## Appendix 1: Assessment of safety

The likelihood of adverse events (AE) occurring during this trial was low. Previous studies have shown that daytime sleepiness, tiredness and vigilance impairment may increase during sleep restriction therapy (SRT), which is one of the behavioural components of CBT-I (Kyle et al., 2014). For the full procedure on how AE and Serious AE (SAE) were reported, see trial protocol (Moukhtarian et al., 2022). AE and SAE during the study period that may or may not have been due to the intervention were recorded by the research team to check for any patterns or trends in events.

The table below summarises the adverse event reports received during the trial. None were judged serious or related to the treatment.

Table 1 Reports of Adverse Events

|  |  |  |
| --- | --- | --- |
| **Adverse Event Description** | **Related/Unrelated** | **Outcome\*** |
| Employee signed off work with mental health burnout | Unrelated | Withdrew from the trial |
| Head injury sustained during the trial | Unrelated | Continued in the trial |
| Signed off work, suspected vitamin deficiency | Unrelated | Continued in the trial |
| Signed off work due to stress after first therapy appointment | Unrelated | Withdrew from the trial |
| Rash from wearing the sleep tracker | Unrelated | Continued in the trial |

\*None of the participants withdrew consent, and their data was therefore not deleted.

## Appendix 2: Variable distributions

Normality of all variables in the study were examined both graphically through histograms and Q-Q plots, and analytically reporting on the Shapiro-Wilk test.

**Primary outcomes**

GAD-7

W (159) = .96, *p* < .01

A graph with blue lines and a black line

Description automatically generated

A graph of a normal q-q plot

Description automatically generated

PHQ-9

W (159) = .97, *p* < .001

A graph of a graph

Description automatically generated with medium confidence

A graph of a normal q-q plot

Description automatically generated

ISI

W (159) = .99, *p* = .29A screenshot of a graph

Description automatically generated

A graph of a normal q-q plot

Description automatically generated

**Secondary questionnaire outcomes**

IJSS

W (159) = .99, *p* = .12

A graph of a graph

Description automatically generated with medium confidence

A graph of a normal graph

Description automatically generated with medium confidence

WEMWBS

W (156) = .98, *p* = .05

A graph of a person with a blue line

Description automatically generated with medium confidence

A graph of a graph with blue dots

Description automatically generated

WPAI1-WTM

W (158) = .29, *p* < .001

A graph with blue and white lines

Description automatically generated

A graph of a normal and observed value

Description automatically generated with medium confidence

WPAI2-IWW

W (159) = .93, *p* < .001

A screenshot of a graph

Description automatically generated

A graph of a normal q-q plot

Description automatically generated

WPAI3-OWI

W (158) = .93, *p* < .001

A graph with blue bars

Description automatically generated

A graph of a normal q-q plot

Description automatically generated

WPAI4-AI

W (159) = .93, *p* < .001

A graph of blue bars

Description automatically generated

A graph of a normal q-q plot

Description automatically generated

EQ5D – Utility score

W (155) = .92, *p* < .001

**A graph with blue bars and black text

Description automatically generated**

**A graph with blue dots and black lines

Description automatically generated**

EQ5D – VAS score

W (156) = .94, *p* < .001

A graph of blue bars

Description automatically generated

**A graph of a normal value

Description automatically generated with medium confidence**

**Secondary outcomes- objective sleep tracker**

Sleep efficiency

W (119) = .84, *p* < .001

A graph with blue lines and a dotted line

Description automatically generated

A graph of a normal graph

Description automatically generated with medium confidence

Total time in bed (TIB) in minutes

W (119) = .95, *p* < .001

A graph of a person with a blue line

Description automatically generated with medium confidence

A graph of a normal q-q plot

Description automatically generated

Total sleep time (TST) in minutes

W (119) = .98, *p* = .10

A graph of a sleep

Description automatically generated with medium confidence

**Normal Q-Q Plot of T1\_TotalSleepTimeminutes**

**T1\_TotalSleepTimeminutes**

A graph showing a normal sleep

Description automatically generated with medium confidence

Total wake time in minutes

W (119) = .77, *p* < .001

A graph with blue and black lines

Description automatically generated

**Normal Q-Q Plot of T1\_TotalWakeTimeminutes**

**T1\_TotalWakeTimeTimeminutes**

A graph with a black line and blue dots

Description automatically generated

**Secondary outcomes- self-reported sleep diary**

Sleep efficiency

W (102) = .94, *p* < .001

A graph with blue bars

Description automatically generated

A graph of a normal sleep efficiency

Description automatically generated

Sleep quality

W (102) = .98, *p* = .18

A screenshot of a graph

Description automatically generated

A graph of a normal q-q plot of sleep quality

Description automatically generated

Sleep Onset Latency (SOL)

