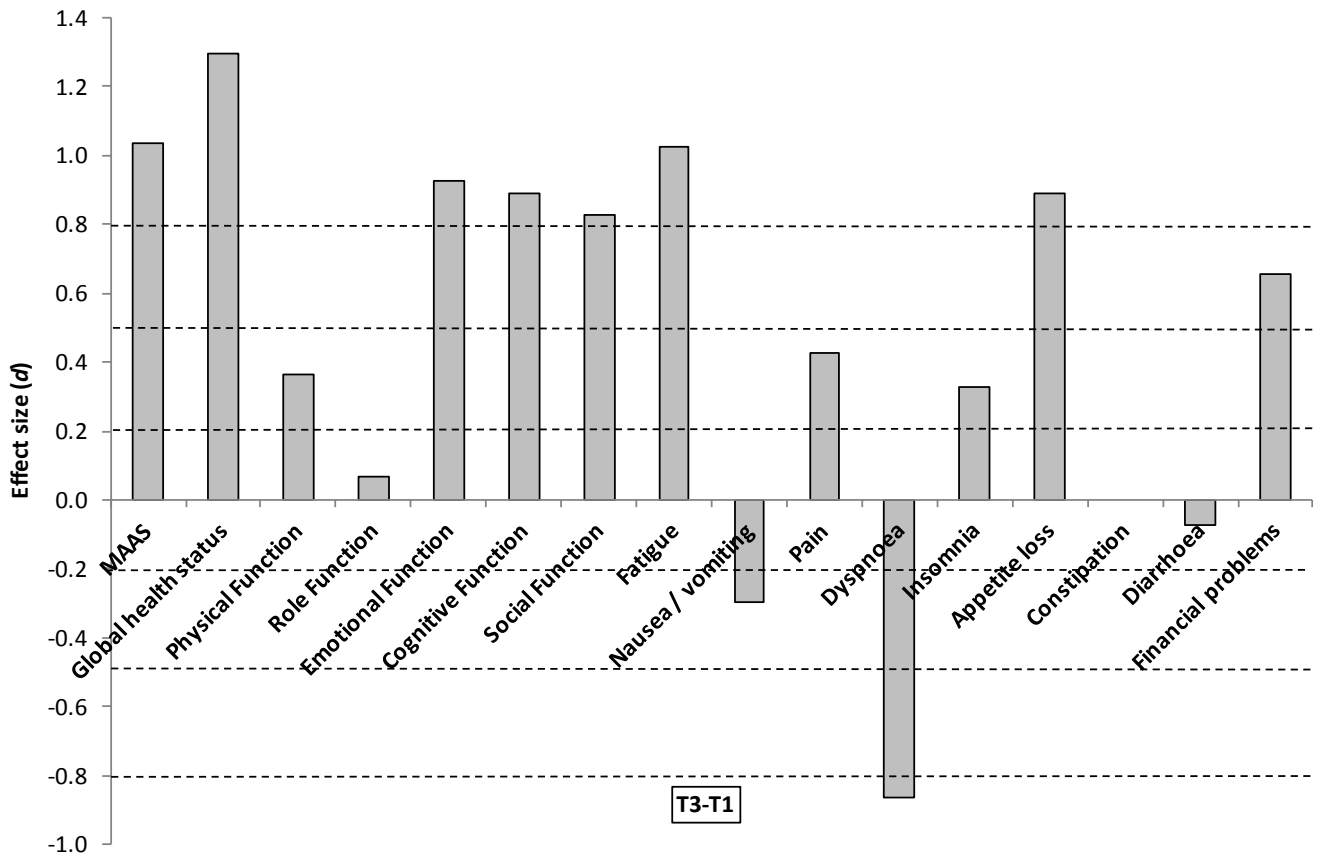


Figure 4. Effect sizes (d) for MAAS scale and QLQ-C30 scales and items: follow-up vs. baseline. Horizontal dashed lines indicate Cohen's benchmarks for effect sizes.

ered very acceptable. Conversely, for the control group the attrition rate may be considered quite high.

