Psycho-Oncology
Psycho-Oncology **24**: 1208–1212 (2015)
Published online 28 January 2015 in Wiley Online Library (wileyonlinelibrary.com). **DOI**: 10.1002/pon.3755

Clinical Correspondence

Home-based mindfulness therapy for lung cancer symptom management: a randomized feasibility trial

Rebecca H. Lehto[1]*, Gwen Wyatt[1], Alla Sikorskii[2], Irena Tesnjak[2] and Vered Hankin Kaufman[3]
[1]*College of Nursing, Michigan State University, USA*
[2]*Department of Statistics/Probability, Michigan State University, USA*
[3]*Department of Medical Social Sciences, Northwestern University, USA*

**Correspondence to: 1355 Bogue, C-344, Michigan State University, East Lansing, MI 48824-1317, USA. E-mail: rebecca.lehto@hc.msu.edu*

Received: 1 August 2014
Revised: 17 November 2014
Accepted: 18 December 2014

Dear Editor,

Patients with advanced lung cancer who are undergoing radiation and/or chemotherapy have high symptom burden and lowered health-related quality of life (HRQOL) [1]. Mindfulness-based therapies, incorporating meditation and gentle yoga practices, target self-regulation of challenging mental and physical symptoms, and may provide an effective approach to symptom management.

Mindfulness-based interventions were originally developed by Kabat-Zinn [2] as an 8-week program, and are grounded in early evidence that training in meditative practices may enhance adaptation to serious health concerns [3,4]. Through such a skill set, patients develop non-judgmental awareness and open acceptance of current mental and physical experiences [4]. Mindfulness-based interventions have been shown to reduce psychological distress, improve HRQOL in mixed population cancer studies [3,5], promote wellbeing, and reduce depressive and anxious symptoms in healthy individuals [2]. There are limited studies that have tested mindfulness-based interventions during active cancer treatment, a time when HRQOL is particularly challenged. This is of strong importance in lung cancer as patients tend to be older and have high co-morbidities and utilization of health services [6]. Lung cancer patients are characterized by heightened vulnerability and lowered representation in intervention research. Thus, home-based non-pharmacological approaches to symptom management are particularly valuable in this population.

A targeted mindfulness protocol was developed using input from patient focus groups [7]. The study purpose was to test acceptability, feasibility, and preliminary efficacy of the protocol on symptom and HRQOL outcomes for patients receiving treatment for advanced lung cancer.

Methods

The study utilized a longitudinal randomized controlled trial (RCT) design, and HRQOL components of symptoms and functioning were primary outcomes. Human studies approval was obtained from all participating institutions. Eligibility criteria included: English speaking; >21 years old; active treatment (radiation and/or chemotherapy); diagnosis of stage III/IV non-small cell lung cancer; and Karnofsky functional status score >80. Following informed consent, patients completing baseline interviews were randomized to intervention or attention control (symptom interviews only) groups using a computerized minimization procedure that balanced study groups on recruitment site, cancer stage, and treatment. Concealment was achieved by running the randomization algorithm from the central study office simultaneously across all sites. The intervention group received a 6-week program with 45-min sessions weekly delivered by a trained provider in the home environment, with patient agreement to daily practice between sessions. The intervention included: meditation/gentle yoga training; practices to expand awareness; and discussions relative to managing internal/external health and stressors.

Both groups received weekly symptom interviews via telephone during the six-week period. While the interviews were part of data collection, they also provided limited amounts of social interaction that occurred equally

between arms. The study hypothesis of improved symptom severity and HRQOL in the intervention group as compared to attention control was tested.

Instruments

Telephone interviews were conducted at baseline (Time 1@study week 1), immediately following the 6-week intervention (Time 2@study week 8), and four weeks following completion (Time 3@study week 11). Symptom severity and interference were measured with the M.D. Anderson Symptom Inventory (MDASI) [8]. The MDASI evaluates severity of 13 symptoms experienced by cancer patients in treatment on a 0–10 Likert scale, and interference from symptoms in daily activities (scored 0–10). Reliability and validity of the instrument are established [8].

HRQOL was measured with the Medical Outcomes study Rand Short Form-36 (SF-36) [9]. The SF-36 measures physical function, physical role functioning, bodily pain, general health perceptions, vitality, social/emotional role functioning, mental health, and composite physical and mental summaries [9]. The SF-36 has demonstrated strong content/construct validity and internal consistency [9].

