

## Tabulation included studies general population

De Bruin 2015, de Bruin 2018, de Bruin 2016, de Bruin 2020

|              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |          |          |             |          |             |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|----------|-------------|----------|-------------|
| Study aim    | To investigate the efficacy of cognitive behavioral therapy for insomnia (CBTI) in adolescents                                                                                                                                                                                                                                                                                                                                                                                                                                                            |          |          |             |          |             |
| Method       | <b>Design:</b> Parallel group RCT with three arms: CBTi in group therapy (GT), CBTi in guided internet therapy (IT), and a waiting list (WL) group                                                                                                                                                                                                                                                                                                                                                                                                        |          |          |             |          |             |
|              | <b>Country:</b> The Netherlands                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |          |          |             |          |             |
|              | <b>Setting:</b> Community                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |          |          |             |          |             |
| Participants | <b>Sample size:</b> 116 (38 in group therapy, 39 in internet therapy, 39 in waitlist)                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |          |          |             |          |             |
|              | <b>Population:</b> Adolescents aged 12-19 yrs<br><b>Age:</b> Mean age 15.6 yrs (SD 1.6 yrs)<br><b>Genders:</b> 25% males<br><b>Sleep disorder:</b> meeting the diagnostic criteria of the DSM-IV for primary insomnia                                                                                                                                                                                                                                                                                                                                     |          |          |             |          |             |
|              | <b>Follow-up time:</b> Post, 2 months, 6 months, 12 months. No 6 and 12 month follow up for waitlist group.                                                                                                                                                                                                                                                                                                                                                                                                                                               |          |          |             |          |             |
|              | <b>Dropouts:</b> GT: 1 participant completed only 4 sessions, and 2 completed 5 sessions. All other participants completed all 6 sessions. IT: 1 opened only 4 sessions and all others opened all 6 sessions. GT: 97.4% of participants provided post and 2 month, 55.3% 6 month and 47.4% provided follow-up measurements. IT: 97.4% provided post, 82.1% provided 2 month, 59% 6 month and 43.6% provided 12 month follow-up measurements. WL: 97.4% provided post and 90% provided follow-up measurements. Attrition too high at 6 and 12 m follow-up. |          |          |             |          |             |
| Intervention | <b>Intervention:</b> GT and IT received 6 weekly sessions of CBT; GT in 1.5 hr sessions in groups of 6-8 participants while IT could log on to a website where at a fixed time of day once a week, a consult was made available with exercises, movies, questionnaires, automated feedback, and personalized bedtime advice and written feedback. Booster session after 2 m.                                                                                                                                                                              |          |          |             |          |             |
| Outcomes     | <b>Outcome measures:</b><br>1. TST<br>2. SOL<br>3. SE<br>5. Night awakenings (WASO) (only post and 2 m)<br>6. Quality of life (EQ-5D; only post and 2 m)<br>7b. Anxiety and depression (YSR subscale anxiety)                                                                                                                                                                                                                                                                                                                                             |          |          |             |          |             |
| Results      | Multilevel regression analysis, adjusting for missing data. Results reported as Cohen's d. Effect sizes calculated as changes from baseline. Mean (SD)                                                                                                                                                                                                                                                                                                                                                                                                    |          |          |             |          |             |
|              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | base     | post     | Effect size | 2 m      | Effect size |
|              | 1 TST                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |          |          |             |          |             |
|              | WL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 421 (73) | 413 (86) | -0.09       | 401 (70) | -0.26       |
|              | IT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 418 (73) | 436 (66) | 0.24        | 427 (56) | 0.13        |
|              | GT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 409 (69) | 415 (79) | 0.08        | 417 (75) | 0.10        |