What can explain the high attrition rate in the control group? One possible explanation may be related with the fact that patients who had been assigned to the control

group were disappointed, even though they knew the rules and randomization was done in their presence [47]. Eventually they became disinterested to do the course after having waited for several months. Another possibility is that in the control group there were more people with lower

Table 5. Effect sizes (Cohen's d) for mindfulness and quality of life, comparing immediate post-intervention with baseline.

	Time point	Control group			Intervention group			F	df	p	d
		n	Mean	SD	n	Mean	SD				
MAAS	T1	9	62.22	11.88	12	52.92	13.03	2.61	19	0.12	0.75
	T2	9	65.56	13.10	12	63.67	11.93				
QLQ-C30											
Global health status	T1	7	71.43	13.49	8	60.42	25.49	0.53	13	0.48	0.40
	T2	7	71.43	13.49	8	65.63	21.56				
Total Score	T1	14	59.68	34.20	10	67.39	28.91	1.84	12	0.19	0.59
	T2	14	45.79	41.73	10	72.39	27.88				
Function score	T1	9	67.41	28.35	8	71.67	18.92	4.53	15	0.05	1.10
	T2	9	69.38	27.73	8	81.11	14.88				
Symptom score	T1	8	82.69	12.54	9	75.50	21.50	0.70	15	0.42	0.43
	T2	8	84.94	9.93	9	82.34	11.06				

SD = standard deviation; F = F statistic; df = degrees of freedom; p = p -value (two-tailed); Bold type d -values are significant to $p \leq 0.05$.

Table 6. Effect sizes (Cohen's *d*) for mindfulness and quality of life, comparing 12-week follow-up with baseline.

	Time point	Control group			Intervention group			<i>F</i>	<i>df</i>	<i>p</i>	<i>d</i>
		<i>n</i>	Mean	SD	<i>n</i>	Mean	SD				
MAAS	T1	6	59.33	12.60	10	49.70	10.56	3.52	14	0.83	1.04
	T3	6	57.67	15.46	10	62.20	12.99				
QLQ-C30											
Global health status	T1	5	71.67	13.94	9	60.18	12.34	4.64	12	0.05	1.30
	T3	5	31.67	12.36	9	34.26	12.80				
Total Score	T1	14	59.68	34.20	12	67.55	26.18	7.07	24	0.01	1.09
	T3	14	28.37	39.54	12	67.64	32.35				
Function score	T1	5	76.89	11.07	9	72.59	15.24	1.47	12	0.25	0.73
	T3	5	79.56	5.75	9	81.73	10.23				
Symptom score	T1	14	76.56	14.74	12	77.35	18.84	11.06	24	0.00	1.36
	T3	14	30.95	43.16	12	73.93	35.31				

SD = standard deviation; *F* = *F* statistic; *df* = degrees of freedom; *p* = *p*-value (two-tailed); Bold type *d*-values are significant to $p \leq 0.05$.

level of education and because of this not acquainted with the mindfulness movement and therefore had less expectation about its potentialities.

Compliance regarding class attendance was high (over 80%), and is similar to the around 80% rates in other studies [44, 45]. Regarding home practice, participants were reluctant to keep a practice journal. Considering this as well as the difficulties associated with the disease, the instructor decided to drop that instrument in order to avoid overloading the patients, hence the absence of data regarding home practice.

Portuguese people of the age group of this study patients' most likely had a strict catholic upbringing. As mentioned above, this could potentially jeopardize the programme's acceptability, but actually it didn't seem to be the case, judging by the lack of attrition rate in the intervention group. In addition, in the intervention group, there were two people who during the programme sessions have affirmed their catholic faith and their engagement in the church activities, who were very committed to the programme and had recommended it to the control group. It thus seems that the programme's meditation practices, which have a secular character, did not clash with participant's religious beliefs, at least for the sample of this study.

In what concerns the intervention outcomes, the *d*-values in Tables 3–6 and Figures 3–5 are in line with some other studies that have assessed the impact of either MBSR or MBCT (or modified versions of those) on QoL, as is briefly surveyed next.