Table 1. Descriptive statistics for demographics, health characteristics, and study outcomes at baseline by study group

	Intervention *N* (%)	**Control *N* (%)**	***P*-value (group comparisons)**
Sex			.74
Male	7 (35.0)	6 (30.0)	
Female	13 (65.0)	14 (70.0)	
Marital status			.54
Never married	1 (5.0)	0 (0)	
Married/living with partner	14 (70)	16 (80)	
Divorced/separated	3 (15.0)	1 (5.0)	
Widowed	2 (10.0)	2 (5.0)	
Refused/NA	0 (0)	1 (5.0)	
Ethnicity			.13
Hispanic/Latino	0 (0)	3 (15.0)	
Not Hispanic/Latino	19 (95.0)	17 (85.0)	
Refused	1 (5.0)	0 (0)	
Race			.71
American Indian/Alaska Native	0 (0)	1 (5.0)	
Asian	1 (5.0)	1 (5.0)	
Black/African American	0 (0)	1 (5.0)	
White	18 (90.0)	16 (80.0)	
Refused/NA	1 (5.0)	1 (5.0)	
Education			.41
High school or less	2 (10.0)	1 (5.0)	
Completed high school	4 (20.0)	8 (40.0)	
Completed some college/technical training	7 (35.0)	6 (30.0)	
College degree	4 (20.0)	2 (10.0)	
Completed graduate/professional degree	3 (15.0)	3 (15.0)	
Disease Stage			.74
Stage 3	6 (30.0)	7 (35.0)	
Stage 4	14 (70.0)	13 (65.0)	
Treatment type			.45
Chemotherapy	12 (60.0)	8 (40.0)	
Radiation	2 (10.0)	3 (15.0)	
Chemotherapy/radiation	6 (30.0)	9 (45.0)	
	Mean (st dev)	Mean (st dev)	
Age	64.5 (9.25)	67.9 (9.5)	.27
Symptom severity	35.00 (21.26)	29.25 (19.18)	.37
Symptom interference	21.25 (16.20)	19.15 (16.41)	.69
Physical function	37.73 (8.90)	35.25 (10.17)	.42
Physical role functioning	38.97 (9.64)	40.31 (10.47)	.67
Bodily pain	41.96 (9.59)	47.36 (12.29)	.13
General health	41.89 (11.60)	46.43 (11.66)	.22
Vitality	42.20 (7.50)	45.91 (11.96)	.25
Social functioning	41.55 (11.42)	47.56 (10.72)	.09
Emotional role functioning	46.77 (11.25)	47.12 (12.75)	.93
Mental health	45.37 (10.07)	49.56 (10.13)	.20
Physical summary score	37.83 (8.91)	39.17 (10.43)	.67
Mental summary score	47.33 (11.01)	51.82 (12.23)	.23

DOI: 10.1002/pon

Data analysis included descriptive statistics and group comparisons using linear mixed effects models [10]. Explanatory variables included baseline values of outcomes, study group, and time. In addition to *p*-values for the tests of differences between trial arms, effect sizes (Cohen's-*d*) were estimated.

Results

Forty patients were recruited from two community-based hospitals and one urban comprehensive cancer center and randomized using computer generated group assignation to receive six weekly mindfulness-based therapy

