

Table 2: Randomized controlled trials of mindfulness for cancer

Source: Cramer H, Moenaert AC, CAM-Cancer Consortium. [Mindfulness \[online document\]](#). October 2019.

First author, year, (ref)	Study design	Participants (number, diagnosis)	Interventions (experimental, control)	Main outcome measures	Main results	Comments
Black 2017 (40)	RCT	57 adult colorectal cancer patients receiving an adjuvant chemotherapy session	<ol style="list-style-type: none"> Mindfulness-meditation practice plus cancer education video during chemotherapy Cancer education video during chemotherapy Standard chemotherapy 	Primary: Salivary cortisol Secondary: distress (DASS), fatigue (MFI), mindfulness (MAAS)	Primary: Relative increase in cortisol reactivity in the Mindfulness group Secondary: Only correlational analysis, no effects reported	Brief video mindfulness intervention; outcomes on psychosocial variables not reported, combined 2 control groups (no significant differences in individual comparisons?), safety not reported.
Bruggeman-Everts 2017 (41)	RCT	179 fatigued cancer survivors (167 randomized)	<ol style="list-style-type: none"> AAF eMBCT Psycho-educational emails 	Primary: fatigue (CIS) Secondary: mental health (PANAS, HADS)	Primary: Stronger decrease in AFF and eMBCT than in the email group. Secondary: No group differences.	Larger attrition in eMBCT and AAT; safety not reported.
Chambers 2017 (42)	RCT	190 adult men with advanced prostate cancer (189 randomized)	<ol style="list-style-type: none"> Group-based MBCT intervention delivered by telephone Minimally enhanced usual care 	Primary: distress (BSI), anxiety (prostate-specific anxiety scale of the MAX-PC) Secondary: FACT-P, PTGI	Primary: No group differences Secondary: Mindful observing increased more in MBCT than in usual care, no further group differences	Safety not reported.
Compen 2018 (43)	RCT	245 distressed adults with a prior cancer diagnosis	<ol style="list-style-type: none"> MBCT eMBCT Usual care 	Primary: distress (HADS) Secondary: psychiatric diagnosis (SCID), FCRI, rumination subscale of the RRQ, MOS-SF12, FFMQ, MHC-SF	Primary: Lower distress in MBCT and eMBCT than in usual care in the short-term. Lower distress in eMBCT than in MBCT in the long-term (9 months). Secondary: Lower fear of cancer recurrence and rumination, increased mental health-related quality of life, mindfulness skills, positive mental health distress in MBCT and eMBCT than in usual care in the short-term. 21 severe adverse events (6 in MBCT, 9 in eMBCT, 6 in usual care)	Long-term effects in Cillessen 2018 (62).

Garland, 2014 (44)	RCT (non-inferiority)	111 adults with non-metastatic cancer after completion of primary treatment	<ol style="list-style-type: none"> 1. MBSR 2. CBT-I 	<p>Primary: Insomnia severity (ISI)</p> <p>Secondary: actigraphy (objective sleep measure), stress(C-SOSI), dysfunctional beliefs and attitudes about sleep (DBAS), sleep quality (PSQI), mood (POMS), sleep diary</p>	<p>Primary: Short-term inferiority of MBSR compared to CBT-I, medium-term non-inferiority.</p> <p>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.</p>	Larger attrition in MBSR; safety not reported.
Kubo 2019 (45)	RCT	98 adults with cancer currently receiving active treatment or receiving active treatment in the prior 6 months (97 randomized)	<ol style="list-style-type: none"> 1. Mindfulness app 2. Wait-list 	<p>Primary: anxiety and depression (HADS)</p> <p>Secondary: feasibility, distress (distress thermometer), pain (PROMIS pain), sleep (PROMIS sleep), quality of life (FACT-G), fatigue (BFI), mindfulness (FFMQ), and posttraumatic growth (PTGI)</p>	<p>Primary: No group difference</p> <p>Secondary: Intervention feasible, stronger increase in overall well-being and mental-wellbeing the mindfulness group than in the WL group</p>	In the protocol, anxiety and depression are registered as primary outcome measures. The publication reports it as if feasibility was primary outcome. Longer-term outcomes included in the protocol but not reported. Safety not reported.
Lehto, 2015 (46)	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 	<p>Primary: Cancer-related symptoms (MDASI), health-related quality of life (SF-36)</p>	<p>Primary: Short-term effect of the mindfulness therapy compared to control on symptom severity and interference (MDASI)</p>	Blinding, conflict of interest, and safety not reported.
Lipschitz, 2015 (47)	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 	<p>Primary: salivary oxytocin, sleep problems (SPI)</p> <p>Secondary: depression (CES-D), cancer-specific quality of life (FACT-G), mindfulness (FFMQ), social support (MOS-SS), perceived stress (PSS), self-compassion (SCS)</p>	<p>Primary: No effects of MBSR on salivary oxytocin, short-term effects on sleep (SPI) compared to mind-body bridging program or sleep hygiene education.</p> <p>Secondary: no group differences between MBST and MBB or sleep hygiene education.</p>	Random sequence generation, allocation concealment and blinding unclear; attrition and safety not reported.
Liu 2019 (48)	RCT	120 adults with differentiated thyroid cancer receiving radioactive iodine therapy	<ol style="list-style-type: none"> 1. MBSR 2. Usual care 	<p>Quality of life (EORTC QLQ-30), depression (Zung SDS), anxiety (Zung SAS) (primary and secondary outcomes not defined).</p>	<p>Greater improvement in emotional function, fatigue, global quality of life, depression, anxiety.</p>	No primary outcome defined. When adjusting p-values for multiple testing, no group differences remain significant. Safety not reported.