Using an adapted MBSR, one study [48] has found significant pre-post improvements in QLQ-C30 global health status ($d = 0.35$), but no significant changes in emotional, cognitive or social function scales; mindfulness was not measured. Another MBSR study [38] reported similar

findings ($d = 0.40$) although using another instrument (SF-36). In the present work, it was found ($d = 0.40$ for global health status and a significant change in cognitive function ($d = 0.10$). It should be noted, however, that neither of those two studies had a control group; it is known that a one-group, pre-post test design cannot really tell whether the observed changes are caused by the intervention itself or are just a result of time alone, and is more likely to give higher *d* values [49].

Significant changes at follow-up in total score of QoL Life Index Cancer Version III, in the MBSR intervention group compared to the control one ($d = 0.7$) were reported [46]; however, mindfulness measured with MAAS showed no changes (significant or otherwise) between the two moments in both groups. In the present work, although QoL total score had a significant change ($d = 1.1$) mindfulness revealed no significant changes (see Table 6). Similarly, in a MBSR RCT study in a Spanish oncologic population that measured QLQ-C30 global health (but not mindfulness) [23], $d = 0.4$ was found but with low significance ($p \geq 0.05$).

In another MBSR study [43], it was observed a significant T2-T1 change for the intervention group in QLQ-C30 "averaged into composite score" (undetailed) ($d = 0.43$), global health ($d = 0.44$), and function score ($d = 0.45$), but none for symptom score, while equivalent measures for the control group were not significant. In the present work it was found that function score did significantly improve in that time period; however, if one does computations similar to those authors' with the data in Table 5 of the present work, no significant changes of any of those quantities are found for either group.

In the first RCT in oncology using MBCT [11], comparing the intervention with the control group, it was found a significant ES in mindfulness measured with short form FMI ($d = 0.55$) as well as a trend for QoL ($d = 0.30$)

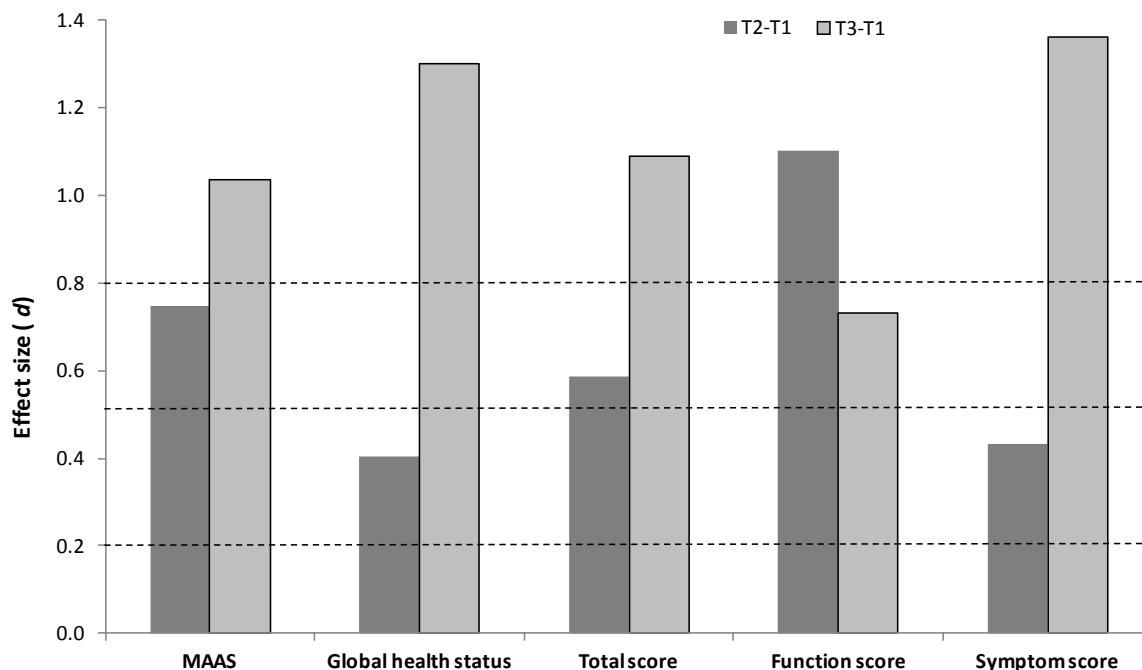


Figure 5. Effect sizes for MAAS scale, QLQ-C30 global health status, total score, function score and symptom score, at post-intervention and follow-up vs. baseline. Horizontal dashed lines indicate Cohen's benchmarks for effect sizes.