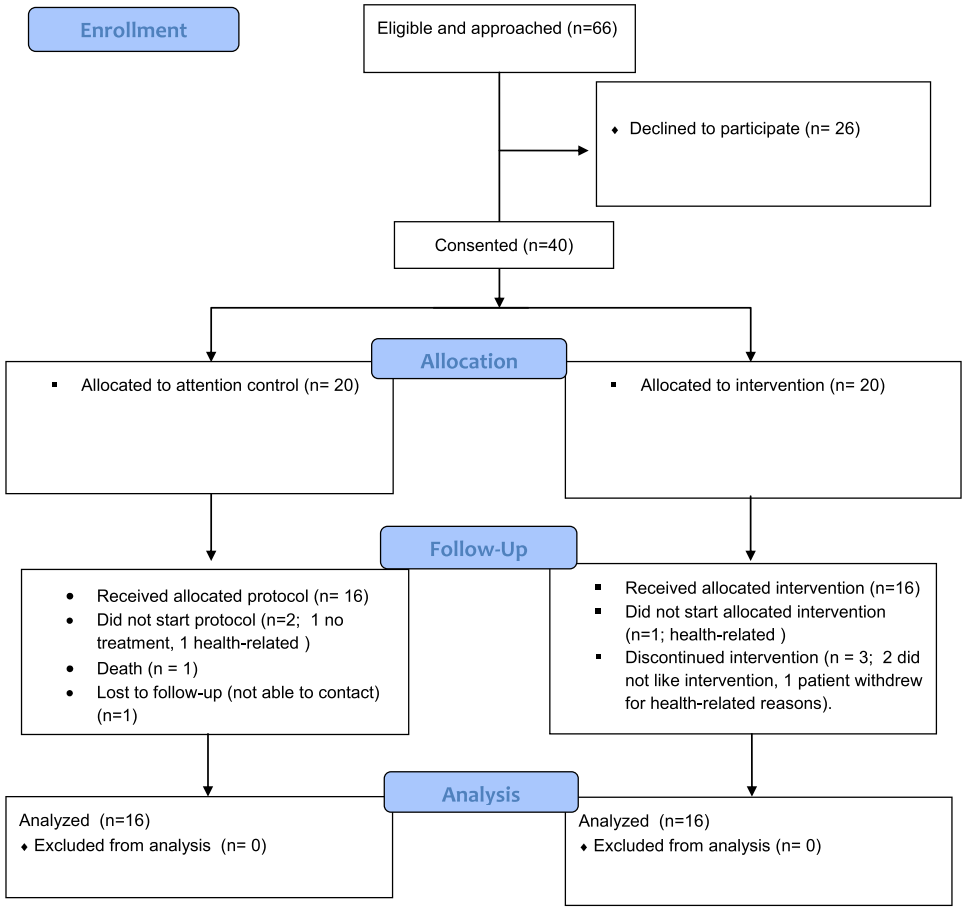

Figure 1. Study flow diagram

Table 2. Least squares (LS) means of outcomes at 8 and 11 weeks by study group adjusted for baseline (average over time from linear mixed effects models)

	Intervention LS mean (SE)[+]	Control LS mean (SE)[+]	*P*-value	Effect size
Symptom severity	26.79 (2.84)	32.11 (2.64)	.19	0.34*
Symptom interference	14.33 (1.87)	18.95 (1.74)	.09	0.44*
Physical function	42.90 (1.82)	35.90 (1.73)	.01*	0.96*
Physical role functioning	42.97 (1.91)	40.69 (1.80)	.42	0.27
Bodily pain	48.89 (2.39)	44.93 (2.25)	.26	0.41*
General health	46.35 (1.82)	44.59 (1.70)	.51	0.24
Vitality	47.92 (2.19)	44.15 (2.06)	.24	0.45*
Social functioning	48.25 (1.86)	41.20 (1.75)	.01*	0.82*
Emotional role functioning	51.28 (1.82)	49.38 (1.68)	.51	0.31
Mental health	54.52 (2.23)	48.97 (2.09)	.11	0.68*
Physical summary score	42.22 (1.96)	37.72 (1.84)	.12	0.59*
Mental summary score	54.62 (2.16)	50.28 (2.02)	.20	0.57*

*P-values <.05; clinically significant effects sizes >0.33.
[+]Least squares (LS) means; standard errors (SE).

DOI: 10.1002/pon

sessions ($N=20$) or the attention control ($N=20$) (symptom interviews). Table 1 summarizes baseline characteristics of the sample. Participants ranged in age from 44 to 87 years (mean = 66.2, standard deviation = 9.5). At baseline, there were no significant differences in demographic and health characteristics between groups (Table 1). Patients had on average 4 comorbid conditions (respiratory, cardiac, and arthritic conditions primarily).

Acceptability and feasibility were determined via rates of patient retention and adherence. There were 32 patients who completed (16 each group, 20% attrition, Figure 1). Attrition reasons included: withdrawal by participant, $n=3$; illness/treatment complications, $n=2$; medical treatment withdrawal, $n=1$; death, $n=1$; and lost to follow-up, $n=1$. Attrition included 4 patients from each group with characteristics not different from patients who completed. Relatively low attrition rates for this sample with advanced disease supported the acceptability and feasibility of the novel protocol.

Upon study completion, the summary of the adjusted means from the linear mixed effects models [10] showed that summed symptom severity and interference scores were both lower in the mindfulness group compared to controls (Table 2). Due to small sample size, statistical significance was not reached, but the effect sizes were moderate and clinically meaningful (severity; $d=0.34$, interference; $d=0.44$). For other HRQOL parameters, there was significant improvement and large effect sizes for physical function ($p=.01$, $d=0.96$) and social function ($p=.01$, $d=0.82$). Moderate effect sizes were also found for mental health ($d=0.68$), overall physical ($d=0.59$) and mental health summary scores ($d=0.57$), vitality ($d=0.45$), and pain ($d=0.41$).