|  |              |                                                                                                                                                                                                                                                                  |                |                |             |              |      |      |
|--|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------|-------------|--------------|------|------|
|  | 2 SOL        |                                                                                                                                                                                                                                                                  |                |                |             |              |      |      |
|  | WL           | 44 (30)                                                                                                                                                                                                                                                          | 48 (33)        | 0.12           | 41 (25)     | -0.10        |      |      |
|  | IT           | 39 (24)                                                                                                                                                                                                                                                          | 20 (15)        | -0.89          | 18 (15)     | -0.96        |      |      |
|  | GT           | 47 (31)                                                                                                                                                                                                                                                          | 25 (24)        | -0.75          | 18 (14)     | -1.13        |      |      |
|  | 3 SE         |                                                                                                                                                                                                                                                                  |                |                |             |              |      |      |
|  | WL           | 76.1 (7.3)                                                                                                                                                                                                                                                       | 74.6 (8.7)     | -0.18          | 75.7 (5.9)  | -0.06        |      |      |
|  | IT           | 76.5 (6.3)                                                                                                                                                                                                                                                       | 82.5 (5.3)     | 0.96           | 82.7 (5.0)  | 1.00         |      |      |
|  | GT           | 75.6 (8.0)                                                                                                                                                                                                                                                       | 80.8 (6.7)     | 0.67           | 81.9 (5.9)  | 0.84         |      |      |
|  | 5 WASO       |                                                                                                                                                                                                                                                                  |                |                |             |              |      |      |
|  | WL           | 78 (33)                                                                                                                                                                                                                                                          | 80 (38)        | 0.05           | 80 (30)     | 0.06         |      |      |
|  | IT           | 74 (29)                                                                                                                                                                                                                                                          | 73 (29)        | -0.05          | 72 (25)     | -0.06        |      |      |
|  | GT           | 77 (30)                                                                                                                                                                                                                                                          | 70 (26)        | -0.26          | 71 (26)     | -0.24        |      |      |
|  | 7b Anxiety   |                                                                                                                                                                                                                                                                  |                |                |             |              |      |      |
|  | WL           | 4.15 (2.11)                                                                                                                                                                                                                                                      | 3.92 (2.07)    | -0.10          | 4.06 (2.19) | -0.04        |      |      |
|  | IT           | 3.85 (2.05)                                                                                                                                                                                                                                                      | 2.59 (1.82)    | -0.62          | 2.42 (1.50) | -0.75        |      |      |
|  | GT           | 3.45 (2.10)                                                                                                                                                                                                                                                      | 2.86 (1.93)    | -0.28          | 2.79 (1.81) | -0.32        |      |      |
|  |              |                                                                                                                                                                                                                                                                  |                |                |             |              |      |      |
|  | 6 QoL        |                                                                                                                                                                                                                                                                  |                |                |             |              |      |      |
|  |              |                                                                                                                                                                                                                                                                  |                |                |             | Diff IT - GT |      |      |
|  |              | base                                                                                                                                                                                                                                                             | post           | 2 m            |             | base         | post | 2 m  |
|  | IT           | 0.83<br>(0.20)                                                                                                                                                                                                                                                   | 0.88<br>(0.16) | 0.93<br>(0.07) |             | -0.03        | 0.00 | 0.02 |
|  | GT           | 0.86<br>(0.15)                                                                                                                                                                                                                                                   | 0.88<br>(0.17) | 0.91<br>(0.13) |             |              |      |      |
|  | Risk of bias | Some concerns                                                                                                                                                                                                                                                    |                |                |             |              |      |      |
|  | Comments     | Economic evaluation in de Bruin 2016. Some differences in reported results between studies; de Bruin 2018 chosen for data. Also 6 and 12 month data reported, but too few participants.de Bruin 2020 contains complementary data on effects of components in IT. |                |                |             |              |      |      |

### Blake 2016, Blake 2017

|              |                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study aim    | To investigate the post intervention effects of a cognitive–behavioral/mindfulness-based group sleep intervention on sleep and mental health among at-risk adolescents                                                                                                                                                                                                                                        |
| Method       | <b>Design:</b> RCT with control group receiving alternative study-skills intervention                                                                                                                                                                                                                                                                                                                         |
|              | <b>Country:</b> Australia                                                                                                                                                                                                                                                                                                                                                                                     |
|              | <b>Setting:</b> School screening                                                                                                                                                                                                                                                                                                                                                                              |
| Participants | <b>Sample size:</b> 123 (60 in sleep intervention, 63 in control group)                                                                                                                                                                                                                                                                                                                                       |
|              | <b>Population:</b> Adolescents 12-17 yrs at risk for Major Depressive Disorder; based on high anxiety according to Spence Children's Anxiety Scale ([SCAS] Total Score >32 for males and >38 for females<br><b>Age:</b> mean 14.48 yrs (SD 0.95 yrs)<br><b>Genders:</b> Boys 40%<br><b>Sleep disorder:</b> Likely presence of sleep problems, based on Pittsburgh Sleep Quality Index ([PSQI] Global Score >4 |
|              | <b>Follow-up time:</b> Post intervention (1 w)                                                                                                                                                                                                                                                                                                                                                                |

