**Supplementary Material**

***Table S1.* Model estimated means, mean differences, 95% confidence intervals and effect sizes at post-baseline time points**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **CBT** | **LDT** | **TAU** | **CBT vs TAU** | **LDT vs TAU** | **CBT vs LDT** |
|  | ***M*, 95%*CI*, *n*** | ***M*, 95%*CI, n*** | ***M*, 95%*CI*, *n*** | **Mean difference, 95%*CI*, *p* value, effect size** | **Mean difference, 95%*CI*, *p* value, effect size** | **Mean difference, 95%*CI*, *p* value, effect size** |
| **Primary Outcome** |  |  |  |  |  |  |
| **ISI** |  |  |  |  |  |  |
| Midpoint-intervention | 7.57 (6.45; 8.69), 37 | 8.50 (7.30; 9.70), 35 | 11.35 (10.46; 12.23), 38 | -3.77 (-5.18; -2.37), *p*<0.001, -1.56 | -2.85 (-4.32; -1.37), *p*<0.001, -1.18 | -0.93, (-2.52; 0.66), *p*=0.25, -0.38 |
| Post-intervention | 5.88 (4.51; 7.25), 35 | 7.08 (5.51; 8.64), 35 | 10.74 (9.60; 11.87), 35 | -4.86 (-6.64; -3.07), *p*<0.001, -2.01 | -3.66 (-5.58; -1.74), *p*<0.001, -1.52 | -1.20 (-3.23; 0.84), *p*=0.25, -0.50 |
| Follow-up | 5.579 (4.22; 6.90), 35 | 7.13(5.33; 8.92), 35 | 9.40 (8.13; 10.66), 38 | -3.82 (-5.70; -1.93), *p*<0.001, -1.58 | -2.27 (-4.47; -0.07), *p*=0.04, -0.94 | -1.55 (-3.78; 0.69), *p*=0.17, -0.64 |
| **Secondary Outcomes** |  |  |  |  |  |  |
| **PROMIS Sleep Disturbance** |  |  |  |  |  |  |
| Midpoint-intervention | 47.56 (46.01; 49.10), 37 | 48.63 (46.80; 50.46), 35 | 55.28 (53.93; 56.62), 38 | -7.72 (-9.72; -5.72), *p*<0.001, -1.39 | -6.65 (-8.85; -4.44), *p*<0.001, -1.19 | -1.07 (-3.28; 1.14), *p*=0.34, -0.19 |
| Post-intervention | 45.48 (43.56; 47.40), 35 | 46.78 (44.66; 48.91), 35 | 54.81 (53.24; 56.39), 35 | -9.33 (-11.78; -6.88), *p*<0.001, -1.68 | -8.03 (-10.65; -5.41), *p*<0.001, -1.44 | -1.30 (-3.98; 1.39), *p*=0.34, -0.23 |
| Follow-up | 44.74 (42.13; 47.35), 35 | 47.58 (44.87; 50.29), 35 | 51.63 (49.92; 53.33), 38 | -6.89 (-10.04; -3.74), *p*<0.001, -1.24 | -4.05 (-7.26; -0.84), *p*=0.013, -0.73 | -2.84 (-6.58; 0.90), *p*=0.14, -0.51 |
| **Epworth Sleepiness Scale** |  |  |  |  |  |  |
| Midpoint-intervention | 5.61 (4.96; 6.26), 37 | 5.65 (4.96; 6.34), 35 | 5.96 (5.25; 6.67), 38 | -0.35 (-0.96; 0.25), *p*=0.25, -0.10 | -0.31 (-0.89; 0.27), *p*=0.30, -0.08 | -0.04 (-0.43; 0.34), *p*=0.82, -0.01 |
| Post-intervention | 4.84 (3.91; 5.77), 35 | 4.97 (4.10; 5.85), 35 | 5.92 (4.77; 7.06), 35 | -1.08 (-2.38; 0.23), *p*=0.11, -0.29 | -0.95 (-2.20; 0.32), *p*=0.14, -0.26 | -0.13 (-1.30; 1.04), *p*=0.82, -0.04 |