Discussion

This pilot study demonstrated acceptability and feasibility of the home-based protocol as evidenced by successful recruitment and retention among highly vulnerable patients and completion of the longitudinal RCT. Importantly, most patients were able to devote time for practice in between sessions. While the sample was small, strong effect sizes for symptom severity and interference, and other HRQOL parameters provide preliminary efficacy evidence. Further, these initial findings show improvement of both perceived social and physical function. Given that patients were in active treatment, these findings support high potential of the self-management mindfulness intervention as supportive care for symptoms and HRQOL improvement.

The home-based mindfulness protocol is non-invasive and thus does not interfere with traditional anti-cancer treatment modalities. Further, once learned, the skills are non-costly and can be used in any setting. Although the study is limited by a small sample size, it does provide important preliminary efficacy data. Given that most participants were married with partners, future studies should address the caregiver role in assisting patients with participation. If benefits are established with larger scale testing, vulnerable patients may gain access to a scientifically sound supportive intervention for symptom and HRQOL improvement.

Appendix A. Mindfulness intervention session components

Component	Contents
Didactic training.	1. Introduction to meditation practices 2. Training and discussion of use of homework log 3. Provision of resources
Formal 1:1 practice.	1. Breathing meditations (breath as anchor) 2. Guided Body Scan (familiarization/observation of body sensations/symptoms) 3. Gentle yoga (standing and/or sitting stretch movements) 4. Visualization and awareness meditation (incremental expansion of sensory experience)
Informal practices.	1. Coming back to experience self 'right now' during day 2. Letting go/acceptance (past/future) 3. Non-judgmental awareness of pleasant/unpleasant feelings, thoughts, and sensations 4. Building self-compassion
Barriers and application.	1. Setting realistic individualized goals. 2. Managing negative thoughts, distractions, and symptoms. 3. Increasing commitment to practice and personal well-being.

Acknowledgements

MSU CTSI Grant-GA013811. Clinical Trials.gov: NCT01565980.

References

1. Akin S, Can G, Aydiner A, Ozdilli K, Durna Z. Quality of life, symptom experience and distress of lung cancer patients undergoing chemotherapy. *Eur J Oncol Nurs* 2010;**14**:400–409.
2. Kabat-Zinn J. *Full Catastrophe Living: Using the Wisdom of your Body and Mind to Face Stress, Pain, and Illness* (15th edition). Delta Trade Paperbacks: New York, NY, 2009.
3. Shennon C, Payne S, Fenlon D. What is the evidence for the use of mindfulness-based interventions in cancer care? A review. *Psycho-Oncology*, *Published online in Wiley Online Library* (wileyonlinelibrary.com) 2010. DOI: 10.1002/pon.1819.
4. Shapiro SFL, Carlson LE, Astin JA, Freedman B. Mechanisms of mindfulness. *J Clin Psychol* 2006;**62**:373–386.
5. Ledesma D, Kumano H. Mindfulness-based stress reduction and cancer: a meta-analysis. *Psycho-Oncology* 2009;**18**:571–579.
6. Schneider N, Dreier M, Amelung VE, Buser K. Hospital stay frequency and duration of patients

with advanced cancer diseases—differences between the most frequent tumour diagnoses: a secondary data analysis. *Eur J Cancer Care* 2007;**16**:172–177.
7. Lehto RH, Wyatt G. Perceptions about using mindfulness therapy: a lung cancer focus group study. *Cancer Nurs* 2013;**36**:E51–E60.
8. Cleeland CS, Mendoza T, Wang XS, *et al*. Assessing symptom distress in cancer patients: The M.D. Anderson Symptom Inventory. *Cancer* 2000;**89**:1634–1646.
9. McHorney CA, Ware JEJ, Lu JFR, Sherbourne CD. The MOS 36-item Short-Form Health Survey (SF-36): III: tests of data quality, scale assumptions, and reliability across diverse patient groups. *Med Care* 1994;**32**:40–66.
10. Zar JH. *Biostatistical Analysis* (2nd Edition). Prentice Hall: Englewood Cliffs, NJ, 1984.

DOI: 10.1002/pon