W (102) = .88, *p* < .001

A graph with blue bars

Description automatically generated

A graph with blue dots

Description automatically generated

Wake After Sleep Onset (WASO)

W (102) = .87, *p* < .001

A graph with blue bars and black text

Description automatically generated

A graph with blue dots and a black line

Description automatically generated

Time in bed (TIB)

W (102) = .96, *p* = .005

A graph of a normal distribution

Description automatically generated

A graph of a normal q-q plot

Description automatically generated

Total sleep time (TST)

W (102) = .98, *p* = .16

A graph of a sleep

Description automatically generated

A graph of a normal sleep time

Description automatically generated

## Appendix 3: Missingness

We created a categorical variable to indicate missingness and non-missingness at T2 (1= missing at T2, 2= complete at T2). We then ran multinomial logistic regression models using missingness as the dependent variable, allocation as factor and each of the outcome measures as covariates to predict missingness with the variables at T1 (i.e. does symptom severity on ISI at baseline predict missingness/drop out at T2).

We report below descriptives divided by allocation across the subgroup of people with missing or non-missing T2 outcomes, and *p* values from the model fitting. Using the Bonferroni corrected *p* value of **0.01667, of all the variables, only the three subscales of the WPAI appear to significantly predict missingness (attrition).**

Table 2 Descriptive statistics and test statistic of the multinomial logistic regression models of all primary and secondary outcomes predicting missingness across the two groups.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Predicting missingness (*p*-value)** | **dCBTI+ER**  **(n= 79)**  **M(SD)** | | **Control**  **(n= 80)**  **M(SD)** | |
|  |  | **Missing**  **(n = 16)** | **Not missing**  **(n = 63)** | **Missing**  **(n = 7)** | **Not missing**  **(n = 73)** |
| **Demographics** |  |  |  |  |  |
| Age, y | 0.110 | 43.88 (9.85) | 44.78 (8.98) | 42.71 (11.70) | 42.53 (9.55) |
| Sex, No. (%) | 0.110 |  |  |  |  |
| Women |  | 12 (75.00) | 47 (74.60) | 5 (71.40) | 58 (79.50) |
| Men, Other |  | 4 (25.00) | 16 (25.40) | 2 (28.60) | 15 (20.50) |
| Ethnicity, No. (%) | 0.036 |  |  |  |  |
| White |  | 14 (87.50) | 50 (79.40) | 7 (100.00) | 57 (78.10) |
| Black, Asian, Mixed, Other |  | 2 (12.50) | 13 (20.60) | 0 (0.00) | 16 (21.90) |
| Relationship status, No. (%) | 0.087 |  |  |  |  |
| Married |  | 6 (37.50) | 33 (52.40) | 5 (71.40) | 38 (52.10) |
| Co-habiting |  | 2 (12.50) | 12 (19.00) | 1 (14.30) | 15 (20.50) |
| Single |  | 4 (25.00) | 10 (15.90) | 1 (14.30) | 13 (17.80) |
| Divorced, Separated, Widowed, Other |  | 4 (25.00) | 8 (12.70) | 0 (0.00) | 7 (9.60) |
| Hours of work | 0.113 | 37.56 (5.34) | 37.59 (7.02) | 37.71 (3.86) | 37.27 (6.89) |
| Education level, No. (%) | 0.091 |  |  |  |  |
| Higher education |  | 11 (68.80) | 38 (60.30) | 1 (14.30) | 39 (53.40) |
| Lower education |  | 5 (31.30) | 25 (39.70) | 6 (85.70) | 34 (46.60) |
| Income No. (%) | 0.066 |  |  |  |  |
| £10,000-£29,999 |  | 5 (31.30) | 7 (11.10) | 1 (14.30) | 19 (26.00) |
| £30,000 or higher |  | 11 (68.80) | 56 (88.90) | 6 (85.70) | 54 (74.00) |
| **Primary outcomes** |  |  |  |  |  |
| Insomnia (ISI) | 0.078 | 16.19 (3.73) | 16.38 (4.25) | 18.29 (3.09) | 15.40 (4.41) |
| Depression (PHQ-9) | 0.11 | 9.50 (4.94) | 10.02 (4.38) | 10.71 (4.54) | 10.36 (4.67) |
| Anxiety (GAD-7) | 0.077 | 8.13 (4.29) | 8.84 (4.64) | 8.00 (3.96) | 9.23 (4.35) |
| **Categorical** |  |  |  |  |  |
| Insomnia | 0.082 |  |  |  |  |
| No clinically significant insomnia |  | 0 (0.00) | 2 (3.20) | 0 (0.00) | 4 (5.50) |
| Subthreshold insomnia |  | 6 (37.50) | 17 (27.00) | 1 (14.30) | 30 (41.10) |
| Clinical insomnia |  | 10 (62.50) | 44 (69.80) | 6 (85.70) | 39 (53.40) |
| Depression (PHQ-9) | 0.111 |  |  |  |  |
| Normal |  | 3 (18.80) | 6 (9.50) | 0 (0.00) | 4 (5.50) |
| Mild |  | 5 (31.30) | 26 (41.30) | 4 (57.10) | 32 (43.80) |
| Mild-moderate |  | 5 (31.30) | 21 (33.30) | 2 (28.60) | 26 (35.60) |
| Moderate |  | 3 (18.80) | 7 (11.10) | 0 (0.00) | 7 (9.60) |
| Severe |  | 0 (0.00) | 3 (4.80) | 1 (14.30) | 4 (5.50) |
| Anxiety (GAD-7) | 0.083 |  |  |  |  |
| No to low risk |  | 5 (31.30) | 10 (15.90) | 1 (14.30) | 9 (12.30) |
| Mild |  | 5 (31.30) | 30 (47.60) | 3 (42.90) | 31 (42.50) |
| Moderate |  | 4 (25.00) | 14 (22.20) | 3 (42.90) | 24 (32.90) |
| Severe |  | 2 (12.50) | 9 (14.30) | 0 (0.00) | 9 (12.30) |
| **Secondary outcomes** |  |  |  |  |  |
| Work productivity (WPAI:GH) |  |  |  |  |  |
| WPAIGH1 | **< 0.001** | 5.39 (18.68) | 1.23 (4.63)3 | 34.69 (47.28) | 3.29 (12.02) |
| WPAIGH2 | **0.013** | 39.38 (30.87) | 32.86 (25.87) | 61.43 (36.71) | 36.03 (25.59) |
| WPAIGH3 | **0.010** | 40.18 (31.89) | 32.54 (25.47)3 | 63.27 (37.52) | 37.48 (26.89) |
| WPAIGH4 | 0.094 | 35.00 (30.98) | 37.30 (26.35) | 57.14 (28.70) | 40.68 (29.17) |
| Job satisfaction (IJSS) | 0.111 | 2.94 (0.39) | 3.02 (0.40) | 3.08 (0.26) | 2.97 (0.39) |
| Well-being (WEMWBS) | 0.098 | 42.80 (6.60)2 | 41.71 (7.48) | 43.86 (9.35) | 40.49 (7.48)1 |
| Quality of life (EQ-5D-5L) |  |  |  |  |  |
| EQ-5D-5L utility score | 0.084 | 0.85 (0.16) | 0.81 (0.10)4 | 0.72 (0.20) | 0.80 (0.15) |
| EQ-5D-5L VAS | 0.091 | 73.38 (21.74) | 68.98 (16.70)5 | 59.29 (19.51) | 67.86 (18.70) |

