Cognitive Behavioral Therapy for Menopausal Insomnia

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Insomnia in Menopause

• 30-60% midlife women suffer from insomnia symptoms\(^1,2\)
• Hot flashes frequently (but not always) awaken women from sleep\(^3,4\)
• Consequences of menopausal insomnia include:
  ↑ healthcare utilization & costs\(^5\)
  ↑ disability\(^5\)
  ↑ risk of medical and psychiatric conditions (e.g., CVD, depression)\(^6\)
  ↓ quality of life\(^7\)
• Tailoring interventions to treat both insomnia and hot flashes may improve sleep and quality of life in midlife women

Objective

To preliminarily examine the efficacy of cognitive behavioral therapy (CBT) for menopausal insomnia in a pilot study compared to menopause education control in midlife women.
What is Cognitive Behavioral Therapy (CBT) for Menopausal Insomnia?

Combine CBT for Insomnia & CBT for Hot Flashes

Behaviors:
- A set of instructions for changing behaviors that are incongruent with good sleep or ability to cope with hot flashes

Cognitions:
- Address thoughts related to sleep and hot flashes that
  - interfere with good sleep
  - increase hot flash bother
- Reduce suffering (hope, realistic expectation, acceptance)
## CBTMI Components

<table>
<thead>
<tr>
<th>Technique</th>
<th>Aim</th>
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<tbody>
<tr>
<td>Sleep restriction</td>
<td>Restrict time in bed to improve sleep depth &amp; consolidation</td>
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<tr>
<td>Stimulus control</td>
<td>In bed only when asleep to strengthen bed/bedroom as sleep stimulus</td>
</tr>
<tr>
<td>Cognitive therapy</td>
<td>Address maladaptive beliefs about sleep &amp; hot flashes</td>
</tr>
<tr>
<td>Sleep hygiene &amp;</td>
<td>Promote habits that help sleep &amp; hot flashes</td>
</tr>
<tr>
<td>Hot flash coping</td>
<td>eliminate bad habits &amp; hot flash triggers</td>
</tr>
<tr>
<td>Relaxation training</td>
<td>Reduce physical/psychological arousal</td>
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</table>
Menopause Education Control (MEC)

• A single 50-minute session
  • Introduced as self-help intervention
  • Educational Handouts

• Discuss menopausal symptoms & sleep hygiene
Procedures

Study Duration = 20 weeks

- **Week 1-2**: Screen Survey PSG*
- **Week 3-10**: S1, S2, S3, S4
- **Week 11-12**: Survey PSG
- **Follow-Up Month 1**: Online Survey
- **Follow-Up Month 3**: Online Survey

*PSG = polysomnography
S = session
Inclusion-Exclusion Criteria

Inclusion criteria
- peri/post women; (STRAW +10 criteria)
- Insomnia disorder diagnosis (DSM-5)
- ISI>10 or PSQI>8
- ≥ 1 nocturnal hot flash/night

Exclusion criteria
- Surgical or chemotherapy/radiation-induced menopause
- Cognitive impairment
- Psychotic disorder, substance use disorder, bipolar disorder
- Recent initiation/change in treatments that may impact sleep or HF
- As needed use of medications or herbs that may affect sleep or HF
- Comorbid sleep disorders [PLMI > 15; OSA (AHI > 15)]

Insomnia Disorder Diagnostic Criteria
- Predominant complaint of dissatisfaction with sleep quantity or quality associated with (≥ 1 symptom):
  1. Difficulty initiating sleep
  2. Difficulty maintaining sleep (frequent awakenings or problems returning to sleep after awakenings)
  3. Early-morning awakening with inability to return to sleep
- Causes significant distress or impairment in functioning.
- Occurs despite adequate opportunity to sleep
- ≥ 3 nights / week  ≥ 3 months
Sleep Measurements

**Insomnia Severity Index**
- 7 item validated self-report scale to assess insomnia
- $\geq 10$ = detect insomnia
- -8.4 point change score = moderate improvement

