

# Best Evidence Summaries of Topics in Mental Healthcare

**BEST in MH** *clinical question-answering service*

## Question

In adults with insomnia, how effective is acceptance and commitment therapy (ACT) or mindfulness, compared to cognitive behavioural therapy (CBT), in improving patient outcomes?

## Clarification of question using *PICO* structure

*Patients:* Adults with insomnia

*Intervention:* Acceptance and commitment therapy (ACT) or mindfulness

*Comparator:* Cognitive behavioural therapy (CBT)

*Outcome:* Improving patient outcomes

## Plain language summary

High quality research is needed into acceptance and commitment therapy or mindfulness therapy compared to cognitive behavioural therapy, in improving symptoms of insomnia.

**Clinical and research implications**

No definite clinical or research implications may be made based on the evidence presented in this BEST summary.

**What does the evidence say?*****Number of included studies/reviews (number of participants)***

One randomised controlled trial (RCT) (Garland et al. 2014) met the inclusion criteria for this BEST summary.

***Main findings***

This non-inferiority trial compared mindfulness-based stress reduction (MBSR) with cognitive behavioural therapy for insomnia (CBT-I) in 111 cancer patients with insomnia. The authors found that MBSR was significantly inferior to CBT-I for improving insomnia severity after eight weeks of treatment, but non-inferior at 5 months' follow-up.

The authors also reported on a number of other outcomes, but did not consistently report statistical between group differences (see data extraction table below). They did, however, report that sleep efficiency (as measured using sleep diaries) was significantly better in the CBT-I group after the programme than in the MBSR group ( $p < 0.001$ ). They also reported that change from baseline differences on measures of sleep quality (using the Pittsburgh Sleep Quality Index), and dysfunctional sleep beliefs (using the Dysfunctional Beliefs and Attitudes About Sleep Scale) were significantly better in the CBT-I group compared to the MBSR group after treatment (between group  $p$  values not reported). Both groups were reported to have similar effects for improving mood and stress symptoms.

***Authors' conclusions***

The authors concluded that "CBT-I remains the treatment of choice for patients with cancer and insomnia."

***Reliability of conclusions/Strength of evidence***

Many aspects of this trial appear to be well-conducted and reported (i.e. method of randomisation, allocation concealment, blinding), and although the authors conducted intention-to-treat analysis, there was a much higher drop-out rate in the MBSR group compared to the CBT-I group (50% vs. 15%). In addition, the authors did not clearly report statistical comparisons for between group differences after the intervention period. They largely reported within group change from baseline differences, and group and time interactions five months *after* the intervention. As such, it is hard to fully interpret all of the results.

**What do guidelines say?**

NICE Guidelines do not comment on acceptance and commitment therapy or mindfulness for the treatment of insomnia.

**Date question received:** 28/06/2016

**Date searches conducted:** 28/06/2016

**Date answer completed:** 13/07/2016

## References

### ***Randomised controlled trials***

Garland, SN., Carlson, LE., Stephens, AJ., Antle, MC., Samuels, C., Campbell, TS. (2014). Mindfulness-Based Stress Reduction Compared with Cognitive Behavioral Therapy for the Treatment of Insomnia Comorbid with Cancer: A Randomised, Partially Blinded, Noninferiority Trial. *Journal of Clinical Oncology*: 32(5), pp449-457.

## Results

### *Randomised controlled trials*

Author (year)	Inclusion criteria	Number of participants	Summary of results	Risk of bias
Garland et al (2014)	<p><b>Participants:</b> Patients were recruited from a tertiary cancer centre in Calgary, Alberta, Canada, if they had completed chemotherapy and radiation treatments at least 1 month before study entry. Participants were required to meet the diagnostic criteria of insomnia, defined as sleep latency or time awake after sleep onset greater than 30 minutes and sleep efficiency of less than 85%, with disturbances occurring 3 or more days per week for at least 1 month and producing significant impairment in functioning.</p> <p><b>Intervention:</b> The MBSR program is delivered to groups of 15 to 20 people over the course of eight, weekly, 90-minute sessions, plus one 6-hour weekend intensive silent retreat, for a total of 18 contact hours.</p> <p><b>Comparator:</b> The CBT-I program was delivered to groups of six to 10 individuals over the course of eight, weekly, 90-</p>	N = 111 (64 to MBSR and 47 to CBT-I)	<p><b>Severity of insomnia:</b> After 8 weeks of treatment, MBSR was found to be inferior to CBT-I for improving insomnia severity (estimate marginal mean: 12.06 [SE 0.61] in MBSR group vs. 8.28 [SE 0.54] in the CBT-I group, p=0.39). At 5 month follow-up, MBSR demonstrated non-inferiority (estimate marginal mean: 11.07 [SE 0.67] in MBSR group vs. 9.05 [0.56] in the CBT-I group, p=0.01).</p> <p><b>Sleep diary and actigraphy assessments:</b> Based on sleep diaries, sleep onset latency (SOL) was 24.0 minutes (SE 2.41) in the CBT-I group and 40.7 (SE 2.68) in the MBSR group after treatment. Wake after sleep onset (WASO) was 36 minutes (SE 3.96) in the CBT-I group and 48.4 (SE 4.30) in the MBSR group. Total sleep time (TST) was 6.48 hours (SE 0.11) in the CBT-I group and 6.37 (SE 0.12) in the MBSR group. Sleep efficiency was 85% (SE 1.08) in the CBT-I group and 78% (SE 1.20) in the MBSR group (p&lt;0.001). Between group tests of significance were not reported (for all outcomes) after the treatment period.</p> <p>Based on actigraphy, SOL was 7.6 minutes (SE 1.25) in the</p>	High (while the authors conducted ITT analysis, there was a high drop-out rate, with a greater number of drop-outs in the MBSR group [50%] compared to the CBT-I group [15%] after treatment)

