

Table 2: Randomized controlled trials of mindfulness for cancer

Source: Cramer H, Moenaert AC, CAM-Cancer Consortium. [Mindfulness \[online document\]](#). October 2016.

First author, year, (ref)	Study design	Participants (number, diagnosis)	Interventions (experimental, control)	Main outcome measures	Main results	Comments
Carlson, 2013 (40)	RCT	271 BC after completion of primary treatment	<ol style="list-style-type: none"> MBCR Supportive-expressive group therapy Stress management seminar 	Primary: Mood (POMS), diurnal cortisol slope Secondary: Stress (C-SOSI), breast cancer-specific quality of life (FACT-B), social support (MOS-SSS), symptoms of stress (SOSI)	Primary: no group difference regarding distress (POMS), significantly flatter cortisol slope in stress management seminar compared to MBCR. Secondary: Significant lower stress (C-SOSI) in MBSR compared to supportive-expressive group therapy and stress management seminar no further group differences in ITT analysis.	Allocation concealment unclear; outcome assessors only partially blinded; required sample size not reached; safety not reported.
Garland, 2014 (39)	RCT (non-inferiority)	111 adults with non-metastatic cancer after completion of primary treatment	<ol style="list-style-type: none"> MBSR CBT-I 	Primary: Insomnia severity (ISI) Secondary: actigraphy (objective sleep measure), stress(C-SOSI), dysfunctional beliefs and attitudes about sleep (DBAS), sleep quality (PSQI), mood (POMS), sleep diary	Primary: Short-term inferiority of MBSR compared to CBT-I, medium-term non-inferiority. Secondary: Better short- and medium-term sleep quality (sleep diary, PSQI) and dysfunctional sleep beliefs (DBAS) in CBT-I compared to MBSR. No further group differences.	Larger attrition in MBSR; safety not reported.
Johannsen, 2016 (41)	RCT	129 BC reporting pain after completion of primary treatment	<ol style="list-style-type: none"> MBCT Usual care 	Primary: Pain (MPQ, pain numerical rating scale) Secondary: Well-being (WBI), anxiety and depression (HADS), pain medication use	Primary: Short- and medium-term effects on pain intensity (numerical rating scale) Secondary: Short- and medium-term effects on quality of life (WBI) and pain medication use	Allocation concealment and blinding unclear; safety not reported.
Johns, 2016 (42)	RCT	71 patients with BC or colorectal cancer with persistent fatigue after completion of primary treatment	<ol style="list-style-type: none"> MBSR Psycho-education and support 	Primary: Fatigue (FSI) Secondary: Pain (BPI), insomnia severity (ISI), fatigue global improvement, generalized anxiety disorder (GAD), mental disorders (PHQ)	Primary: No effects of MBSR compared to psychoeducation and support Secondary: Short-term effects on vitality and global improvement, no medium-term effects	Safety not reported.