|              | <b>Dropouts:</b> Modified ITT; randomized nonattenders (n=20) excluded. 5 participants did not complete at least 4/7 intervention sessions (Sleep SENSE=4, Study SENSE=1) and were classified as noncompleters and included in analyses. Missing data (4.75%) imputed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |       |             |       |             |       |             |       |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------------|-------|-------------|-------|-------------|-------|--|--|--|-----|----|------|----|-----|----|------|----|---|--------|-------|--------|-------|--------|-------|--------|-------|---|-------|-------|-------|-------|-------|-------|-------|-------|---|-------|------|-------|------|-------|------|-------|------|---|------|------|------|------|------|------|------|------|---|-------|-------|-------|-------|-------|-------|-------|-------|---------|-------|-------|-------|-------|-------|-------|-------|-------|----------|-------|------|-------|------|-------|------|-------|------|
| Intervention | <b>Intervention:</b> 7 90-min-long cognitive-behavioral and mindfulness-based group sleep sessions delivered over 7 weeks, including workbook and home tasks (Sleep SENSE)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |       |             |       |             |       |             |       |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
|              | <b>Control:</b> Active control condition: group sessions on study skills educational program (Study SENSE).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |       |             |       |             |       |             |       |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| Outcomes     | <b>Outcome measures:</b><br>1. TST<br>2. SOL<br>3. SE<br>4 Sleep quality (PSQI global)<br>5. Night awakenings (WASO)<br>7b. Anxiety and depression                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |       |             |       |             |       |             |       |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| Results      | <div>Results reported as means.</div> <table><tr><th></th><th colspan="4">Sleep SENSE</th><th colspan="4">Study SENSE</th></tr><tr><th></th><th>pre</th><th>sd</th><th>post</th><th>sd</th><th>pre</th><th>sd</th><th>post</th><th>sd</th></tr><tr><td>1</td><td>423.64</td><td>45.43</td><td>427.34</td><td>38.46</td><td>409.23</td><td>40.17</td><td>416.85</td><td>34.55</td></tr><tr><td>2</td><td>27.97</td><td>18.08</td><td>21.71</td><td>13.62</td><td>28.00</td><td>21.81</td><td>33.12</td><td>24.36</td></tr><tr><td>3</td><td>79.50</td><td>6.04</td><td>79.83</td><td>5.54</td><td>78.93</td><td>6.91</td><td>78.24</td><td>6.68</td></tr><tr><td>4</td><td>6.23</td><td>2.51</td><td>4.79</td><td>1.97</td><td>6.39</td><td>2.83</td><td>5.93</td><td>2.32</td></tr><tr><td>5</td><td>60.51</td><td>19.57</td><td>64.69</td><td>21.21</td><td>61.92</td><td>22.12</td><td>61.56</td><td>21.29</td></tr><tr><td>7b SCAS</td><td>35.37</td><td>13.73</td><td>29.70</td><td>12.53</td><td>30.66</td><td>11.49</td><td>29.59</td><td>13.88</td></tr><tr><td>7b CES-D</td><td>16.19</td><td>9.80</td><td>13.65</td><td>8.44</td><td>15.32</td><td>8.62</td><td>14.60</td><td>8.01</td></tr></table> |       | Sleep SENSE |       |             |       | Study SENSE |       |  |  |  | pre | sd | post | sd | pre | sd | post | sd | 1 | 423.64 | 45.43 | 427.34 | 38.46 | 409.23 | 40.17 | 416.85 | 34.55 | 2 | 27.97 | 18.08 | 21.71 | 13.62 | 28.00 | 21.81 | 33.12 | 24.36 | 3 | 79.50 | 6.04 | 79.83 | 5.54 | 78.93 | 6.91 | 78.24 | 6.68 | 4 | 6.23 | 2.51 | 4.79 | 1.97 | 6.39 | 2.83 | 5.93 | 2.32 | 5 | 60.51 | 19.57 | 64.69 | 21.21 | 61.92 | 22.12 | 61.56 | 21.29 | 7b SCAS | 35.37 | 13.73 | 29.70 | 12.53 | 30.66 | 11.49 | 29.59 | 13.88 | 7b CES-D | 16.19 | 9.80 | 13.65 | 8.44 | 15.32 | 8.62 | 14.60 | 8.01 |
|              | Sleep SENSE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |       |             |       | Study SENSE |       |             |       |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
|              | pre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | sd    | post        | sd    | pre         | sd    | post        | sd    |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| 1            | 423.64                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 45.43 | 427.34      | 38.46 | 409.23      | 40.17 | 416.85      | 34.55 |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| 2            | 27.97                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 18.08 | 21.71       | 13.62 | 28.00       | 21.81 | 33.12       | 24.36 |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| 3            | 79.50                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 6.04  | 79.83       | 5.54  | 78.93       | 6.91  | 78.24       | 6.68  |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| 4            | 6.23                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 2.51  | 4.79        | 1.97  | 6.39        | 2.83  | 5.93        | 2.32  |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| 5            | 60.51                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 19.57 | 64.69       | 21.21 | 61.92       | 22.12 | 61.56       | 21.29 |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| 7b SCAS      | 35.37                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 13.73 | 29.70       | 12.53 | 30.66       | 11.49 | 29.59       | 13.88 |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| 7b CES-D     | 16.19                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 9.80  | 13.65       | 8.44  | 15.32       | 8.62  | 14.60       | 8.01  |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| Risk of bias | Low                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |       |             |       |             |       |             |       |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |
| Comments     | Long-term evaluation planned but not found in literature. Data provided in supplement to Blake 2016. Other results reported in Blake 2017, due to difference in number of days of actigraphy (5 school nights in Blake 2017, 7 days in Blake 2016).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |       |             |       |             |       |             |       |  |  |  |     |    |      |    |     |    |      |    |   |        |       |        |       |        |       |        |       |   |       |       |       |       |       |       |       |       |   |       |      |       |      |       |      |       |      |   |      |      |      |      |      |      |      |      |   |       |       |       |       |       |       |       |       |         |       |       |       |       |       |       |       |       |          |       |      |       |      |       |      |       |      |