measured with FACT-G. A MBCT pilot study in advanced prostate cancer patients [39], reported high and significant increase in mindfulness (measured with FFMQ) but no significant changes in QoL (measured with FACT-P), either in global health or subscales, when either post-intervention or 12-week follow-up were compared to baseline. In contrast, as already stated, in the present work (Tables 5 and 6) no significant changes in MAAS have been obtained, but significant and high changes at follow-up were found for global health, and for emotional, cognitive and social functions.

Based on the brief survey above, it can be said that global health has been observed to improve with mindfulness-based programmes, and the same was measured in the present work for follow-up compared to baseline. However, it has not been tested the role of mindfulness as mediator, either because mindfulness has not been measured, or its values were not significant.

In addition to global health, the studies in this brief review report on emotional, cognitive and social functions, mostly without significant results contrarily to what was found here. Those studies do not discuss the symptom scales and items, and little can be said here about it, as in this work only one of the three symptom scales (fatigue) and two of the six symptom items (constipation and financial problems) showed significant changes. In view of these facts, the QLQ-C30 aggregated scores may bring some insight into this type of studies.

Here only the function score change was significant at T2, but at T3 global health, total score and symptom score showed significant and high improvements (Tables 5–6

and Figure 5). Larger studies should be performed to confirm the trends we can infer from Figure 5: (a) improvements in global health, total score and symptom score are effective and more so as time increases; (b) changes in mindfulness follow a similar trend but with a less time influence; (c) function score also improves, even if with an opposite time pattern.

It should be emphasized that one has to be careful in comparing results as in the foregoing brief survey, since there is a variation in research design, sampling, intervention programmes (or their versions) delivered, and measuring instruments. Comparisons among different scales are difficult to make, for not only the mindfulness scales do not all measure exactly the same [50], but also the ways QoL is conceptualized differ [51].

Another point pertaining to mindfulness scales it that in the present study several participants, while completing MAAS questionnaire, queried on some items as they were confused about the meaning of the questions. This may be connected with the already mentioned language issues that were reported apropos the Spanish version of that questionnaire [52].

This work has several shortcomings. One is the fact that the main researcher and the MBI instructor were the same person (the reason being that, at the time the study was performed, there was no one else in the country qualified to administer that particular program). The fact that participants were aware of that dual role, and also of the academic purpose of the study, might have induced a distortion (trying to please) in their statements and in answering the questionnaires.

Another limitation is the sample size (very small), which entails a lack of statistical power. The lack of significance is a major limitation.

Randomization has produced fairly similar groups from the point of view of demographic and clinical features. However, it should be noted the high SD of average number of years of education, particularly for centre B. At baseline, the ten significant variables have large or very large *d*-values, and this discrepancy between the two groups is somewhat surprising, especially regarding mindfulness.

There is a lack of information regarding protocol adherence as no formal information about home practice was collected. However, it was a priority not to overburden the patients.

It's not unprecedented in MBIO studies a heterogeneity of cancer types [9-11, 53-56] and a gender bias [10]. Even so, the study sample does not reflect the oncologic population from the geographical area where the study took place, in terms of gender, age and cancer type. Therefore it is not possible to generalize the conclusions of this work to the whole of the northern Portuguese cancer patients.

Also the absence of information regarding cancer staging may have been detrimental to significance. The present authors are aware that some patients had terminated treatment one or more years before, while others had received chemotherapy some months prior to admission; some were still dealing with breast reconstruction issues while others had those matters resolved.

In conclusion, this work was the first randomized controlled pilot study of a MBI with cancer patients in Portugal. Mindfulness-based programmes are a novelty in this country, which is culturally quite different from those where most of the research on MBIs has been performed. So the primary interest of this study was to test the feasibility and acceptability of a programme such as this. In a small sample of twenty six patients, the attrition rate was null in the intervention group of twelve. Mindfulness measured by MAAS showed an increase after the intervention. After the 12-week follow-up, QoL measured with QLQ-C30 had significant improvements in general health scale as well as in the aggregated scales: total score, function score and symptom score.