	<p>minute sessions, for a total of 12 contact hours.</p> <p><b>Outcome:</b> Insomnia Severity – The Insomnia Severity Index (ISI).</p> <p>Sleep Quality: subjective – A sleep diary was used to calculate subjective reports of sleep efficiency, sleep onset latency, wake after sleep onset and total sleep time.</p> <p>Sleep Quality: objective – The GT1M actigraph.</p> <p>Psychological Outcomes – The Calgary Symptoms of Stress Inventory is a 56-item measure of physical, psychological, and behavioural responses to stressful situations.</p>		<p>CBT-I group and 14.16 (SE 1.41) in the MBSR group. WASO was 83.6 minutes (SE 4.30) in the CBT-I group and 97.1 (SE 4.85) in the MBSR group. TST was 376.6 minutes (SE 5.46) in the CBT-I group and 393.03 (SE 6.17) in the MBSR group. Sleep efficiency was 82% (SE 0.81) in the CBT-I group and 79% (SE 0.92) in the MBSR group. Between group tests of significance were not reported after the treatment period.</p> <p><b>Sleep quality, sleep beliefs, symptoms of stress, and mood disturbances:</b></p> <p>Insomnia severity index (ISI) total score was 8.28 (SE 0.54) in the CBT-I group and 12.06 (SE 0.61) in the MBSR group. Pittsburgh Sleep Quality Index (PSQI) total score was 7.19 (SE 0.32) in the CBT-I group and 10.93 (SE 0.36) in the MBSR group. Calgary Symptoms of Stress Inventory (C-SOSI) was 49.04 (SE 2.05) in the CBT-I group and 53.54 (SE 2.31) in the MBSR group. Profile of Mood States-Short Form (POMS-SF) was 12.22 (SE 2.17) in the CBT-I group and 16.52 (SE 2.45) in the MBSR group. Dysfunctional Beliefs and Attitudes About Sleep Scale (DBAS-16) total score was 2.96 (SE 0.16) in the CBT-I group and 4.61 (SE 0.19) in the MBSR group. Between group tests of significance were not reported after the treatment period.</p> <p>Data were also reported at 5 months' follow-up, but have not been extracted.</p>	
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**Risk of bias*****Randomised controlled trials***

Study	RISK OF BIAS					
	Random allocation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective Reporting
Garland et al (2014)						

 Low risk High risk Unclear risk

## Search details

Source	Search Strategy	Number of hits	Relevant evidence identified
<i>Guidelines</i>			
NICE	Acceptance and commitment therapy Insomnia	0	
MEDLINE	19. Medline; (insomnia).ti,ab; 14194 results. 20. Medline; ((sleep* adj2 (disorder* OR disease* OR condition* OR problem* OR issue*))).ti,ab; 24623 results. 21. Medline; ((sleepless* OR wakeful* OR dyssomn*)).ti,ab; 10432 results. 23. Medline; exp ACCEPTANCE AND COMMITMENT THERAPY/; 111 results. 24. Medline; exp MINDFULNESS/; 841 results. 25. Medline; ((acceptance* adj2 (commitment* adj2 (therap*))).ti,ab; 388 results. 26. Medline; ACT.ti,ab; 207254 results. 27. Medline; (mindful*).ti,ab; 4307 results. 28. Medline; ((accept* adj3 therap*)).ti,ab; 6016 results. 29. Medline; exp SLEEP INITIATION AND MAINTENANCE DISORDERS/; 10129 results. 30. Medline; exp SLEEP/ OR exp SLEEP DEPRIVATION/; 66003 results. 31. Medline; 19 OR 20 OR 21 OR 29 OR 30; 99154 results. 32. Medline; 23 OR 24 OR 25 OR 26 OR 27 OR 28; 217194 results. 33. Medline; 31 AND 32; 867 results. 34. Medline; 33 [Limit to: (Document type Clinical Trial or Controlled Clinical Trial or Meta-analysis or Randomized Controlled Trial or Review)]; 326 results.	326	
EMBASE	1. EMBASE; exp INSOMNIA/; 50495 results. 3. EMBASE; exp SLEEP/ OR exp SLEEP DEPRIVATION/ OR exp SLEEP DISORDER/; 254860 results. 4. EMBASE; (insomnia).ti,ab; 24166 results. 5. EMBASE; ((sleep* adj2 (disorder* OR disease* OR condition* OR problem* OR issue*))).ti,ab; 36176 results. 6. EMBASE; ((sleepless* OR wakeful* OR dyssomn*)).ti,ab; 14001 results. 7. EMBASE; 1 OR 3 OR 4 OR 5 OR 6; 264867 results. 8. EMBASE; exp ACCEPTANCE AND COMMITMENT THERAPY/; 578 results.	34	