### Corkum 2016

|              |                                                                                                                                                                                                                                                                                    |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study aim    | To evaluate Better Nights/Better Days, a distance intervention for insomnia in school-aged children (with and without [ADHD]), to determine its effectiveness on children's sleep and psychosocial functioning.                                                                    |
| Method       | <b>Design:</b> Parallel group RCT (stratified on ADHD diagnosis) with telephone delivered parent education and waitlist control group                                                                                                                                              |
|              | <b>Country:</b> Canada                                                                                                                                                                                                                                                             |
|              | <b>Setting:</b> Family physicians, community                                                                                                                                                                                                                                       |
| Participants | <b>Sample size:</b> 61 (n=31 Intervention; n=30 Waitlist control)                                                                                                                                                                                                                  |
|              | <b>Population:</b> Parents of school-aged children (5–12 years), including both typically developed children and children with ADHD. Diagnosed with ADHD I: 38.7%, C: 33.3%<br><b>Age:</b> mean I: 108.0 (23.65) m, C: 110.60 (23.72) m<br><b>Genders:</b> Boys I: 48.4%, C: 43.3% |

|              | <b>Sleep disorder:</b> Child experienced trouble falling asleep with/without bedtime resistance, i.e. as SOL taking more than 25 min and occurring three or more times per week, problems for > 1 month, with impairment to the daily functioning of the child and/or parent(s). Based on the DSM-IV criteria for primary insomnia, with the 25-min SOL criteria added.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                   |                   |                   |                   |                   |              |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|--------------|------------|--------------|--|--|-----|------|-----|-----|------|-----|------|------------|--|-------------------|--|--|--------|--|--|--|--|---|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|------|------|---|------------------|------------------|------------------|------------------|------------------|------------------|------|------|---|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|------|------|----|-----------------|-----------------|-----------------|------------------|------------------|-----------------|------|------|
|              | <b>Follow-up time:</b> Post (2 m), 6 m from randomization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                   |                   |                   |                   |                   |              |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
|              | <b>Dropouts:</b> ITT-analysis. 5 from intervention and 2 from control group. Maximum Likelihood Methods using the EM Algorithm was conducted to generate values for missing data.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                   |                   |                   |                   |                   |              |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
| Intervention | <b>Intervention:</b> Five-session 35-40 minutes weekly behavioral sleep distance intervention, delivered via written manual with telephone support by a paraprofessional coach                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                   |                   |                   |                   |                   |              |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
|              | <b>Control:</b> Waitlist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                   |                   |                   |                   |                   |              |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
| Outcomes     | <b>Outcome measures:</b> Only 50% in intervention group report actigraphy data.<br>1. TST (sleep duration)<br>2. SOL<br>4. CSHQ Total<br>7b. Anxiety and Depression (CBCL Internalizing)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                   |                   |                   |                   |                   |              |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
| Results      | <div>Results reported as effect sizes calculated using partial eta squared. Mean (SD)</div> <table><tr><th></th><th colspan="3">Intervention</th><th colspan="3">Control</th><th colspan="2">Effect sizes</th></tr><tr><th></th><th>pre</th><th>post</th><th>6 m</th><th>pre</th><th>post</th><th>6 m</th><th>time</th><th>time*group</th></tr><tr><td></td><td colspan="3">Actigraphy (n=14)</td><td colspan="3">(n=21)</td><td></td><td></td></tr><tr><td>1</td><td>541.66<br/>(37.96)</td><td>535.88<br/>(49.22)</td><td>544.96<br/>(42.32)</td><td>559.57<br/>(42.00)</td><td>547.54<br/>(50.23)</td><td>551.48<br/>(40.16)</td><td>0.07</td><td>0.05</td></tr><tr><td>2</td><td>46.04<br/>(20.81)</td><td>52.61<br/>(23.25)</td><td>36.25<br/>(18.02)</td><td>36.69<br/>(14.05)</td><td>42.66<br/>(21.15)</td><td>39.93<br/>(20.01)</td><td>0.23</td><td>0.24</td></tr><tr><td>4</td><td>50.39<br/>(7.13)</td><td>42.00<br/>(5.58)</td><td>42.71<br/>(5.95)</td><td>49.93<br/>(7.81)</td><td>47.53<br/>(9.01)</td><td>47.13<br/>(8.25)</td><td>0.41</td><td>0.16</td></tr><tr><td>7b</td><td>51.54<br/>(9.09)</td><td>45.05<br/>(8.75)</td><td>46.15<br/>(9.54)</td><td>52.07<br/>(10.19)</td><td>51.25<br/>(10.11)</td><td>49.21<br/>(9.24)</td><td>0.30</td><td>0.12</td></tr></table> |                   | Intervention      |                   |                   | Control           |              |            | Effect sizes |  |  | pre | post | 6 m | pre | post | 6 m | time | time*group |  | Actigraphy (n=14) |  |  | (n=21) |  |  |  |  | 1 | 541.66<br>(37.96) | 535.88<br>(49.22) | 544.96<br>(42.32) | 559.57<br>(42.00) | 547.54<br>(50.23) | 551.48<br>(40.16) | 0.07 | 0.05 | 2 | 46.04<br>(20.81) | 52.61<br>(23.25) | 36.25<br>(18.02) | 36.69<br>(14.05) | 42.66<br>(21.15) | 39.93<br>(20.01) | 0.23 | 0.24 | 4 | 50.39<br>(7.13) | 42.00<br>(5.58) | 42.71<br>(5.95) | 49.93<br>(7.81) | 47.53<br>(9.01) | 47.13<br>(8.25) | 0.41 | 0.16 | 7b | 51.54<br>(9.09) | 45.05<br>(8.75) | 46.15<br>(9.54) | 52.07<br>(10.19) | 51.25<br>(10.11) | 49.21<br>(9.24) | 0.30 | 0.12 |
|              | Intervention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                   |                   | Control           |                   |                   | Effect sizes |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
|              | pre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | post              | 6 m               | pre               | post              | 6 m               | time         | time*group |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
|              | Actigraphy (n=14)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                   |                   | (n=21)            |                   |                   |              |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
| 1            | 541.66<br>(37.96)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 535.88<br>(49.22) | 544.96<br>(42.32) | 559.57<br>(42.00) | 547.54<br>(50.23) | 551.48<br>(40.16) | 0.07         | 0.05       |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
| 2            | 46.04<br>(20.81)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 52.61<br>(23.25)  | 36.25<br>(18.02)  | 36.69<br>(14.05)  | 42.66<br>(21.15)  | 39.93<br>(20.01)  | 0.23         | 0.24       |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
| 4            | 50.39<br>(7.13)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 42.00<br>(5.58)   | 42.71<br>(5.95)   | 49.93<br>(7.81)   | 47.53<br>(9.01)   | 47.13<br>(8.25)   | 0.41         | 0.16       |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
| 7b           | 51.54<br>(9.09)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 45.05<br>(8.75)   | 46.15<br>(9.54)   | 52.07<br>(10.19)  | 51.25<br>(10.11)  | 49.21<br>(9.24)   | 0.30         | 0.12       |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
| Risk of bias | Some concerns                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                   |                   |                   |                   |                   |              |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |
| Comments     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                   |                   |                   |                   |                   |              |            |              |  |  |     |      |     |     |      |     |      |            |  |                   |  |  |        |  |  |  |  |   |                   |                   |                   |                   |                   |                   |      |      |   |                  |                  |                  |                  |                  |                  |      |      |   |                 |                 |                 |                 |                 |                 |      |      |    |                 |                 |                 |                  |                  |                 |      |      |

### Kaplan 2019

|              |                                                                                                                                                                                                                           |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study aim    | To determine whether an intervention, using both light exposure during sleep and cognitive behavioral therapy (CBT), would increase total sleep time in teenagers by enabling them to go to sleep earlier.                |
| Method       | <b>Design:</b> Double-blind placebo controlled RCT, with light therapy or sham light (phase 1).                                                                                                                           |
|              | <b>Country:</b> USA                                                                                                                                                                                                       |
|              | <b>Setting:</b> Community, sleep clinic, pediatricians                                                                                                                                                                    |
| Participants | <b>Sample size:</b> 72 (36 in each group)                                                                                                                                                                                 |
|              | <b>Population:</b> General population 14-18 years<br><b>Age:</b> mean 15.6 yrs (SD 1.1 yrs)<br><b>Genders:</b> 47.1% boys<br><b>Sleep disorder:</b> Expressing difficulty going to bed earlier and waking up early enough |
|              | <b>Follow-up time:</b> Post (5 w)                                                                                                                                                                                         |
|              | <b>Dropouts:</b> ITT-analysis. 2 in each group.                                                                                                                                                                           |