Even though the sample may not be considered representative of the Portuguese oncologic population, it is likely that MBIOs are acceptable programmes and hence future research is worth proceeding. A larger research team is needed to avoid research bias. A larger sample, with statistical power to detect at least small-to-medium ESs and representative of the Portuguese oncologic population, is warranted. The gates to this pathway may open as a result of this study, as well as of its preparatory work. Hopefully, the fact that so many health professionals have attended MBSR courses may have started to weave a regional network of health professionals and institutions willing to support this kind of intervention and research.

Abbreviations

BU: Bangor University; EORTC QLQ-C30: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; ES: Effect size; MAAS: Mindful Attention Awareness Scale; MBCT: Mindfulness-Based Cognitive Therapy; MBI: Mindfulness-Based Intervention; MBIO: Mindfulness-Based Intervention in Oncology; MBSR: Mindfulness-Based Stress Reduction; QoL: Quality of life; RCT: Randomised controlled trial (RCT)

Competing interests

The authors declare no conflict of interest.

References

- Kabat-Zinn J. Mindfulness-Based Interventions in Context: Past, Present, and Future. *Clinical Psychology: Science and Practice* 2003; 10:144-56. <http://dx.doi.org/10.1093/clipsy.bpg016>
- Baer RA. *Mindfulness-Based Treatment Approaches*. Burlington, MA: Academic Press; 2006.
- Kabat-Zinn J. An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. *General Hospital Psychiatry* 1982; 4:33-47. [http://dx.doi.org/10.1016/0163-8343\(82\)90026-3](http://dx.doi.org/10.1016/0163-8343(82)90026-3)
- Kabat-Zinn J. *Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness*. New York, NY: Delacorte Press; 1990.
- Segal ZV, Williams JMG, Teasdale JD. *Mindfulness-based cognitive therapy for depression: a new approach to preventing relapse*. New York: Guilford Press; 2002.
- Khoury B, Lecomte T, Fortin G, Masse M, Therien P, Bouchard V, et al. Mindfulness-based therapy: A comprehensive meta-analysis. *Clinical Psychology Review*. 2013; 33:763-71. <http://dx.doi.org/10.1016/j.cpr.2013.05.005>
- Cohen J. *Statistical power analysis for the behavioral sciences*. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
- Shennan C, Payne S, Fenlon D. What is the evidence for the use of mindfulness-based interventions in cancer care? A review. *Psycho-Oncology* 2011; 20:681-97. <http://dx.doi.org/10.1002/pon.1819>
- Birnie K, Garland SN, Carlson LE. Psychological benefits for cancer patients and their partners participating in mindfulness-based stress reduction (MBSR). *Psycho-Oncology* 2010; 19:1004-9. <http://dx.doi.org/10.1002/pon.1651>
- Bränström R, Kvillemo P, Brandberg Y, Moskowitz J. Self-report Mindfulness as a Mediator of Psychological Well-being in a Stress Reduction Intervention for Cancer Patients—A Randomized Study. *Annals of Behavioral Medicine* 2010; 39:151-61. <http://dx.doi.org/10.1007/s12160-010-9168-6>
- Foley E, Baillie A, Huxter M, Price M, Sinclair E. Mindfulness-based cognitive therapy for individuals whose lives have been affected by cancer: a randomized controlled trial. *Journal of Consulting and Clinical Psychology* 2010; 78:72-9. <http://dx.doi.org/10.1037/a0017566>
- Matchim Y, Armer JM, Stewart BR. Mindfulness-based stress reduction among breast cancer survivors: a literature review and discussion. *Oncology Nursing Forum* 2011; 38:E61-71. <http://dx.doi.org/10.1188/11.ONF.E61-E71>
- Bohlmeijer E, Prenger R, Taal E. Meta-analysis on the effectiveness of mindfulness-based stress reduction therapy on mental health of adults with a chronic disease: What should the reader not make of it? *Journal of Psychosomatic Research* 2010; 69:614-5. <http://dx.doi.org/10.1016/j.jpsychores.2010.09.005>