| Follow-up | 4.77 (3.90; 5.64), 35 | 4.72 (3.86; 5.57), 35 | 5.46 (4.44; 6.47), 38 | -0.69 (-1.93; 0.55), *p*=0.28, -0.19 | -0.74 (-1.99; 0.50), *p*=0.24, -0.20 | 0.05 (-1.10; 1.20), *p*=0.93, 0.02 |
| **Karolinska Sleepiness Scale** |  |  |  |  |  |  |
| Midpoint-intervention | 5.26 (4.29; 6.23), 37 | 5.32 (4.41; 6.22), 35 | 5.94 (5.47; 6.41), 38 | -0.68 (-1.83; 0.46), *p*=0.24, -0.41 | -0.62 (-1.70; 0.45), *p*= 0.25, -0.37 | -0.06 (-0.89; 0.77), *p*=0.89, -0.04 |
| Post-intervention | 5.33 (4.54; 6.11), 35 | 5.38 (4.59; 6.18), 35 | 5.96 (5.36; 6.56), 35 | -0.63 (-1.33; 0.07), *p*=0.08, -0.38 | -0.58 (-1.27; 0.12), *p*=0.10, -0.34 | -0.06 (-0.82; 0.71), *p*=0.89, -0.03 |
| Follow-up | 5.24 (4.57; 5.91), 35 | 4.77 (3.98; 5.60), 35 | 6.05 (5.54; 6.56), 38 | -0.81 (-1.65; 0.03), *p*=0.06, -0.48 | -1.28 (-2.21; -0.36), *p*=0.007, -0.76 | 0.47 (-0.56; 1.50), *p*= 0.37, 0.28 |
| **Fatigue Assessment Scale** |  |  |  |  |  |  |
| Midpoint-intervention | 12.62 (11.67; 13.57), 37 | 13.91 (12.85; 14.98), 35 | 14.94 (14.11; 15.78), 38 | -2.32 (-3.49; -1.15), *p*<0.001, -0.64 | -1.03 (-2.27; 0.21), *p*=0.10, -0.29 | -1.29 (-2.66; 0.07), *p*=0.06, -0.36 |
| Post-intervention | 11.52 (10.46; 12.59), 35 | 13.23 (11.84; 14.63), 35 | 14.59 (13.58; 15.60), 35 | -3.07 (-4.51; -1.62), *p*<0.001, -0.85 | -1.36 (-3.01; 0.29), *p*=0.11, -0.38 | -1.71 (-3.45; 0.03), *p*=0.05, -0.47 |
| Follow-up | 11.31 (10.22; 12.40), 35 | 12.29 (10.10; 13.59), 35 | 13.96 (12.80; 15.11), 38 | -2.68 (-4.21; -1.09), *p*=0.001, -0.73 | -1.67 (-3.36; 0.02), *p*=0.05, -0.46 | -0.98 (-2.68; 0.72), *p*=0.26, -0.27 |
| **PROMIS Depression** |  |  |  |  |  |  |
| Midpoint-intervention | 49.32 (47.33; 51.32), 37 | 48.96 (47.28; 50.65), 35 | 50.50 (48.80; 52.21), 38 | -1.18 (-3.13; 0.76), *p*=0.23, -0.18 | -1.54 (-3.58; 0.50), *p*=0.14, -0.24 | 0.36 (-1.73; 2.44), *p*=0.74, 0.06 |
| Post-intervention | 47.29 (45.50; 49.09), 35 | 46.74 (44.11; 49.38), 35 | 49.11 (46.90; 51.32), 35 | -1.82 (-4.57; 0.93), *p*=0.20, -0.28 | -2.37 (-5.63; 0.89), *p*=0.16, -0.36 | 0.55 (-2.75; 3.84), *p*=0.74, 0.08 |
| Follow-up | 46.66 (44.59; 48.74), 35 | 47.50 (44.82; 50.08), 35 | 49.11 (46.82; 51.40), 38 | -2.45 (-5.4; 0.51), *p*=0.10, -0.38 | -1.66 (-5.06; 1.73), *p*=0.34, -0.26 | -0.79 (-4.11; 2.54), *p*=0.64, -0.12 |
