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Reasonable access to brief behavioural insomnia treatment among medical and psychiatric outpatients (RABBIT): a multicentre randomised controlled trial protocol

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ABSTRACT

Introduction Insomnia is a significant global health issue associated with substantial economic costs. International guidelines recommend cognitive behavioural therapy for insomnia (CBT-I) as the first-line treatment for chronic insomnia; however, pharmacotherapy remains more common in clinical practice. Maintaining the effectiveness while reducing the time and frequency of CBT-I is essential for its implementation. We conducted a randomised controlled trial (RCT) to evaluate the effectiveness of a brief behavioural treatment for insomnia (BBTI) that focuses on sleep restriction and stimulus control (SC)—both established as effective standalone interventions. This article presents the study protocol to examine whether adding BBTI to treatment as usual improves outcomes in patients with chronic insomnia.

Methods and analysis We will conduct a multicentre RCT. We will randomly assign patients with chronic insomnia to two groups (BBTI vs sleep hygiene) in a 1:1 ratio. The BBTI consists of three 15 min sessions over 4 weeks delivered by healthcare professionals following a detailed manual. The primary outcome is the Insomnia Severity Index at 8 weeks. Secondary outcomes include sleep latency, wake after sleep onset, total sleep time, sleep efficiency, Generalized Anxiety Disorder-7, Patient Health Questionnaire-9 and EuroQol-5D-5L. We will conduct the assessment at weeks 0 (baseline), 4 (end of intervention), 8 (post-intervention, primary endpoint) and 12 (follow-up). We will assess each sleep variable from the sleep diary at weeks 0 and 8. The analysis will be performed on an intention-to-treat basis.

Ethics and dissemination This study has been approved by the Ethics Committee for Clinical and Epidemiological Research of Toyama University (approval no. R2023152).

Trial registration number UMIN000052911; pre-results.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study features a brief intervention that requires approximately 15 min per session, highlighting its feasibility in routine clinical practice.
⇒ The intervention can be delivered by trained medical staff who are not experts in cognitive behavioural therapy for insomnia (CBT-I), enhancing accessibility for a broad patient population across multiple clinical settings.
⇒ The multicentre design and inclusion of both medical and psychiatric patients in outpatient settings contribute to the generalisability of the findings.
⇒ A key limitation is the reliance on subjective assessments, such as the Insomnia Severity Index and sleep diaries, which may be influenced by individual perception and reporting biases.
⇒ Although the study addresses time constraints as a key barrier to implementation, it does not account for broad contextual factors; thus, feasibility should be interpreted with caution.

INTRODUCTION

Insomnia affects 4–22% of the US population and is a significant global health issue.[1] In Japan, the prevalence of insomnia is estimated at 12.2% in men and 14.6% in women.[2]

Insomnia is a risk factor for several medical conditions such as cardiovascular disease, cancer or dementia and psychiatric disorders such as major depression, anxiety disorder or alcohol use disorder.[3–5]

Cognitive behavioural therapy for insomnia (CBT-I) is recommended as the first-line treatment in international insomnia treatment guidelines, considering both risks and benefits.[6 7] However, in practice, the usage of CBT-I remains limited and the common practices involve high rates of pharmacotherapy and are often limited to sleep hygiene (SH) guidance only, which general practitioners (GPs) often perceive as inadequate.[8 9]

This evidence–practice gap is problematic in two regards. First, while pharmacotherapy may be effective for the short-term symptom

management, it lacks long-term efficacy and carries potential side effects.[7 10] Indeed, a recent systematic review has demonstrated that CBT-I beats common pharmacotherapies in the long term by increasing the remission rates by 10% or more and reducing the dropouts by 20% or more.[11] Second, although SH is often included in the CBT-I treatment package, it is not an effective ingredient[12] and is considered ineffective by itself.[7] To bridge these gaps, the European Sleep Research Society is promoting novel insomnia treatments, as well as encouraging efforts to increase access to and implementation of CBT-I.[13]

One of the major barriers to implementing CBT-I is the shortage of suitable personnel who can provide CBT-I. Despite the effectiveness of CBT-I, SH is common in the brief non-pharmacological treatment of insomnia for the majority of healthcare professionals.[8 9 14] Standard CBT-I involves six sessions of 50 min each,[15] which is burdensome for both users and therapists, making it challenging to implement it in the Japanese clinical settings. Therefore, maintaining efficacy while reducing the duration and number of sessions is necessary for CBT-I implementation. This can be achieved by focusing on sleep restriction (SR) and stimulus control (SC),[7 12] which are effective standalone treatments. Preliminary studies have indicated the effectiveness of such brief behavioural treatment for insomnia (BBTI) programmes compared with SH-only controls.[16–19] Our pilot study showed a remission rate of 55.5% at treatment completion and 3 months later, after an average of four sessions, each lasting 12 min.[20]

Aims

The aim of this study is to evaluate the effectiveness of a programme consisting of evidence-based treatment components delivered in three sessions of approximately 15 min each. This article presents a clinical trial protocol for BBTI that is suitable for clinical practice.