14. Grossman P, Niemann L, Schmidt S, Walach H. Mindfulness-based stress reduction and health benefits: A meta-analysis. *Journal of Psychosomatic Research* 2004; 57:35-43. [http://dx.doi.org/10.1016/S0022-3999\(03\)00573-7](http://dx.doi.org/10.1016/S0022-3999(03)00573-7)
15. Ledesma D, Kumano H. Mindfulness-based stress reduction and cancer: a meta-analysis. *Psycho-Oncology* 2009; 18:571-9. <http://dx.doi.org/10.1002/pon.1400>
16. Hofmann SG, Sawyer AT, Witt AA, Oh D. The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review. *Journal of Consulting and Clinical Psychology* 2010; 78:169-83. <http://dx.doi.org/10.1037/a0018555>
17. Musial F, Büssing A, Heusser P, Choi KE, Ostermann T. Mindfulness-Based Stress Reduction for Integrative Cancer Care – a Summary of Evidence. *Forschende Komplementärmedizin / Research in Complementary Medicine* 2011; 18:192–202. <http://dx.doi.org/10.1159/000330714>
18. Zainal NZ, Booth S, Huppert FA. The efficacy of mindfulness-based stress reduction on mental health of breast cancer patients: a meta-analysis. *Psycho-Oncology* 2013; 22:1457–65. <http://dx.doi.org/10.1002/pon.3171>
19. Abercrombie PD, Zamora A, Korn AP. Lessons learned: providing a mindfulness-based stress reduction program for low-income multi-ethnic women with abnormal pap smears. *Holistic Nursing Practice* 2007; 21:26-34. <http://dx.doi.org/10.1097/00004650-200701000-00006>
20. Marlatt GA, Kristeller JL. Mindfulness and meditation. In: Miller WR, editor. *Integrating spirituality into treatment*. Washington, DC American Psychological Association; 1999. p. 68. <http://dx.doi.org/10.1037/10327-004>
21. Roth B, Calle-Mesa L. Mindfulness-Based Stress Reduction (MBSR) with Spanish- and English-Speaking Inner-City Medical Patients. In: Baer RA, editor. *Mindfulness-Based Treatment Approaches*. Burlington, MA: Academic Press; 2006. p. 263-84. <http://dx.doi.org/10.1016/B978-012088519-0/50013-7>
22. National Institutes of Health. Clinical trials registry. USA: NIH; 2014.
23. León C, Mirapeix RM, Blasco T, Jovell E, Arcusa À, Martín A, et al. Mindfulness para la reducción del malestar emocional en pacientes oncológicos. Estudio comparativo con una intervención psicoeducativa estándar. *Psicooncología* 2013; 10:263-74.
24. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: A Quality-of-Life Instrument for Use in International Clinical Trials in Oncology. *Journal of the National Cancer Institute* 1993; 85:365-76. <http://dx.doi.org/10.1093/jnci/85.5.365>
25. Pais-Ribeiro J, Pinto C, Santos C. Validation study of the portuguese version of the QLC-C30-V.3. *Psicologia, Saúde e Doenças* 2008; 9:89-102.
26. Hinz AA, Einenkel JJ, Briest SS, Stolzenburg JU, Papsdorf KK, Singer SS. Is it useful to calculate sum scores of the quality of life questionnaire EORTC QLQ-C30? *European Journal Of Cancer Care* 2012; 21:677-83. <http://dx.doi.org/10.1111/j.1365-2354.2012.01367.x>
27. Brown KW, Ryan RM. The benefits of being present: mindfulness and its role in psychological well-being. *Journal of Personality and Social Psychology* 2003; 84:822-48. <http://dx.doi.org/10.1037/0022-3514.84.4.822>
28. Carlson LE, Brown KW. Validation of the Mindful Attention Awareness Scale in a cancer population. *Journal of Psychosomatic Research* 2005; 58:29–33. <http://dx.doi.org/10.1016/j.jpsychores.2004.04.366>
29. Gregório S, Pinto-Gouveia J. Mindful Attention and Awareness: Relationships with Psychopathology and Emotion Regulation. *The Spanish Journal of Psychology* 2013; 16:1–10. <http://dx.doi.org/10.1017/sjp.2013.79>