| **PROMIS Anxiety** |  |  |  |  |  |  |
| Midpoint-intervention | 51.90 (49.93; 53.87), 37 | 50.97 (49.29; 52.66), 35 | 52.40 (50.49; 54.19), 38 | -0.44 (-2.21; 1.33), *p*=0.63, -0.06 | -1.37 (-3.07; 0.34), *p*=0.12, -0.18 | 0.93 (-0.70; 2.55), *p*=0.26, 0.13 |
| Post-intervention | 49.72 (47.50; 51.95), 35 | 47.88 (45.03; 50.73), 35 | 50.59 (47.94; 53.24), 35 | -0.87 (-4.22; 2.48), *p*=0.61, -0.12 | -2.71 (-6.39; 0.97), *p*=0.15, -0.36 | 1.84 (-1.91; 5.59), *p*=0.34, 0.25 |
| Follow-up | 48.16 (45.82; 50.50), 35 | 48.74 (45.86; 51.63), 35 | 48.72 (46.39; 51.05), 38 | -0.56 (-3.80; 2.69), *p*=0.74, -0.08 | 0.03 (-3.57; 3.62), *p*=0.99, 0.00 | -0.58 (-4.15; 2.99), *p*=0.75, -0.08 |
| **Other Outcomes** |  |  |  |  |  |  |
| **Total sleep time (hrs)** |  |  |  |  |  |  |
| Midpoint-intervention | 6.80 (6.55; 7.06), 37 | 6.64 (6.33; 6.96), 35 | 6.29 (6.05; 6.53), 38 | 0.51 (0.20; 0.83), *p*=0.001, 0.44 | 0.36 (-0.02; 0.73), *p*=0.06, 0.31 | 0.16 (-0.18; 0.50), *p*=0.35, 0.14 |
| Post-intervention | 7.08 (6.80; 7.36), 35 | 6.87 (6.51; 7.22), 35 | 6.39 (6.08; 6.69), 35 | 0.69 (0.51; 1.08), *p*<0.001, 0.59 | 0.48 (0.02; 0.94), *p*=0.04, 0.41 | 0.21 (-0.24; 0.67), *p*=0.36, 0.18 |
| Follow-up | 7.05 (6.68; 7.42), 35 | 6.88 (6.48; 7.29), 35 | 6.52 (6.17; 6.86), 38 | 0.53 (0.04; 1.03), p=0.04, 0.45 | 0.37 (-0.15; 0.89), *p*=0.16, 0.32 | 0.17 (-0.37; 0.70), *p*=0.55, 0.14 |
| **Sleep efficiency (%)** |  |  |  |  |  |  |
| Midpoint-intervention | 76.40 (73.46; 79.34), 37 | 74.95 (71.45; 78.45), 35 | 69.50 (66.90; 72.09), 38 | 6.91 (3.36; 10.45), *p*<0.001, 0.55 | 5.45 (1.32; 9.59), *p*=0.01, 0.43 | 1.45 (-2.52; 5.42), *p*=0.47, 0.12 |
| Post-intervention | 79.10 (75.79; 82.41), 35 | 77.28 (73.50; 81.08), 35 | 70.47 (67.38; 73.56) 35 | 8.63 (4.33; 12.93), *p*<0.001, 0.68 | 6.81 (1.91; 11.71), *p*=0.006, 0.54 | 1.82 (-3.19; 6.82), *p*=0.48, 0.14 |
| Follow-up | 78.96 (74.98; 82.95), 35 | 75.56 (71.05; 80.07), 35 | 72.67 (68.74; 76.60), 38 | 6.29 (0.92; 11.66, *p*=0.02, 0.50 | 2.88 (-2.84; 8.61), *p*=0.34, 0.23 | 3.41 (-2.52; 9.33), *p*=0.26, 0.27 |

CBT, cognitive behavioural therapy; LDT, light dark therapy; TAU, treatment-as-usual; *M*, mean; 95%*CI*, 95% confidence interval. Midpoint-intervention = Week 3. Post-intervention = Week 6. Follow-up = Week 10. Total sleep time and sleep efficiency are self-reported. See Table 1 of manuscript for values at baseline.