Lehto, 2015 (43)	RCT	40 patients with non-small cell lung cancer currently undergoing radiation or chemotherapy	<ol style="list-style-type: none"> 1. Home-based mindfulness therapy plus symptom interview 2. Symptom interview 	Primary: Cancer-related symptoms (MDASI), health-related quality of life (SF-36)	Primary: short-term effect of the mindfulness therapy compared to control on symptom severity and interference (MDASI)	Blinding, conflict of interest, and safety not reported.
Lengacher, 2016 (44)	RCT	322 BC after completion of primary treatment	<ol style="list-style-type: none"> 1. MBSR 2. Usual care 	Pain (BPI), depression (CES-D), Concerns about Recurrence Scale, perceived stress (PSS), health-related quality of life (SF-36), anxiety (STAI)	Short- and medium-term group differences favouring MBSR(BC) over usual care for anxiety (STAI), concerns about recurrence, and fatigue. No further group differences.	Allocation concealment unclear; outcome assessors only partially blinded; safety not reported.
Lipschitz, 2015 (45)	RCT	30 adults with a diagnosis of cancer and sleep disturbances after completion of primary treatment	<ol style="list-style-type: none"> 1. MBSR 2. Mind-body bridging program 3. Sleep hygiene education 	Primary: salivary oxytocin, sleep problems (SPI) Secondary: depression (CES-D), cancer-specific quality of life (FACT-G), mindfulness (FFMQ), social support (MOS-SS), perceived stress (PSS), self-compassion (SCS)	Primary: no effects of MBSR on salivary oxytocin, short-term effects on sleep (SPI) compared to mind-body bridging program or sleep hygiene education. Secondary: no group differences between MBST and MBB or sleep hygiene education.	Random sequence generation, allocation concealment and blinding unclear; attrition and safety not reported.
Van der Lee, 2010 (38)	RCT	100 severely fatigued adults with a diagnosis of cancer after completion of primary treatment	<ol style="list-style-type: none"> 1. MBCT 2. Usual care 	Primary: fatigue (CIS fatigue subscale) Secondary: Impact of disease on quality of life (SIP), Dutch Health and Disease Inventory.	Primary: moderate short- and medium-term effect of MBCT compared to usual care on fatigue (CIS). Secondary: short- and medium-term effects on of MBCT compared to usual care on well-being (Dutch Health and Disease Inventory); medium-term effects on functional impairment (SIP)	Inadequate randomization; no allocation concealment; blinding unclear; safety not reported; randomized patients excluded from analysis; no ITT analysis.
Victorson, 2016 (46)	RCT	43 adults with prostate cancer on active surveillance	<ol style="list-style-type: none"> 1. MBSR 2. Book on mindfulness 	Intolerance of uncertainty (IUS), mindfulness (MAAS), anxiety (MAX-PC), global health (PGH-10), posttraumatic growth (PTGI)	Group differences favouring MBSR over the book on posttraumatic growth (PTGI). No other significant group differences.	Allocation concealment unclear; safety not reported.
Zernicke, 2014 (47)	RCT	62 adults with a diagnosis of cancer after completion of primary treatment	<ol style="list-style-type: none"> 1. Online MBCR 2. Usual care 	Stress (C-SOSI), spiritual well-being (FACIT-Sp), mindfulness (FFMQ), mood 8POMS, posttraumatic growth (PTGI)	Group differences favouring MBCR over usual care on distress (POMS), stress (C-SOSI), Spirituality (FACIT-Sp), mindfulness (FFMQ).	Safety not reported.

Abbreviations: BC, women diagnosed with breast cancer; BPI, Brief Pain Inventory; CBT-I, Cognitive Behavioral Therapy for Insomnia; CIS, Checklist Individual Strength; C-SOSI, Calgary Symptoms of Stress Inventory; DBAS, Dysfunctional Beliefs and Attitudes About Sleep Scale; FACIT-Sp, Functional Assessment of Chronic Illness Therapy Spiritual Well-being; FACT-B, Functional Assessment of Cancer Therapy-Breast; FACT-G, Functional Assessment of Cancer Therapy-General; FFMQ, Five-Facet Mindfulness Questionnaire; FSI, Fatigue Symptom Inventory; GAD, Generalized Anxiety Disorder scale; HADS, Hospital Anxiety Depression Scale; IIT, intention-to-treat; ISI, Insomnia Severity Index; IUS, Intolerance of Uncertainty; MAAS, Mindful Attention Awareness Scale; MAX-PC, Memorial Anxiety Scale for Prostate Cancer; MBCR, Mindfulness-based Cancer Recovery; MBSR, Mindfulness-based Stress Reduction; MDASI, M.D. Anderson Symptom Inventory; MOS-SS, Medical Outcomes Study Sleep Scale; MOS-SSS Medical Outcomes Study Social Support Survey; MPQ, McGill Pain Questionnaire; PGH-10, PROMIS Global Health-10; PHQ, Patient Health Questionnaire; POMS, Profile of Mood States; PSQI, Pittsburgh Sleep Quality Index; PTGI, Posttraumatic Growth Inventory; RCT, randomized controlled trial; SCS, Self-Compassion Scale; SHE, sleep hygiene education; SIP, Sickness Impact Profile; SOSI, Symptoms of Stress Inventory; SPI, Sleep Problems Index; STAI, State-Trait Anxiety Inventory; WBI, World Health Organization-5 Well-Being Index