| Intervention | <b>Intervention:</b> 4 weeks of daily light therapy in the form of brief light pulses began 3 hours before the participant’s target weekday wake time. Approximately 4000 lux of broad-spectrum white light (approximately 200-600 lux at the cornea after eyelid filtration) was delivered in each 3-millisecond flash, occurring 20 seconds apart. Light was generated by a custom-designed xenon flash bulb (Moflash Signaling).                                                                                                                                                                                                                                                  |                 |                 |                 |        |              |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------|-----------------|--------|--------------|--------|--|--|-----|------|-----|------|------|--------------|---|-----------------|-----------------|-----------------|-----------------|------|------|---|----------------|----------------|----------------|----------------|-------|-------|---|-------------|-------------|-------------|-------------|------|------|
|              | <b>Control:</b> 4 weeks of 1 minute of light pulses (appearing in 20-second intervals, for a total of 3 pulses) each hour; insufficient to shift the circadian system.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                 |                 |                 |        |              |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |
| Outcomes     | <b>Outcome measures:</b> Sleep diary measurements<br>1. TST<br>2. SOL<br>3. SE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                 |                 |                 |        |              |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |
| Results      | Results reported as Cohen’s d <table><tr><th></th><th colspan="2">Light</th><th colspan="2">Sham</th><th colspan="2">Effect</th></tr><tr><th></th><th>pre</th><th>post</th><th>pre</th><th>post</th><th>time</th><th>time*therapy</th></tr><tr><td>1</td><td>445.0<br/>(60.5)</td><td>460.0<br/>(67.3)</td><td>452.0<br/>(48.0)</td><td>465.2<br/>(53.8)</td><td>0.29</td><td>0.02</td></tr><tr><td>2</td><td>35.4<br/>(45.2)</td><td>26.4<br/>(49.6)</td><td>19.4<br/>(19.6)</td><td>16.3<br/>(14.7)</td><td>-0.09</td><td>-0.14</td></tr><tr><td>3</td><td>89<br/>(8.5)</td><td>92<br/>(8.9)</td><td>92<br/>(5.0)</td><td>93<br/>(4.5)</td><td>0.07</td><td>0.25</td></tr></table> |                 | Light           |                 | Sham   |              | Effect |  |  | pre | post | pre | post | time | time*therapy | 1 | 445.0<br>(60.5) | 460.0<br>(67.3) | 452.0<br>(48.0) | 465.2<br>(53.8) | 0.29 | 0.02 | 2 | 35.4<br>(45.2) | 26.4<br>(49.6) | 19.4<br>(19.6) | 16.3<br>(14.7) | -0.09 | -0.14 | 3 | 89<br>(8.5) | 92<br>(8.9) | 92<br>(5.0) | 93<br>(4.5) | 0.07 | 0.25 |
|              | Light                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                 | Sham            |                 | Effect |              |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |
|              | pre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | post            | pre             | post            | time   | time*therapy |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |
| 1            | 445.0<br>(60.5)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 460.0<br>(67.3) | 452.0<br>(48.0) | 465.2<br>(53.8) | 0.29   | 0.02         |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |
| 2            | 35.4<br>(45.2)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 26.4<br>(49.6)  | 19.4<br>(19.6)  | 16.3<br>(14.7)  | -0.09  | -0.14        |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |
| 3            | 89<br>(8.5)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 92<br>(8.9)     | 92<br>(5.0)     | 93<br>(4.5)     | 0.07   | 0.25         |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |
| Risk of bias | Some concerns                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                 |                 |                 |        |              |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |
| Comments     | Only phase 1 of study included in review, as too few participants (n=30) in phase 2.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                 |                 |                 |        |              |        |  |  |     |      |     |      |      |              |   |                 |                 |                 |                 |      |      |   |                |                |                |                |       |       |   |             |             |             |             |      |      |