METHODS AND ANALYSIS

Study design

This study is a multicentre, randomised, open-label, parallel-group comparison trial to evaluate the effectiveness of BBTI. Participants will be randomly assigned in a 1:1 ratio to an intervention group receiving BBTI or SH control group (see figure 1). The study protocol follows the Standard Protocol Items: Recommendations for Interventional Trials[21] and the Template for Intervention Description and Replication checklists and guidelines.[22]

Participants and recruitment

We will recruit study participants from three hospitals and one private clinic in Japan. Recruitment began on 15

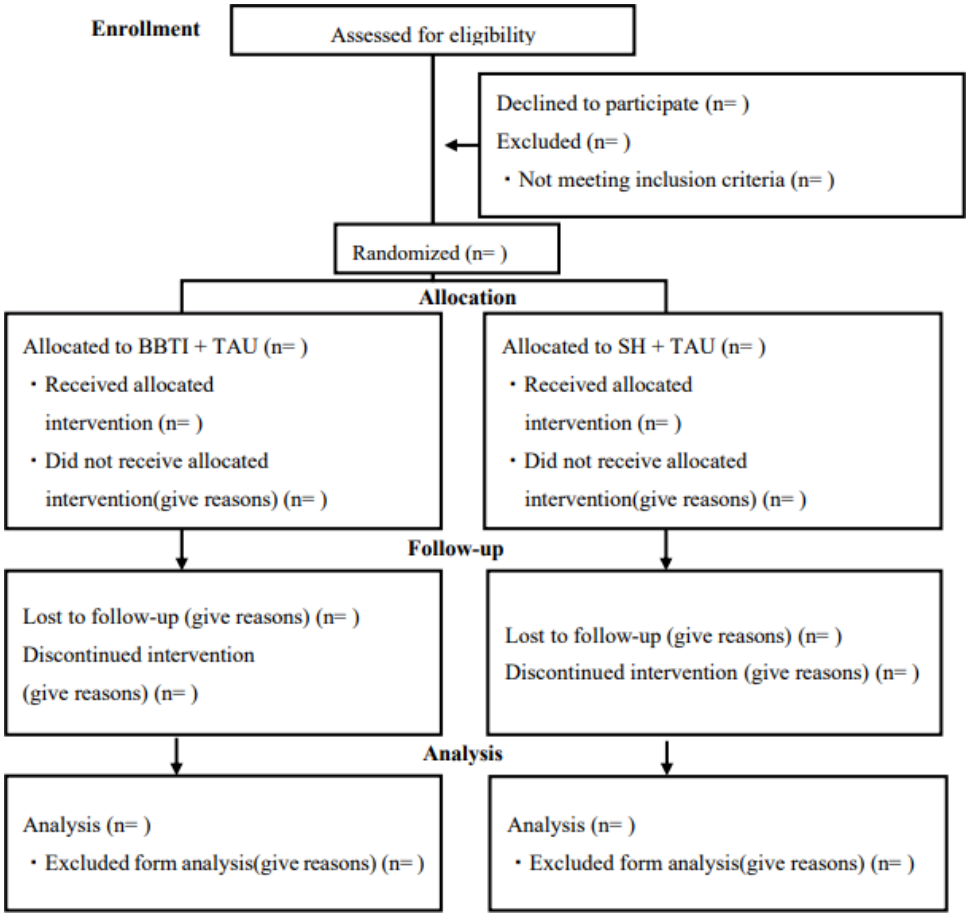

Figure 1 CONSORT patients' flow diagram during inclusion, randomisation and treatment. BBTI, brief behavioural treatment for insomnia; CONSORT, Consolidated Standards of Reporting Trials; SH, sleep hygiene; TAU, treatment as usual.

January 2024 and will continue until 30 March 2026. GPs or psychiatrists identify eligible patients from their practices and explain the study to the outpatients. All GPs were psychiatrists or board-certified instructors of the Japanese Society of Sleep Research. If the patient shows interest, the study personnel will assist in obtaining their informed consent in writing in a separate room. We will also post recruitment posters to increase outpatient interest.

The inclusion criteria are (1) men and women of 20 years or older who can understand the study's purpose; (2) meets the DSM-5[23] criteria for chronic insomnia; (3) an Insomnia Severity Index (ISI) score of 8 or higher[24]; (4) may be on or off sleep medications and (5) stable use of other psychotropic medications for at least 3 months before the study, with no change expected for 12 weeks post-study initiation (sleep medications can be reduced or discontinued). Exclusion criteria include (1) physical illness causing severe distress (eg, pain or dyspnoea) when it is the primary disease or comorbidity; (2) patients with schizophrenia, bipolar disorder, dementia, substance abuse, personality disorders, eating disorders, intellectual or developmental disabilities, or depression or anxiety disorders with serious suicidal ideations, as judged by the study physician; (3) shift workers; (4) severe life problems that may interfere with treatment; (5) difficulty reading or writing in Japanese and (6) any other issues, as judged by the GP, that may make participation difficult.