Mohammadi 2018 (49)	RCT	40 adult women with breast cancer	<ol style="list-style-type: none"> 1. Mindfulness (program unclear) 2. Control group (unclear) 	Illness perception (B-IPQ), mindfulness (MAAS) (primary and secondary outcomes not defined).	Stronger worsening of illness perception in the mindfulness group compared to the control group, stronger increase in mindfulness in the mindfulness group compared to the control group.	Randomization unclear, no primary outcome defined, inclusion criteria unclear, unclear which interventions the groups received, attrition not reported, safety not reported, negative effects on illness perception interpreted as positive.
Pintado 2017 (50)	RCT	29 adult women with breast cancer not currently receiving adjuvant treatment	<ol style="list-style-type: none"> 1. MBSR 2. Personal image advice group 	Body image (BIS), body awareness/dissociation (SBC) (primary and secondary outcomes not defined).	Stronger improvement in body image but not body awareness/dissociation in MBSR than in advice group.	Allocation concealment unclear, no primary outcome defined, safety not reported, different reporting of findings in abstract and main text.
Pouy 2018 (51)	RCT	70 patients diagnosed with breast cancer	<ol style="list-style-type: none"> 1. Mindfulness-based group training (program unclear) 2. Usual care 	Quality of life (WHOQOL-BREF), life expectancy (Schneider's life expectancy questionnaire) distress (DASS) (primary and secondary outcomes not defined).	Stronger improvement in quality of life, life expectancy, depression, anxiety and stress in mindfulness than in usual care.	Randomization used obsolete methods, allocation concealment unclear, no primary outcome defined, statistical analysis unclear, safety not reported.
Rosen 2018 (52)	RCT	112 adult women diagnosed with breast cancer less than 5 years ago	<ol style="list-style-type: none"> 1. Mindfulness app 2. Wait-list 	Primary: quality of life (FACT-B) Secondary: mindfulness (MAAS)	Stronger improvement in quality of life and dispositional mindfulness in mindfulness than in wait-list group.	Allocation concealment unclear, safety not reported.
Russel 2019 (53)	RCT	69 adults who have completed treatment for stage 2c or 3 melanoma	<ol style="list-style-type: none"> 1. Online mindfulness-based program 2. Usual care 	Primary: study feasibility and acceptability Secondary: fear of cancer recurrence (FCRI), rumination (rumination subscale of the RRQ), worry (PSQW-A), mindfulness (CAMS-R), stress (PSS)	Primary 80% study completion rate Secondary: Lower fear of cancer recurrence in the mindfulness group than in the usual care group.	Blinding, safety not reported.
Schellekens 2017 (54)	RCT	63 adults with nonsmall cell or small cell lung cancer and their caregivers	<ol style="list-style-type: none"> 1. MBSR 2. Usual care 	Primary: distress (HADS) Secondary: quality of life (EORTC QLQ-30), relationship satisfaction (Investment Model Scale-Satisfaction)	Primary: Stronger reduction in distress in MBSR than in usual care. Secondary: Stronger improvement in quality of life, mindfulness skills, self-	Allocation concealment unclear, safety not reported.