***Table S2.* CONSORT 2010, CONSORT-SPI 2018 and CONSORT PRO checklists**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Section** | **Item #** | **CONSORT 2010 Checklist item** | **CONSORT-SPI 2018a Checklist item** | **CONSORT PROb Checklist item** | **Page No.** |
| **Title and abstract** | | | | | |
|  | 1a | Identification as a randomised trial in the title |  |  | 1 |
|  | 1b | Structured summary of trial design, methods, results, and conclusions | Refer to CONSORT extension for social and psychological intervention trial abstracts | The PRO should be identified in the abstract as a primary or secondary outcome | 2 |
| **Introduction** | | | | | |
| Background and  Objectives | 2a | Scientific background and explanation of rationale |  | Including background and rationale for PRO assessment | 3-5 |
| 2b | Specific objectives or hypotheses | If pre-specified, how the intervention was hypothesised to work | The PRO hypothesis should be stated and relevant domains identified, if applicable | 3 |
| **Methods** | | | | | |
| Trial Design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio |  |  | 3 |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  |  | 9 |
| Participants | 4a | Eligibility criteria for participants | When applicable, eligibility criteria for settings and those delivering the interventions | Not PRO-specific, unless the PROs were used in eligibility or stratification criteria | 6-9 |
| 4b | Settings and locations where the data were collected |  |  | 7 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered |  |  | 7, 8 |
| 5a |  | Extent to which interventions were actually delivered by providers and taken up by participants as planned |  | 10, 11 |
| 5b |  | Where other informational materials about delivering the intervention can be accessed |  | 5 |
| 5c |  | When applicable, how intervention providers were assigned to each group |  | NA |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed |  | Evidence of PRO instrument validity and reliability should be provided or cited if available including the person completing the PRO and methods of data collection (paper, telephone, electronic, other) | 6, 8, 9 |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |  |  | NA |
| Sample Size | 7a | How sample size was determined |  | Not required for PRO unless it is a primary study outcome | 9 |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines |  |  | NA |
| **Randomisation** | | | | | |
| Sequence  generation | 8a | Method used to generate the random allocation sequence |  |  | 6 |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) |  |  | 6 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned |  |  | 6 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions |  |  | 6 |
| Awareness of assignment | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |  |  | 6 |
| 11b | If relevant, description of the similarity of interventions |  |  | NA |
| Analytical  methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | How missing data were handled, with details of any imputation method | Statistical approaches for dealing with missing data are explicitly stated | 9, 10 |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |  |  | 9, 10 |
| **Results** | | | | | |
| Participant flow | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | Where possible, the number approached, screened, and eligible prior to random assignment, with reasons for non-enrolment | The number of PRO outcome data at baseline and at subsequent time points should be made transparent | 10, 11, Figure 1 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons |  |  | 10, 11, Figure 1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |  |  | 10 |
| 14b | Why the trial ended or was stopped |  |  | 10 |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Include socioeconomic variables where applicable | Including baseline PRO data when collected | Table 1 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups |  | Required for PRO results | 10, Figure 1 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Indicate availability of trial data | For multidimensional PRO results from each domain and time point | 11, 12, Table 2, Figure 2 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |  |  | NA |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |  | Including PRO analyses, where relevant | 12 |
| Harms | 19 | All important harms or unintended effects in each group |  |  | 12, (see CONSORT harms Extension: Table 3 below) |
| **Discussion** | | | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |  | PRO–specific limitations and implications for generalisability and clinical practice | 14 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings |  | 14 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |  | PRO data should be interpreted in relation to clinical outcomes including survival data, where relevant | 12-14 |
| **Important information** | | | | | |
