

Table 2: Randomized controlled trials of mindfulness for cancer

Source: Cramer H, CAM-Cancer Consortium. Mindfulness [online document]. <https://cam-cancer.org/en/mindfulness-cam>, February 2021.

First author year	Study design	Participants (number, diagnosis)	Interventions (experimental, control)	Main outcome measures	Main results	Comments
Ahmadi-qaragezlou 2020	RCT	110 adult colorectal or breast cancer patients	1. MBSR 2. Control intervention not reported	Fear of cancer recurrence (FCRI)	Short-term effects of MBSR compared to an undefined control intervention on 'Trigger', 'Severity', Psychological distress', 'Coping strategies', 'Dysfunction', 'Reassurance'. No group difference on 'Insight'.	Drop-out rate of 65%, no reasons for drop-out reported, some patients were excluded from analysis. Unclear control intervention. Random sequence generation, allocation concealment, blinding unclear. Unclear which of the FCRI subscales was the primary outcome.
Bagherzad eh 2020	RCT	52 adult women with breast cancer	1. MBSR 2. No intervention	Sexual function (FSFI)	No group differences.	No significant group differences but interpreted as showing effects of MBSR. Random sequence generation, allocation concealment, blinding unclear. Unclear which of the FSFI subscales was the primary outcome.
Black 2017	RCT	57 adult colorectal cancer patients receiving an adjuvant chemotherapy session	1. Mindfulness-meditation practice plus cancer education video during chemotherapy 2. Cancer education video during chemotherapy 3. 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.

Gok Metin 2019	RCT	92 adult women with early breast cancer	<ol style="list-style-type: none"> <li>1. Mindfulness meditation</li> <li>2. Progressive muscle relaxation</li> <li>3. Single-session health education (attention control)</li> </ol>	<p>Primary: Fatigue (BFI) Secondary: Coping (Brief COPE), quality of life (FLIC)</p>	<p>Primary: Short- and medium-term effects of mindfulness meditation compared to attention control on total BF and fatigue severity. No further group differences. Secondary: Short- and medium-term effects of mindfulness meditation compared to attention control on some COPE subscales, no group differences on quality of life.</p>	Allocation concealment unclear.
Gucht, van der 2020	RCT	33 adult women with breast cancer and cognitive impairment	<ol style="list-style-type: none"> <li>1. Mindfulness-based intervention based on MBSR and MBCT</li> <li>2. Wait-list</li> </ol>	<p>Cognitive function (CFQ), neurocognitive assessment, fMRI, distress (DASS), fatigue (CIS fatigue subscale), mindfulness (CHIME) (primary and secondary outcomes not defined).</p>	<p>Stronger improvement in CFQ, DAAS and CIS fatigue in mindfulness group compared to wait-list group. No group differences in neurocognitive assessment. Higher brain connectivity in mindfulness group compared to wait-list group.</p>	Random sequence generation, allocation concealment, blinding unclear.
Hunter 2019	RCT	474 adult cancer patients undergoing chemotherapy	<ol style="list-style-type: none"> <li>1. Single-session mindfulness relaxation prior to chemotherapy</li> <li>2. Single session of relaxation music prior to chemotherapy</li> <li>3. Standard care (same duration of contact)</li> </ol>	<p>Primary: Nausea, emesis (MANE) Secondary: Quality of life (FACT)</p>	<p>Primary: Medium-term effects on nausea. No further group differences. Secondary: No group differences.</p>	Single-session nurse-delivered intervention. More outcomes assessed (including multiple primary outcomes in the trial registry) but not reported (non-reporting was disclosed).
Kubo 2019	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"> <li>1. Mindfulness app</li> <li>2. Wait-list</li> </ol>	<p>Primary: anxiety and depression (HADS) 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 Secondary: Intervention feasible, stronger increase in overall well-being and mental well-being 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.
Kubo 2020	Cluster RCT	104 adults with metastatic solid cancer or hematological cancer	<ol style="list-style-type: none"> <li>1. Mobile-based mindfulness program</li> </ol>	<p>Primary: anxiety, depression (HADS) Secondary: Retention, adherence, patient quality of life (FACIT-Pal), caregiver quality of life (CQOLC),</p>	<p>Primary: Stronger reduction in anxiety but not depression in cancer patients after mindfulness compared to wait list. No group differences in caregivers.</p>	Cluster randomization of 16 hospitals who chose, which mindfulness program was used.