30. Zernicke KA, Campbell TS, Specia M, McCabe-Ruff K, Flowers S, Carlson LE. A Randomized Wait-List Controlled Trial of Feasibility and Efficacy of an Online Mindfulness-Based Cancer Recovery Program: The eTherapy for Cancer AppLYing Mindfulness Trial. *Psychosomatic Medicine* 2014; 76:257-67. <http://dx.doi.org/10.1097/PSY.0000000000000053>
31. Bartley T. *Mindfulness-based cognitive therapy for cancer: gently turning towards*. Chichester, UK: Wiley-Blackwell; 2012.
32. Kabat-Zinn J. *Coming to our senses: healing ourselves and the world through mindfulness*. 1st ed. New York: Hyperion; 2005.
33. Lopes JC. "Mindfulness-Based Intervention in Cancer Recovery": Manual de participante num curso de 8 semanas. Aveiro, Portugal: Centro de Prática e Estudo de Mindfulness; 2013.
34. Thalheimer W, Cook S. How to calculate effect sizes from published research articles: A simplified methodology. 2002 – [cited 2014 Jun 30]. Available from: http://work-learning.com/effect_sizes.htm.
35. European Organization for Research and Treatment of Cancer. EORTC QLQ-C30 Scoring Manual. 3rd ed. Brussels: EORTC; 2001.
36. Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods* 2007; 39:175-91. <http://dx.doi.org/10.3758/BF03193146>
37. Lengacher CA, Johnson-Mallard V, Post-White J, Moscoso MS, Jacobsen PB, Klein TW, et al. Randomized controlled trial of mindfulness-based stress reduction (MBSR) for survivors of breast cancer. *Psycho-Oncology* 2009; 18:1261-72. <http://dx.doi.org/10.1002/pon.1529>
38. Lengacher CA, Johnson-Mallard V, Barta M, Fitzgerald S, Moscoso MS, Post-White J, et al. Feasibility of a Mindfulness-Based Stress Reduction Program for Early-Stage Breast Cancer Survivors. *Journal of Holistic Nursing* 2011;29:107-17. <http://dx.doi.org/10.1177/0898010110385938>
39. Chambers S, Foley E, Galt E, Ferguson M, Clutton S. Mindfulness groups for men with advanced prostate cancer: a pilot study to assess feasibility and effectiveness and the role of peer support. *Supportive Care in Cancer* 2012; 20:1183-92. <http://dx.doi.org/10.1007/s00520-011-1195-8>
40. Altschuler A, Rosenbaum E, Gordon P, Canales S, Avins AL. Audio recordings of mindfulness-based stress reduction training to improve cancer patients' mood and quality of life--a pilot feasibility study. *Support Care Cancer* 2012; 20:1291-7. <http://dx.doi.org/10.1007/s00520-011-1216-7>
41. Kingston T, Collier S, Hevey D, McCormick MM, Besani C, Cooney J, et al. Mindfulness-based cognitive therapy for psycho-oncology patients: an exploratory study. *Irish Journal of Psychological Medicine* 2015;32:265-74. <http://dx.doi.org/10.1017/ipm.2014.81>
42. van den Hurk DGM, Schellekens MPJ, Molema J, Speckens AEM, van der Drift MA. Mindfulness-Based Stress Reduction for lung cancer patients and their partners: Results of a mixed methods pilot study. *Palliative Medicine* 2015; 29:652-60. <http://dx.doi.org/10.1177/0269216315572720>
43. Lerman R, Jarski R, Rea H, Gellish R, Vicini F. Improving Symptoms and Quality of Life of Female Cancer Survivors: a Randomized Controlled Study. *Annals of Surgical Oncology* 2012; 19:373-8. <http://dx.doi.org/10.1245/s10434-011-2051-2>
44. Shapiro SL, Bootzin RR, Figueredo AJ, Lopez AM, Schwartz GE. The efficacy of mindfulness-based stress reduction in the treatment of sleep disturbance in women with breast cancer: An exploratory study. *Journal of Psychosomatic Research* 2003; 54:85-91. [http://dx.doi.org/10.1016/S0022-3999\(02\)00546-9](http://dx.doi.org/10.1016/S0022-3999(02)00546-9)
45. Carlson LE, Specia M, Patel KD, Goodey E. Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress and levels of cortisol, dehydroepiandrosterone sulfate (DHEAS) and melatonin in breast and prostate cancer outpatients. *Psychoneuro-*