Interventions

Brief behavioural treatment for insomnia

The research team defined BBTI based on insights from our pilot study[20] and previous research. BBTI programmes presented in previous studies[18 25] combined face-to-face sessions and phone calls; however, recent research[12] has suggested the efficacy of face-to-face CBT. Therefore, BBTI focuses solely on in-person sessions of shorter durations. In our pilot study,[20] we chose essential components of CBT-I based on individual needs; however, recent reports have emphasised the efficacy of SR and SC as standalone treatments.[7 12] Thus, we revised to incorporate SR and SC in this trial. In examining the number of sessions of the BBTI, a previous study found the most long-term effects with four sessions, which required 45 min or more to listen to an educational audiotape on sleep in the first session.[26] In our study, by focusing on SR and SC, we aimed to limit the number of sessions to three, each lasting 15 min. Specifically, we reorganised the sleep assessment sheet for the participants to prioritise lifestyle habits related to SR and SC, and the educational sheets have been aligned accordingly for quick reference (see ref.[20] for each sheet's structure).

BBTI consists of one 15 min session every 2 weeks for a total of three sessions (45 min in total). BBTI includes the following steps:

First session: The most troubling insomnia symptoms are briefly discussed, and the sleep record and assessment sheets are explained and assigned as homework.
Second session: The items related to SR and SC from the sleep assessment sheet are prioritised, and the relevant educational sheets are selected. The improvement strategies are collaboratively discussed and assigned as homework. The therapist interacts with the study participants to help them empathise and self-determine their concerns to practice at home.
Third session: The homework results are discussed, and the improvements or reasons for difficulties are addressed. Furthermore, if improvements are observed, plans for relapse prevention are discussed.

Treatment of control group

The control group will receive SH from a GP or psychiatrist via an educational pamphlet during the first session.

Following the requirements of a pragmatic trial, there are no restrictions on usual care in both groups. Both groups will continue their treatment as usual (TAU) prescribed by their GP or psychiatrist, ensuring a fair comparison of the clinical utility of BBTI (+TAU) versus SH (+TAU). After the follow-up survey, the control group participants will be offered BBT if they wish.

Therapists and treatment integrity

Considering cost-effectiveness and the need for widespread use of CBT-I, the BBTI therapists involved in this study will include clinical psychologists, nurses and occupational therapists who have completed at least 6 hours of BBTI training. They will have also undergone at least 6 hours of online training specific to BBTI, particularly to promote an understanding of how SR and SC work, followed by a 2-hour in-person workshop focusing on role-playing scenarios. During the study, the therapists will receive regular supervision from experienced CBT-I researchers (SN, MS, MN and HO) based on recorded sessions with participant consent. All supervisors are certified public psychologists and have clinical experience after attending an advanced seminar in CBT-I. To ensure the quality of the intervention, each therapist will work with no more than three patients simultaneously during the study period.

Outcomes and data collection methods

Evaluations are conducted at baseline (week 0), the end of the intervention (week 4), post-intervention (week 8) and follow-up (week 12). The sleep diary was completed for the last 7 days of week 2 and the last 7 days of week 8. We will collect data primarily via electronic devices, with participants entering their responses (the therapist will help if participants have difficulty inputting data). We will store data in the Research Electronic Data Capture (REDCap) system managed by the Clinical Research Management Center at Toyama University.

The therapists will photograph participants' sleep diaries, and a data management assistant (KM) will

quantify the time spent in bed, sleep onset time, wake (or re-sleep) time after sleep onset, wake-up time and get-up time.

The data manager (JS) will oversee the overall integrity of the data. The data manager will report to the principal investigator (MN) if there are any missing data, such as in sleep diaries. The REDCap setup allows only the data analyst (KM) access to the final data set.

Baseline and clinical characteristics

We will use baseline surveys to collect information on participants' gender, age, education, occupation, marital status and duration of insomnia. The therapists will gather information on patients' primary diagnoses and comorbidities from medical records.

Primary outcomes

The primary outcome is the ISI score at 8 weeks. The ISI includes seven items measuring night-time and daytime symptoms on a 5-point scale, with total scores ranging from 0 to 28. It has high internal consistency (Cronbach's α=0.91) and temporal stability (r=0.80), and is sensitive to therapeutic changes.[27] The scores are interpreted as follows: 0–7 (no clinical insomnia), 8–14 (subthreshold insomnia), 15–21 (moderate insomnia) and 22–28 (severe insomnia). The change in total score is the primary outcome, while the responder rate (≥8-point reduction) and remission rate (final score<8)[23] are evaluated as secondary outcomes.