### Paine 2011

|              |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study aim    | Evaluate cognitive-behaviour therapy (CBT) for school-aged children with Behavioural Insomnia of Childhood                                                                                                                                                                                                                                                                                                                               |
| Method       | <b>Design:</b> RCT with waitlist control group                                                                                                                                                                                                                                                                                                                                                                                           |
|              | <b>Country:</b> Australia                                                                                                                                                                                                                                                                                                                                                                                                                |
|              | <b>Setting:</b> Community                                                                                                                                                                                                                                                                                                                                                                                                                |
| Participants | <b>Sample size:</b> 42 children (21 in each group)                                                                                                                                                                                                                                                                                                                                                                                       |
|              | <b>Population:</b> General population<br><b>Age:</b> mean 9.3 yrs (range 7-13 yrs)<br><b>Genders:</b> 24 boys (57.1%)<br><b>Sleep disorder:</b> A semi-structured interview to assess each criterion for insomnia disorders (e.g., Psychophysiological Insomnia, Behavioural Insomnia of Childhood, Insomnia Due to a Mental Disorder) outlined in the ICSD-2, and DSM-IV-TR (AASM, 2005; American Psychiatric Association [APA], 2000). |
|              | <b>Follow-up time:</b> Pre-test (t1), Post treatment (t2), 1 m (t3), 6 m. Control group only post and 1 m.                                                                                                                                                                                                                                                                                                                               |
|              | <b>Dropouts:</b> 0 from intervention at 1 m, 6 children from control group.                                                                                                                                                                                                                                                                                                                                                              |
| Intervention | <b>Intervention:</b> Cognitive-behaviour treatment included behavioural sleep medicine (BSM) components and anxiety techniques adapted from adult treatment studies. 6 (individual?) 45-60 minutes sessions (for the children?), the first four weekly, final two biweekly.                                                                                                                                                              |
|              | <b>Control:</b> Waitlist                                                                                                                                                                                                                                                                                                                                                                                                                 |



|              |                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              | “Post-hoc analyses revealed that total anxiety scores were significantly lower in children in the CBT group compared to children in the WL group at both post-treatment and 1-month follow-up ( $p = .016$ , $p = .003$ , respectively), and similarly lower SAD and OCD scores at posttreatment ( $p = .029$ , $p < .018$ , respectively), which were maintained at 1-month follow-up ( $p < .001$ , $p < .018$ , respectively).” |
| Risk of bias | Some concerns                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Comments     |                                                                                                                                                                                                                                                                                                                                                                                                                                    |

### Schlarb 2018

|              |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|-------|----------|-----------|----------|--|--|--|-----|-----------|---|-----|-----------|---|
| Study aim    | Evaluate the short- and long-term effects of cognitive behavior therapy for insomnia (CBT-I) in groups for school-age children and their parents, the KiSS-program.                                                                                                                                                                                                                                                                                 |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
| Method       | <b>Design:</b> RCT, intervention vs waitlist control group.                                                                                                                                                                                                                                                                                                                                                                                         |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
|              | <b>Country:</b> Germany                                                                                                                                                                                                                                                                                                                                                                                                                             |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
|              | <b>Setting:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                     |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
| Participants | <b>Sample size:</b> 112 children (86 intervention, 26 control).                                                                                                                                                                                                                                                                                                                                                                                     |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
|              | <b>Population:</b> General population, 5-10 years.<br><b>Age:</b> mean 8.1 yrs (range 5-11.5 yrs)<br><b>Genders:</b> 52.7 % boys<br><b>Sleep disorder:</b> According to the International Classification of Sleep Disorders (ICSD-3; American Academy of Sleep Medicine, 2014). At baseline all children fulfilled criteria of chronic insomnia, as problems initiating or maintaining sleep persisted over a time period of at least three months. |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
|              | <b>Follow-up time:</b> After treatment (t2), three months (t3), six months (t4), and 12 months (t5) after treatment. Waitlist control only after treatment t2 6 weeks).                                                                                                                                                                                                                                                                             |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
|              | <b>Dropouts:</b> Attrition high at follow-up (t2:83%; t3:71%; t4:65%; t5:49% of participants supplied data). 40 children (<50%) of children in intervention group accepted actigraphy, 15 in control group.                                                                                                                                                                                                                                         |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
| Intervention | <b>Intervention:</b> Cognitive behavior therapy for insomnia (CBT-I) normally consists of sleep restriction, stimulus control therapy, sleep hygiene, relaxation, and cognitive therapy. The CBT-I manual-based program KiSS contains 6 100-minutes group (minimum 4 families) sessions; 3 for parents and 3 for children.                                                                                                                          |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
|              | <b>Control:</b> Waitlist                                                                                                                                                                                                                                                                                                                                                                                                                            |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
| Outcomes     | <b>Outcome measures:</b> Only diary outcomes as too few participants with actigraphy data.<br>1. TST<br>2. SOL<br>3. SE<br>4. Sleep quality (CSHQ total)<br>5. Night awakenings                                                                                                                                                                                                                                                                     |           |       |          |           |          |  |  |  |     |           |   |     |           |   |
| Results      | Results reported as Cohen’s d. Mean (SD) <table><tr><td></td><td colspan="3">CBT-I</td><td colspan="3">Waitlist</td></tr><tr><td></td><td>pre</td><td>post (t2)</td><td>d</td><td>pre</td><td>post (t2)</td><td>d</td></tr></table>                                                                                                                                                                                                                 |           | CBT-I |          |           | Waitlist |  |  |  | pre | post (t2) | d | pre | post (t2) | d |
|              | CBT-I                                                                                                                                                                                                                                                                                                                                                                                                                                               |           |       | Waitlist |           |          |  |  |  |     |           |   |     |           |   |
|              | pre                                                                                                                                                                                                                                                                                                                                                                                                                                                 | post (t2) | d     | pre      | post (t2) | d        |  |  |  |     |           |   |     |           |   |