**Actigraphy**
- Wrist-worn device to objectively measure sleep

**Daily Sleep Diary**
- 7-day diary modeled after Consensus Sleep Diary\(^1\) (9 items)

**Sleep Efficiency**

$$\text{Total Sleep Time} \times 100$$
$$\text{Time in Bed}$$

E.g., if a woman spends 8 hours in bed in a given evening, but only actually sleeps for 4 of those hours, her sleep efficiency for that evening would be 50%

**Wake After Sleep Onset**
- Amount of time an individual is awake during the night after she falls asleep

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\(^1\) Carney et al., 2012. *SLEEP*, 35(2), 287-302.
## Baseline Characteristics (N=40)

<table>
<thead>
<tr>
<th>Measure</th>
<th>CBT-I</th>
<th>MEC</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, M (SD)</td>
<td>53 (5.2)</td>
<td>56 (7.1)</td>
<td>.10</td>
</tr>
<tr>
<td><strong>Race/ethnicity, N (%) nonwhite</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity, N (%) nonwhite</td>
<td>12 (63)</td>
<td>5 (25)</td>
<td>.04</td>
</tr>
<tr>
<td>Menopause stage, N (%) peri</td>
<td>6 (30)</td>
<td>8 (40)</td>
<td>.68</td>
</tr>
<tr>
<td>Sleep hot flashes/night (self-report), M (SD)</td>
<td>1.7 (1.2)</td>
<td>1.4 (.4)</td>
<td>.52</td>
</tr>
<tr>
<td>Insomnia Severity Index, M (SD)</td>
<td>15 (3.4)</td>
<td>16 (4.3)</td>
<td>.59</td>
</tr>
<tr>
<td><strong>Sleep Diary</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep Efficiency %, M (SD)</td>
<td>79 (12.2)</td>
<td>84 (9.3)</td>
<td>.20</td>
</tr>
<tr>
<td>Wake After Sleep Onset mins, M (SD)</td>
<td>38 (21.0)</td>
<td>30 (28.8)</td>
<td>.34</td>
</tr>
<tr>
<td><strong>Actigraphy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep Efficiency %, M (SD)</td>
<td>85 (4.1)</td>
<td>85 (4.8)</td>
<td>.96</td>
</tr>
<tr>
<td>Wake After Sleep Onset mins, M (SD)</td>
<td>42 (11.8)</td>
<td>44 (15.0)</td>
<td>.77</td>
</tr>
</tbody>
</table>
**Insomnia Severity Index**

![Graph showing the Insomnia Severity Index over time with error bars. The graph compares two conditions: MEC Control and CBTM Intervention. The table to the right lists the effects and their corresponding p-values: Time (0.001), Condition (0.007), and Interaction (0.003). Error Bars: 95% CI.
**Sleep Efficiency**

**Sleep Diary**

- Time: $p = .002$
- Condition: $p = .017$
- Interaction: $p = .01$

**Actigraphy**

- Condition: $p = .006$
- Interaction: $p < .001$

Error Bars: 95% CI
Time Awake After Sleep Onset

Sleep Diary

- Time: p = .007
- Condition: p = .05
- Interaction: p = .005

Actigraphy

- Time: p = .013
- Condition: p = .009
- Interaction: p < .001

Error Bars: 95% CI
Similar Outcomes

**McCurry et al 2016**

**Treatments**

- **Telephone-based CBT-I MsFlash**
  - 106 peri-/post-menopausal women (age 40-65)
  - ISI ≥12 & ≥2 daily hot flashes

- **CBT-I**: 6 telephone sessions in 8 weeks

- **MEC**: 6 telephone sessions - information about menopause and women’s health

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**Current study**

- **Condition**
  - MEC Control
  - CBT-I Intervention

**Graph**

- **Insomnia Severity Index**
- **Baseline**
- **Post-Tx**
- **Month 1**
- **Month 3**

**Error Bars**: 95% CI
Summary

For midlife women experiencing insomnia and hot flashes, cognitive behavioral therapy for menopausal insomnia led to clinically meaningful improvements

1. insomnia severity
2. sleep efficiency (actigraphy & sleep diary)
3. time awake after sleep onset (actigraphy & sleep diary)
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