- endocrinology 2004; 29:448-74.
[http://dx.doi.org/10.1016/S0306-4530\(03\)00054-4](http://dx.doi.org/10.1016/S0306-4530(03)00054-4)
46. Witek-Janusek L, Albuquerque K, Chroniak KR, Chroniak C, Durazo-Arvizu R, Mathews HL. Effect of mindfulness based stress reduction on immune function, quality of life and coping in women newly diagnosed with early stage breast cancer. *Brain, Behavior, and Immunity* 2008; 22:969-81.
<http://dx.doi.org/10.1016/j.bbi.2008.01.012>
 47. Specia M, Carlson LE, Mackenzie MJ, Angen M. A randomized, wait-list controlled clinical trial: the effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosomatic Medicine* 2000; 62:613-22.
<http://dx.doi.org/10.1097/00006842-200009000-00004>
 48. Carlson LE, Specia M, Patel KD, Goodey E. Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress, and immune parameters in breast and prostate cancer outpatients. *Psychosomatic Medicine* 2003; 65:571-81.
<http://dx.doi.org/10.1097/01.PSY.0000074003.35911.41>
 49. Hempel S, Suttrop MJ, Miles JNV, Wang Z, Maglione M, Morton S, et al. Empirical Evidence of Associations Between Trial Quality and Effect Sizes. Methods Research Report In: Quality. AfHRa, editor. (Prepared by the Southern California Evidence-based Practice Center under Contract No. 290-2007-10062-I). AHRQ Publication No. 11-EHC045-EF. Rockville, MD.: Agency for Healthcare Research and Quality. Available from: <http://effectivehealthcare.ahrq.gov>; 2011.
 50. Bergomi C, Tschacher W, Kupper Z. The Assessment of Mindfulness with Self-Report Measures: Existing Scales and Open Issues. *Mindfulness* 2013; 4:191-202.
<http://dx.doi.org/10.1007/s12671-012-0110-9>
 51. Pukrop R, Möller H-J, Steinmeyer EM. Quality of life in psychiatry: a systematic contribution to construct validation and the development of the integrative assessment tool "modular system for quality of life". *European Archives of Psychiatry and Clinical Neuroscience* 2000; 250:120-32.
<http://dx.doi.org/10.1007/s004060070028>
 52. Inchausti F, Prieto G, Delgado AR. Rasch analysis of the Spanish version of the Mindful Attention Awareness Scale (MAAS) in a clinical sample. *Revista de Psiquiatría y Salud Mental* 2014;7:32-41.
<http://dx.doi.org/10.1016/j.rpsm.2013.07.003>
 53. Carlson LE, Garland SN. Impact of mindfulness-based stress reduction (MBSR) on sleep, mood, stress and fatigue symptoms in cancer outpatients. *International Journal of Behavioral Medicine* 2005;12:278-85.
http://dx.doi.org/10.1207/s15327558ijbm1204_9
 54. Garland S, Carlson L, Cook S, Lansdell L, Specia M. A non-randomized comparison of mindfulness-based stress reduction and healing arts programs for facilitating post-traumatic growth and spirituality in cancer outpatients. *Supportive Care in Cancer* 2007;15:949-61.
<http://dx.doi.org/10.1007/s00520-007-0280-5>
 55. Monti D, Peterson C. Mindfulness-based art therapy for cancer patients. *Psycho-Oncology* 2005;15:363--73.
<http://dx.doi.org/10.1002/pon.988>
 56. Kieviet-Stijnen A, Visser A, Garssen B, Hudig W. Mindfulness-based stress reduction training for oncology patients: patients' appraisal and changes in well-being. *Patient Education and Counseling* 2008;72:436-42.
<http://dx.doi.org/10.1016/j.pec.2008.05.015>