		patients, 39 informal caregivers	2. Webinar-based mindfulness program 3. Waitlist	Distress Thermometer, mindfulness (FFMQ)	Secondary: Stronger improvement in overall well-being, physical well-being and mindfulness in cancer patients after mindfulness compared to wait list. No further group differences. No group differences in caregivers. 68% of patients and 47% practiced at least 50% of days.	Only allocation to mindfulness or waitlist was randomized. Random sequence generation, allocation concealment unclear. 104 patients according to the publication, 142 according to the trial registry. Retention and adherence not in trial registry.
Lee, van der 2010	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 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.
Lehto 2015	RCT	40 patients with non-small cell lung cancer currently undergoing radiation or chemotherapy	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.
Lipschitz 2015	RCT	30 adults with a diagnosis of cancer and sleep disturbances after completion of primary treatment	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.
Mirmahmoodi 2020	RCT	51 adult women with breast cancer	1. MBSR 2. No specific intervention	Primary: depression (BDI), anxiety (BAI), stress (CPSS), C-reactive protein, blood cortisol	Primary: Stronger reduction in anxiety in mindfulness group than in control group. No further group differences.	Allocation concealment unclear. Five primary outcomes without alpha adjustment.
Mohammadi 2018	RCT	40 adult women with breast cancer	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.
Nissen 2019	RCT	137 adult breast cancer and 13 adult prostate cancer patients	<ol style="list-style-type: none"> <li>1. Internet-delivery MBCT</li> <li>2. Wait-list</li> </ol>	<p>Primary: Anxiety (STAI), depression (BDI)</p> <p>Secondary: stress (CPSS), quality of life (WBI), insomnia (ISI)</p>	<p>Primary: Stronger short- and medium-term improvement in anxiety and short-term effects in depression in mindfulness compared to wait-list group.</p> <p>Secondary: Stronger medium-term improvement in well-being in mindfulness compared to wait-list group.</p> <p>No further group differences</p>	<p>Randomisation, allocation concealment unclear.</p> <p>Cost-effectiveness in trial registry but not reported.</p>
Park 2020	RCT	74 adult women with breast cancer	<ol style="list-style-type: none"> <li>1. MBCT</li> <li>2. No specific intervention</li> </ol>	<p>Primary: HADS</p> <p>Secondary: CARS, BFI, FACIT-Sp, FACT-G, FFMQ, adherence, adverse events</p>	<p>Primary: Stronger short- and medium-term improvement in anxiety and depression in MBCT compared to control group.</p> <p>Secondary: Stronger short- and medium-term improvement in all secondary outcomes in MBCT compared to control group. 6.76 out of 8 session attended. No adverse events occurred.</p>	<p>Allocation concealment and blinding unclear.</p>
Pintado 2017	RCT	29 adult women with breast cancer not currently receiving adjuvant treatment	<ol style="list-style-type: none"> <li>1. MBSR</li> <li>2. Personal image advice group</li> </ol>	<p>Body image (BIS), body awareness/dissociation (SBC) (primary and secondary outcomes not defined).</p>	<p>Stronger improvement in body image but not body awareness/dissociation in MBSR than in advice group.</p>	<p>Allocation concealment unclear, no primary outcome defined, safety not reported, different reporting of findings in abstract and main text.</p>
Pouy 2018	RCT	70 patients diagnosed with breast cancer	<ol style="list-style-type: none"> <li>1. Mindfulness-based group training (program unclear)</li> <li>2. Usual care</li> </ol>	<p>Quality of life (WHOQOL-BREF), life expectancy (Schneider's life expectancy questionnaire) distress (DASS) (primary and secondary outcomes not defined).</p>	<p>Stronger improvement in quality of life, life expectancy, depression, anxiety and stress in mindfulness than in usual care.</p>	<p>Randomization used obsolete methods, allocation concealment unclear, no primary outcome defined, statistical analysis unclear, safety not reported.</p>
Price-Blackshear 2020	RCT	117 young adult women with breast cancer and their partners	<ol style="list-style-type: none"> <li>1. Online couples mindfulness-based intervention</li> <li>2. Online individual mindfulness-based intervention</li> </ol>	<p>Primary: CPSS, PROMIS depression, PROMIS, anxiety, MAAS</p> <p>Secondary: DAS, QMI, IMS, feasibility</p>	<p>Group differences not reported.</p>	<p>Random sequence generation, allocation concealment and blinding unclear.</p> <p>Primary and secondary outcomes inconsistent between trial registry and publication. 117 patients according to publication, 130 according to trial registry.</p>