| Registration | 23 | Registration number and name of trial registry |  |  | 2, 6 |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |  |  | 5 |
| Declaration of Interests | 25a | Sources of funding and other support (such as supply of drugs), role of funders |  |  | 16 |
| 25b |  | Declaration of any other potential interests |  | 16 |
| Stakeholder investments | 26a |  | Any involvement of the intervention developer in the design, conduct, analysis, or reporting of the trial |  | NA |
| 26b |  | Other stakeholder involvement in trial design, conduct, or analyses |  | NA |
| 26c |  | Incentives offered as part of the trial |  | NA |

This table lists items from the CONSORT 2010 checklist (with some modifications for social and psychological intervention trials) and additional items in the CONSORT-SPI 2018 extension. Empty rows in the ‘CONSORT-SPI 2018’ and ‘CONSORT PRO’ columns indicate that there is no extension to the CONSORT 2010 item.a From: Montgomery, P., Grant, S., Mayo-Wilson, E., Macdonald, G., Michie, S., Hopewell, S., … CONSORT-SPI Group. (2018). Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 Extension. *Trials, 19*(1), 407. doi:10.1186/s13063-018-2733-1 b From: Calvert, M., Blazeby, J., Altman, D. G., Revicki, D. A., Moher, D., … CONSORT PRO Group (2013). Reporting of patient-reported outcomes in randomized trials: the CONSORT PRO extension. *JAMA, 309*(8), 814–822. doi:10.1001/jama.2013.879

***Table S3:* CONSORT harms extension**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section** | **Item #** | **Relevant CONSORT 2010 Checklist item** | **CONSORT Harms Extension** | **Page No.** |
| **Title and abstract** | | | | |
|  | 1a | Identification as a randomised trial in the title | If the study collected data on harms and benefits, the title or abstract should so state | 1, 2 |
|  | 1b | Structured summary of trial design, methods, results, and conclusions |
| **Introduction** | | | | |
| Background and  Objectives | 2a | Scientific background and explanation of rationale | If the trial addresses both harms and benefits, the introduction should so state. | 2-5 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | List addressed adverse events with definitions for each (with attention, when relevant, to grading, expected vs. unexpected events, reference to standardised and validated definitions, and description of new definitions).  Clarify how harms-related information was collected (mode of data collection, timing, attribution methods, intensity of ascertainment, and harms-related monitoring and stopping rules, if pertinent) | 9 |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |
| **Randomisation** | | | | |
| Analytical  methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | Describe plans for presenting and analysing information on harms (including coding, handling of recurrent events, specification of timing issues, handling of continuous measures and any statistical analyses) | NA |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |
| **Results** | | | | |
| Participant flow | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | Describe for each arm the participant withdrawals that are due to harms and the experience with the allocated treatment | 12 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Provide the denominators for analyses on harms | 12 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Present the absolute risk of each adverse event (specifying type, grade, and seriousness per arm), and present appropriate metrics for recurrent events, continuous variables and scale variables, whenever pertinent.  Describe any subgroup analyses and exploratory analyses for harms | 12 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |
| Harms | 19 | All important harms or unintended effects in each group |
| **Discussion** | | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Provide a balanced discussion of benefits and harms with emphasis on study limitations, generalisability and other sources of information on harms | 12-15 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |

CONSORT 2010 checklist items have been condensed for readability: only relevant items that corresponded to CONSORT Harms items are displayed. See: Ioannidis, J. P., Evans, S. J., Gøtzsche, P. C., O'Neill, R. T., Altman, D. G., Schulz, K., … CONSORT Group. (2004). Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Annals of Internal Medicine, 141*(10), 781–788. doi:10.7326/0003-4819-141-10-200411160-00009



***Figure S1*. Model estimated changes in additional secondary outcomes over time**

CBT, cognitive behavioural therapy group; LDT, light dark therapy group; TAU, treatment-as-usual control group. Model estimated means and 95% confidence intervals are presented. All models adjusted for baseline levels and strata of the outcome. A reference line is added wherever applicable to facilitate interpretation: the T-score 50 for PROMIS scales indicates population mean; a sleep efficiency of 85% or above is typically considered “good” sleep.