|              |                                                                                                                                                                                                                                                                                |                   |                   |      |                   |                   |      |  |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------------------|------|-------------------|-------------------|------|--|
|              | 1                                                                                                                                                                                                                                                                              | 591.91<br>(41.99) | 595.79<br>(43.17) | 0.09 | 593.02<br>(35.74) | 592.97<br>(43.45) | 0.20 |  |
|              | 2                                                                                                                                                                                                                                                                              | 37.72<br>(22.22)  | 32.36<br>(23.17)  | 0.24 | 35.57<br>(29.67)  | 36.27<br>(24.82)  | 0.07 |  |
|              | 3                                                                                                                                                                                                                                                                              | 93.28<br>(3.43)   | 94.43<br>(3.58)   | 0.02 | 93.90<br>(4.64)   | 93.51<br>(3.84)   | 0.25 |  |
|              | 4                                                                                                                                                                                                                                                                              | 53.35<br>(6.25)   | 44.55<br>(7.25)   | 1.31 | 53.98<br>(7.15)   | 51.25<br>(6.84)   | 0.39 |  |
|              | 5                                                                                                                                                                                                                                                                              | 5.17<br>(8.14)    | 2.96<br>(4.71)    | 0.33 | 5.44<br>(8.97)    | 5.36<br>(9.73)    | 0.15 |  |
| Risk of bias | Some concerns                                                                                                                                                                                                                                                                  |                   |                   |      |                   |                   |      |  |
| Comments     | The KiSS manual is described in Schlarb, A. A. (2013). KiSS-Therapeutenmanual: Das Training für Kinder von 5 bis 10 Jahren mit Schlafstörungen [KiSS treatment manual: treatment for children aged 5 to 10 years with sleep disorders]. Stuttgart, Germany: Kohlhammer Verlag. |                   |                   |      |                   |                   |      |  |

### van Maanen 2017

|              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Study aim    | Compare the effects of melatonin and bright light treatment with a placebo condition in children with chronic sleep onset insomnia and late melatonin onset.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Method       | <b>Design:</b> RCT with three arms (melatonin, placebo, bright light therapy)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|              | <b>Country:</b> The Netherlands                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|              | <b>Setting:</b> Out-patient sleep clinic at general hospital                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Participants | <b>Sample size:</b> 84 children (Melatonin n=26, placebo n=28, bright light therapy n=30)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|              | <p><b>Population:</b> General population aged 7-12 yrs including ADHD and ASD</p> <p><b>Age:</b> Mean 10.0 years (SD 1.5 years)</p> <p><b>Genders:</b> 61% boys</p> <p><b>Sleep disorder:</b> Chronic sleep onset problems: (a) complaints of inability to fall asleep at the desired clock time (sleep onset later than 20:45 h in children aged 7 years and for older children 15 minutes later per year) and a latency between lights-off time and sleep onset (sleep onset latency) of more than 30 minutes, and (b) the symptoms were present for at least four nights a week, for at least 1 month during a regular school period; (c) the sleep problems resulted in problems with daytime functioning.</p> <p><b>Diagnoses:</b> Melatonin: 5 children with diagnosis of AD(H)D, 2 children with ASD; placebo: 6 children with diagnosis of ADHD, 1 child with ASD, 2 children with both; bright light therapy: 8 children with a diagnosis of AD(H)D, 1 child with ASD, 2 children with both.</p> |
|              | <b>Follow-up time:</b> Post treatment (3-4 weeks)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|              | <b>Dropouts:</b> ITT analysis. 2 children (1 each from melatonin and bright light groups) dropped out, 2 children switched to melatonin (1 each from placebo and bright light groups)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Intervention | <b>Interventions:</b> All parents received written sleep hygiene instructions. Melatonin: 3 mg at 19.00 h. Placebo melatonin: at 19.00 h. Daily bright blue-green light exposure: 500 nm peak, 8000 lux during 30 minutes between 6:00 and 8:00 h. The light was fixed to a cap.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Outcomes     | Outcome measures<br>1. TST                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