	<p>9. EMBASE; exp MINDFULNESS/; 2333 results.</p> <p>10. EMBASE; ((acceptance* adj2 (commitment* adj2 (therap*)))) .ti,ab; 649 results.</p> <p>11. EMBASE; ACT.ti,ab; 246456 results.</p> <p>12. EMBASE; (mindful*).ti,ab; 6233 results.</p> <p>13. EMBASE; ((accept* adj3 therap*).ti,ab; 6663 results.</p> <p>14. EMBASE; 8 OR 9 OR 10 OR 11 OR 12 OR 13; 259037 results.</p> <p>15. EMBASE; 7 AND 14; 2674 results.</p> <p>16. EMBASE; 15 [Limit to: (EBM-Evidence Based Medicine Evidence Based Medicine or Meta Analysis or Systematic Review) and (Clinical Trials Clinical Trial or Randomized Controlled Trial or Controlled Clinical Trial)]; 34 results.</p>		
PsycINFO/CINAHL	<p>35. PsycInfo; exp INSOMNIA/; 4814 results.</p> <p>37. PsycInfo; (insomnia).ti,ab; 9125 results.</p> <p>38. PsycInfo; ((sleep* adj2 (disorder* OR disease* OR condition* OR problem* OR issue*))) .ti,ab; 11949 results.</p> <p>39. PsycInfo; ((sleepless* OR wakeful* OR dyssomn*)) .ti,ab; 5529 results.</p> <p>41. PsycInfo; exp ACCEPTANCE AND COMMITMENT THERAPY/; 1047 results.</p> <p>42. PsycInfo; exp MINDFULNESS/; 5632 results.</p> <p>43. PsycInfo; ((acceptance* adj2 (commitment* adj2 (therap*)))) .ti,ab; 1154 results.</p> <p>44. PsycInfo; ACT.ti,ab; 59406 results.</p> <p>45. PsycInfo; (mindful*).ti,ab; 8827 results.</p> <p>46. PsycInfo; ((accept* adj3 therap*).ti,ab; 2601 results.</p> <p>48. PsycInfo; exp SLEEP/ OR exp SLEEP DEPRIVATION/ OR exp SLEEP DISORDERS/; 33266 results.</p> <p>49. PsycInfo; 35 OR 37 OR 38 OR 39 OR 48; 42328 results.</p> <p>50. PsycInfo; 41 OR 42 OR 43 OR 44 OR 45 OR 46; 69628 results.</p> <p>51. PsycInfo; 49 AND 50; 467 results.</p> <p>52. PsycInfo; 51 [Limit to: (Methodology Meta Analysis or Systematic Review or Treatment Outcome/Clinical Trial)]; 24 results.</p>	24	
CENTRAL	<p>#1 MeSH descriptor: [Sleep Initiation and Maintenance Disorders] explode all trees 1457</p> <p>#2 MeSH descriptor: [Sleep] explode all trees 4522</p> <p>#3 MeSH descriptor: [Sleep Wake Disorders] explode all trees 5065</p> <p>#4 MeSH descriptor: [Sleep Deprivation] explode all trees 494</p> <p>#5 (insomnia) .ab,ti. 79</p> <p>#6 (sleep* adj2 (disorder* or disease* or condition* or problem* or issue*)) .ab,ti. 41</p>	79	

#7	(sleepless* or wakeful* or dyssomn*) .ab,ti.	26		
#8	#1 or #2 or #3 or #4 or #5 or #6 or #7	8027		
#9	MeSH descriptor: [Acceptance and Commitment Therapy] explode all trees	39		
#10	MeSH descriptor: [Mindfulness] explode all trees	212		
#11	(acceptance* adj2 (commitment* adj2 (therap*))) .ab,ti.	7		
#12	(ACT) .ab,ti.	205		
#13	(mindful*) .ab,ti.	30		
#14	(accept* adj3 therap*) .ab,ti.	292		
#15	#9 or #10 or #11 or #12 or #13 or #14	684		
#16	#8 and #15	79		

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