Footnote:

1. n = 71
2. n = 15
3. n = 62
4. n = 59
5. n = 60

## Appendix 4: Caseness

We defined caseness on the outcomes according to the Improving Access to Psychological Therapies (IAPT) framework. This is defined as those with a PHQ-9 score of at least 10, a GAD-7 score of at least 8 (NHS England, 2018), and an ISI score of at least 8 (Harvey et al., 2014). Binary (yes/no) variables were computed for baseline and week 8 for these three outcomes indicating caseness. Clinically significant change (CSC), or symptom reduction of reliable change was also explored; this is defined as those with a reduction of at least 8 points on the ISI (Morin et al., 2011), 4 points on the GAD and 6 points on the PHQ-9 (England, 2018). We created change score variables from baseline to week 8 for the primary outcome measures, then created binary (yes/no) CSC variables with the above benchmark scores. Differences of CSC between the control and treatment groups are tested by Chi-Square tests.

## Appendix 5: Fixed effects of group x time interactions on secondary outcomes

* WPAI-WTM: F(1, 133.48) = 0.66, *p =* 0.4184
* WPAI-IWW: F(1, 134) = 1.99, *p =* 0.1610
* WPAI-OWI: F(1, 131.92) = 1.09, *p =* 0.2985
* WPAI-AI: F(1, 134) = 4.82, ***p =* 0.0298** (did not withstand Bonferroni correction)
* IJSS: F(1, 134) = 0.16, *p* = 0.6897
* EQ-5D-5L Utility: F(1, 130.24) = 1.83, *p =* 0.17818
* E5-5D-5L VAS: F(1, 131.34) = 3.35, *p =* 0.06939
* Time in Bed: F(1, 101) = 13.34, *p =* **0.0004**
* Sleep Onset Latency: F(1, 101) = 11.21, ***p =* 0.0011**
* Wake After Sleep Onset: F(1, 101) = 6.78, *p =* **0.0106**
* Sleep efficiency: F(1, 101) = 12.52, ***p =* 0.0006**
* Sleep quality: F(1, 100.19) = 14.25, ***p =* 0.0003**

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