				Subscale), mindfulness (FFMQ), self-compassion (SCF), rumination (brooding subscale of the RRS)	compassion, rumination in MBSR than in usual care.	
Van der Lee, 2010 (55)	RCT	100 severely fatigued adults with a diagnosis of cancer after completion of primary treatment	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 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.
Vaziri 2017 (56)	RCT	16 women with breast cancer undergoing radiotherapy	1. MBCT 2. Wait-list	Distress (DASS), emotion regulation (CERQ), (no primary outcome defined but multivariate analysis used to keep the formal significance level).	No group differences occurred.	Extremely small sample without sample size calculation, likely underpowered, allocation concealment, blinding unclear, 2 patients inadequately excluded from analysis, safety not reported.
Victorson, 2016 (57)	RCT	43 adults with prostate cancer on active surveillance	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.
Witek Janusek 2019 (58)	RCT	192 adult women diagnosed with early-stage breast cancer	1. MBSR 2. Attention-control intervention	Primary: immune parameters (NKCA, cytokines) Secondary: stress (PSS), depression (CES-D), fatigue (MFSI), sleep (PSQI), mindfulness (FFMQ)	Primary: More rapid restoration of NKCA, lower circulating TNF-alpha levels, lower IL-6 production, greater IFN-gamma production in MBSR than in attention-control. Secondary: Lower stress, fatigue, sleep disturbance	Relatively large attrition.
Zhang 2017 (59)	RCT	76 adults with leukaemia undergoing chemotherapy	1. Mindfulness-based psychological care 2. Standard care	Sleep (PSQI), anxiety (Zung-SAS), depression (Zung-SDS) (no primary outcome defined)	Stronger improvement in sleep, anxiety, depression in the mindfulness than in the standard care group.	Methods of randomization, allocation concealment unclear, inadequate statistics, no primary outcome defined, safety not reported.

Zernicke, 2014 (60)	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 (POMS), posttraumatic growth (PTGI)	Group differences favouring MBCR over usual care on distress (POMS), stress (C-SOSI), Spirituality (FACIT-Sp), mindfulness (FFMQ).	Safety not reported.
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AAF, Web-based Ambulant Activity Feedback; BIS, Body Image Scale; BC, women diagnosed with breast cancer; BPI, Brief Pain Inventory; CAMS-R, Cognitive and Affective Mindfulness Scale-Revised; CBT-I, Cognitive Behavioral Therapy for Insomnia; CERQ, Cognitive Emotion Regulation Questionnaire; CIS, Checklist Individual Strength; C-SOSI, Calgary Symptoms of Stress Inventory; DASS, Depression Anxiety Stress Scale, DBAS, Dysfunctional Beliefs and Attitudes About Sleep Scale; eMBCT, web-based Mindfulness-based Cognitive Therapy; EORTC QLQ-30, European Organization for Research and Treatment quality of life questionnaire-30 Items; FACT-P, Functional Assessment of Cancer Therapy-Prostate; 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; FCRI, Fear of Cancer Recurrence Inventory; 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; B-IPQ, Brief Illness Perception Questionnaire; MAAS, Mindful Attention Awareness Scale; MAX-PC, Memorial Anxiety Scale for Prostate Cancer; MBCR, Mindfulness-based Cancer Recovery; MBCT, Mindfulness-based Cognitive Therapy; MBSR, Mindfulness-based Stress Reduction; MDASI, M.D. Anderson Symptom Inventory; MFSI, Multidimensional Fatigue Scale Inventory; MHC-SF, Mental Health Continuum-Short Form; MOS-SF, Medical Outcomes Studies Short-form General Health Survey; MOS-SS, Medical Outcomes Study Sleep Scale; MOS-SSS Medical Outcomes Study Social Support Survey; MPQ, McGill Pain Questionnaire; NKCA, Natural killer cell lytic activity; PANAS, Positive and Negative Affect Schedule; PGH-10, PROMIS Global Health-10; PHQ, Patient Health Questionnaire; POMS, Profile of Mood States; PSQI, Pittsburgh Sleep Quality Index; PSQW-A, Penn State Worry Questionnaire-Abbreviated; PTGI, Posttraumatic Growth Inventory; RCT, randomized controlled trial; RRS, Ruminative Response Scale; RRQ, Rumination and Reflection Questionnaire; SBC, Scale of Body Connection; SCID, Structured Clinical Interview for DSM-IV-TR Axis I Disorders; 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, WBI, World Health Organization-5 Well-Being Index; WHOQOL-BREF Zung SAS, Zung Self-rating Depression Scale; SDS, Zung Self-rating Depression Scale