						Online within-group differences reported.
Rosen 2018	RCT	112 adult women diagnosed with breast cancer less than 5 years ago	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.
Victorson 2020	RCT	126 young adult cancer patients	1. MBSR 2. Wait-list	Primary: feasibility and acceptability Secondary: fatigue, sleep disturbances, pain interference, anxiety, depression, social isolation (PROMIS), mindfulness (MAAS), self-compassion (SCS), post-traumatic growth (PTGI)	Primary: 26.5% of eligible participants consented. 72-78% reported mindfulness was logical and useful Secondary: Greater increase in self-kindness in MBSR group compared to wait-list group. No further group differences.	Allocation concealment unclear. Differences in outcomes between trial registry and publication.
Wirth 2019	RCT	36 adults with cancer	1. Mindfulness-based cancer survivorship (adapted from MBSR) 2. Breathing control	Primary: Physical activity, sleep, salivary cortisol, inflammatory markers Secondary: depression (CES-D), mindfulness (MAAS), stress (CPPS), sleep quality (PSQI)	Primary: Worsening of sleep quality in mindfulness group compared to wait-list group. No further group differences. Secondary: No group differences.	Random sequence generation, allocation concealment and blinding unclear. Control intervention inconsistent between trial registry and publication. 16 primary outcomes without alpha adjustment. Cortisol in trial registry but not in publication.
Witek Janusek 2019	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 2019	RCT	70 adult women with cervical cancer and insomnia	1. MBSR 2. No specific intervention	Sleep diary, insomnia (ISI), polysomnography, actigraphy (primary and secondary outcomes not defined).	Greater improvement in total wake time, sleep efficacy, and total sleep time in MBSR compared to no specific intervention. No further group differences.	Random sequence generation, allocation concealment and blinding unclear. Another version of this article was retracted due to an error in the data.

Zhao 2019	RCT	136 adult women with breast cancer and insomnia	<ol style="list-style-type: none"> <li>1. MBCT-I</li> <li>2. Wait-list</li> </ol>	<p>Primary outcome: insomnia (ISI) Secondary: actigraphy, mindfulness (FFMQ)</p>	<p>Primary: Greater short-, medium- and long-term improvement in insomnia in MBCT-I group compared to wait-list group. Secondary: Greater short-, medium- and long-term improvement in wake after sleep onset, total sleep time, sleep efficiency in MBCT-I group compared to wait-list group. Greater short--term improvement in sleep onset latency in MBCT-I group compared to wait-list group.</p>	
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AAF, Web-based Ambulant Activity Feedback; DAI, Beck Anxiety Inventory; BDI, Beck Depression Inventory; 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; CFQ, Cognitive Failure Questionnaire; CHIME, Comprehensive Inventory of Mindfulness Experiences; CIS, Checklist Individual Strength; CPSS, Cohen Perceived Stress Scale; CQOLC, Caregiver Quality of Life Index – Cancer; 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; FACIT-Pal, Functional Assessment of Chronic Illness Therapy – Palliative care; 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; FLIC, Functional Living Index – Cancer; FSFI, Female Sexual Function Index; 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; MANE, Morrow Assessment of Nausea and Emesis, 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; PROMIS, Patient-Reported Outcomes Measurement Information System; 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, World Health Organization-5 Well-Being Index; WHOQOL-BREF Zung SAS, Zung Self-rating Depression Scale; SDS, Zung Self-rating Depression Scale