Influence of Cognitive Behavioral Therapy for Insomnia (CBT-I) on Quality of Life (QOL) in Cancer Survivors

Anita R. Peoples


1University of Rochester Medical Center, Rochester, NY, USA
2Memorial University, Newfoundland, Canada
Quality of life (QOL)

- Sleep disturbances: 30-60% of cancer patients

- Poor sleep quality can have detrimental effects on QOL
  - prognostic factor for survival

- Interventions improving sleep quality may improve associated QOL

(Roscoe JA et al. 2015; Montazeri A 2009)
Aims

• In cancer patients following the completion of chemotherapy and/or radiotherapy:
  
  □ To examine whether CBT-I treatments for cancer survivors improve QOL

  □ To examine the potential mechanism of improvement in QOL via CBT-I
Original Study

- 4-Arm RCT study examining CBT-I and armodafinil efficacy in cancer survivors with chronic insomnia:
  - participants must have completed all treatments
  - be considered in remission
  - had any diagnosis of cancer
Study Interventions

• Cognitive Behavioral Therapy for Insomnia (CBT-I):
  – Sleep restriction, stimulus control, cognitive restructuring, and sleep hygiene instructions
  – 7-week intervention

• Armodafinil:
  – wakefulness promoting agent (50 mg b.i.d)

(Perlis ML, et al., 2005; Sharma MP, et al., 2012; Mitchell MD, et al., 2012)
## CBT-I (Yes/No)

<table>
<thead>
<tr>
<th>Arm 1</th>
<th>Arm 2</th>
<th>Arm 3</th>
<th>Arm 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBT-I + Placebo</td>
<td>CBT-I + Armodafinil</td>
<td>Placebo</td>
<td>Armodafinil</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Event</th>
<th>Arm Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBT-I</td>
<td>CBT-I (N=36)</td>
</tr>
<tr>
<td></td>
<td>CBT-I + Placebo or Armodafinil</td>
</tr>
<tr>
<td>No CBT-I</td>
<td>No CBT-I (N=33)</td>
</tr>
<tr>
<td></td>
<td>Placebo or Armodafinil</td>
</tr>
</tbody>
</table>
## Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total Sample (N=69)</th>
<th>CBT-I (N=36)</th>
<th>No CBT-I (N=33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>56 (9.7)</td>
<td>57 (9.7)</td>
<td>55 (9.9)</td>
</tr>
<tr>
<td>Male</td>
<td>10%</td>
<td>8%</td>
<td>12%</td>
</tr>
<tr>
<td>Female</td>
<td>90%</td>
<td>92%</td>
<td>88%</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>70%</td>
<td>72%</td>
<td>67%</td>
</tr>
<tr>
<td>Other Cancers</td>
<td>30%</td>
<td>28%</td>
<td>33%</td>
</tr>
</tbody>
</table>
Aim 1 – Measures & Analysis

• QOL – assessed by Functional Assessment of Cancer Therapy-General (FACT-G):
  – 0-108 scale ⇒ higher is better

• ANCOVA controlling for baseline scores:
  – post-intervention QOL score
  – follow-up QOL score
QOL (FACT-G)

- **N = 69**
- **CBT-I**
- **No CBT-I**

- **Mean (post) = 90.6**
- **Mean (follow-up) = 92.8**
- **P < 0.0001**
- **Mean (post) = 78.7**
- **Mean (follow-up) = 78.3**
- **Post-Intervention**

**Number of days from providing consent**

**Total score (higher is better)**

- 70
- 75
- 80
- 85
- 90
- 95
- 100
Aim 2 – Measures & Analysis

• Sleep Quality assessed by:
  ▪ Pittsburgh Sleep Quality Inventory (PSQI)
    – \( \leq 5 \) on a scale of 0-21 \( \Rightarrow \) good sleep quality
  ▪ Sleep Diary (SD)
    – 1-4 scale \( \Rightarrow \) higher is better

• Pearson correlations – QOL and sleep quality

• Path analysis was performed using SEM
Pearson Correlations

• Changes in QOL from baseline were significantly correlated with concurrent changes in sleep quality:
  
  – PSQI: both r’s ≈ 0.40-0.41 (both p’s=0.001)
  
  – SD: both r’s ≈ 0.31-0.49 (both p’s≤0.012)
Sleep Quality (PSQI)

N=69

Total score (lower is better)

Number of days from providing consent

Pre-intervention

7-Week Intervention

Post-intervention

Follow-up

Mean (post) = 9.1

P < 0.0001

Mean (post) = 4.5

Mean (follow-up) = 9.6

Mean (follow-up) = 4.1

> 5 ⇒ Poor sleep quality

≤ 5 ⇒ Good sleep quality

Sleep Quality (PSQI):

Total score (lower is better)

N=69

Number of days from providing consent

Pre-intervention

7-Week Intervention

Post-intervention

Follow-up

Mean (post) = 9.1

P < 0.0001

Mean (post) = 4.5

Mean (follow-up) = 9.6

Mean (follow-up) = 4.1

> 5 ⇒ Poor sleep quality

≤ 5 ⇒ Good sleep quality
Sleep Quality (Sleep Diary)

- CBT-I
- No CBT-I

Pre-intervention

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Post-intervention</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-Week</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Number of days from providing consent

Total score (higher is better)

- Mean (post) = 2.8
- Mean (follow-up) = 2.8
- P < 0.0001

- Mean (post) = 2.2
- Mean (follow-up) = 2.2
- P < 0.0001

N=69
Effects of CBT-I & Sleep Quality on QOL

- Baseline PSQI to Post-PSQI: 0.26 (p=0.028)
- CBT-I (Yes/No) to Post-PSQI: -4.34 (p<0.0001)
- Post-PSQI to Post-QOL: 4.66 (p=0.005)
- Baseline QOL to Post-QOL: -1.07 (p=0.001)
- CBT-I (Yes/No) to Post-QOL: 4.81 (p=0.047)

0.69 (p<0.0001)
Conclusions

- CBT-I resulted in clinically significant improvement in QOL.

- This improvement remained stable even 3 months after the completion of CBT-I.

- Changes in QOL over time were strongly associated with concurrent changes in sleep quality.

- Improvement in QOL due to CBT-I was partially mediated through improvement in sleep quality.
Acknowledgements

• Joseph A. Roscoe, PhD
• Charles E. Heckler, PhD, MS
• Sheila N. Garland, PhD
• Charles S. Kamen, PhD, MPH
• Luke J. Peppone, PhD, MPH
• Michelle C. Janselsins, PhD, MPH
• Karen M. Mustian, PhD, MPH
• Gary R. Morrow, PhD, MS

Funding: NCI Grants R01 CA126968, UG1CA189961 and R25 CA10618

Study medication: Provided by Teva Pharmaceuticals, USA

Clinical trials information: NCT01091974
Thank you!