Table 2: Randomized controlled trials of mindfulness for cancer


<table>
<thead>
<tr>
<th>First author, year, (ref)</th>
<th>Study design</th>
<th>Participants (number, diagnosis)</th>
<th>Interventions (experimental, control)</th>
<th>Main outcome measures</th>
<th>Main results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carlson, 2013 (40)</td>
<td>RCT</td>
<td>271 BC after completion of primary treatment</td>
<td>1. MBCR  2. Supportive-expressive group therapy 3. Stress management seminar</td>
<td>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)</td>
<td>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.</td>
<td>Allocation concealment unclear; outcome assessors only partially blinded; required sample size not reached; safety not reported.</td>
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<tr>
<td>Garland, 2014 (39)</td>
<td>RCT (non-inferiority)</td>
<td>111 adults with non-metastatic cancer after completion of primary treatment</td>
<td>1. MBSR  2. CBT-I</td>
<td>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</td>
<td>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.</td>
<td>Larger attrition in MBSR; safety not reported.</td>
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<tr>
<td>Johannsen, 2016 (41)</td>
<td>RCT</td>
<td>129 BC reporting pain after completion of primary treatment</td>
<td>1. MBCT  2. Usual care</td>
<td>Primary: Pain (MPQ, pain numerical rating scale) Secondary: Well-being (WBI), anxiety and depression (HADS), pain medication use</td>
<td>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</td>
<td>Allocation concealment and blinding unclear; safety not reported.</td>
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<tr>
<td>Johns, 2016 (42)</td>
<td>RCT</td>
<td>71 patients with BC or colorectal cancer with persistent fatigue after completion of primary treatment</td>
<td>1. MBSR  2. Psycho-education and support</td>
<td>Primary: Fatigue (FSI) Secondary: Pain (BPI), insomnia severity (ISI), fatigue global improvement, generalized anxiety disorder (GAD), mental disorders (PHQ)</td>
<td>Primary: No effects of MBSR compared to psychoeducation and support Secondary: Short-term effects on vitality and global improvement, no medium-term effects</td>
<td>Safety not reported.</td>
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<td>Study</td>
<td>Year</td>
<td>Patients</td>
<td>Intervention</td>
<td>Outcomes</td>
<td>Blinding, conflict of interest, and safety not reported.</td>
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<td>Lehto, 2015 (43)</td>
<td>RCT</td>
<td>40 patients with non-small cell lung cancer currently undergoing radiation or chemotherapy</td>
<td>1. Home-based mindfulness therapy plus symptom interview 2. Symptom interview</td>
<td>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)</td>
<td>Blinding, conflict of interest, and safety not reported.</td>
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<td>Lengacher, 2016 (44)</td>
<td>RCT</td>
<td>322 BC after completion of primary treatment</td>
<td>1. MBSR 2. Usual care</td>
<td>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.</td>
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<td>Lipschitz, 2015 (45)</td>
<td>RCT</td>
<td>30 adults with a diagnosis of cancer and sleep disturbances after completion of primary treatment</td>
<td>1. MBSR 2. Mind-body bridging program 3. Sleep hygiene education</td>
<td>Primary: saliva 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.</td>
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<td>Van der Lee, 2010 (38)</td>
<td>RCT</td>
<td>100 severely fatigued adults with a diagnosis of cancer after completion of primary treatment</td>
<td>1. MBCT 2. Usual care</td>
<td>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.</td>
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<td>Victorson, 2016 (46)</td>
<td>RCT</td>
<td>43 adults with prostate cancer on active surveillance</td>
<td>1. MBSR 2. Book on mindfulness</td>
<td>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.</td>
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<tr>
<td>Zernicke, 2014 (47)</td>
<td>RCT</td>
<td>62 adults with a diagnosis of cancer after completion of primary treatment</td>
<td>1. Online MBCR 2. Usual care</td>
<td>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.</td>
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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