Secondary outcomes

Secondary outcomes include sleep latency (SL), wake after sleep onset (WASO), total sleep time (TST) and sleep efficiency (SE) from sleep records as well as Generalized Anxiety Disorder-7 (GAD-7; seven items, four subscales, scale 0–21; lower scores indicate lower generalised anxiety)[28] for anxiety, Patient Health Questionnaire-9 (PHQ-9: nine items, four subscales, scale 0–27; lower scores indicate lower symptom severity of depression)[29] for depression and EuroQol-5D-5L (Euro QOL 5 dimensions 5-level: health status is assessed with five items, five subscales)[30] for quality of life. Treatment responders (reduction of 8 or more points) and remission rates (final score<8) on ISI scores[27] will also be evaluated. To measure the effects of increasing or lowering sleeping pill dosage and the effects of antidepressants and anti-anxiety drugs, medication data (names and dosages) will be collected from medical records and converted to standard equivalents. Adverse events are monitored at each assessment point after receiving information from the GP or patient. Assessments are performed at baseline (week 0), end of the intervention (week 4), post-intervention (week 8) and follow-up (week 12). Sleep data from weeks 0 and 8 will be analysed. The overall dropout rates are calculated post-study.

Randomisation and allocation

After obtaining the consent and completing the baseline survey, the research personnel at each site will register participants in REDCap, where they will be assigned to either the BBTI or SH group in a 1:1 ratio by simple randomisation. Since we use central randomisation independently of the research personnel involved in the patient recruitment, the allocation will be concealed. The results of the allocation will be explained at the start of the intervention. The schedules for the clinical registration, intervention and evaluation are shown in table 1.

Table 1 Schedule of outcome measures

	Baseline	End of intervention	Post	Follow-up
Weeks	0 week	4	8	12
ISI	P	P	P	P
EQ-5D-5L	P	P	P	P
PHQ-9	P	P	P	P
GAD-7	P	P	P	P
SL	D		D	
TST	D		D	
SE	D		D	
WASO	D		D	
Sleeping pills	T	T	T	T
Adverse event	Dr	Dr	Dr	Dr

D, evaluation by sleep diary; Dr, evaluation by doctor; EQ-5D-5L, Euro QOL 5 dimensions 5-level; GAD7, Generalized Anxiety Disorder-7; ISI, Insomnia Severity Index; P, evaluation by patient; PHQ-9, Patient Health Questionnaire-9; SE, sleep efficacy; SL, sleep latency; T, evaluation by therapist; TST, total sleep time; WASO, wake after sleep onset.

Sample size

In a previous meta-analysis of the effects of BBTI on ISI, the effect size was shown to be 0.8 (*Cohens' d*) (Edinger *et al*[31], Appendix pp. 66, Fig. 82). We estimated the sample size based on an effect size of 0.8, an α level of 0.05 (two-sided) and a β level of 0.10 (using SAS V.9.4), resulting in 34 patients per group. Accounting for a 10% dropout rate, the target number is 38 participants per group for a total of 76 participants. The study may be halted early if continuation becomes untenable due to economic, human or physical constraints.

Data analysis plan

Primary analysis

A mixed model for repeated measures will compare changes in ISI scores at 8 weeks, with individuals (intercepts) as random effects, and treatment conditions, evaluation times and their interactions as fixed effects. The covariates will include occupation (employment status), baseline ISI score, age and gender. A two-sided test with an α level of 5% will be used. Effect sizes (Cohen's *d*) using the SD of observed endpoint scores, differences in change scores between groups and their 95% CIs will be estimated.

Exploratory analysis

To complement the primary analysis, additional evaluations of secondary outcomes will be performed. These analyses are exploratory, and multiplicity will not be controlled. We will also perform an analysis that applies the multiple imputation method in addition to a complete case analysis to validate the findings. All analyses will consider statistical significance at $p<0.05$ with two-sided tests.

We will use the same analytical model as for the primary outcome for the ISI at weeks 4 and 12, and for the EQ-5D-5L, PHQ-9 and GAD-7. We will use the same analytical model using the logit link function to analyse the remission and response rates on the ISI.

A cost–utility analysis will examine quality-adjusted life-years (QALYs) gained by collecting health status data with the EQ-5D-5L at baseline and at 4, 8 and 12 weeks, and calculating the area under the curve. The incremental cost-effectiveness ratios will be calculated using costs per QALY over 12 months. Statistical analyses will be conducted using SAS V.9.4.

Sleep latency, wake after sleep onset, total sleep time and sleep efficiency

SL, WASO, TST and SE will be summarised and compared between baseline and at 8 weeks.

Sleep medications and antidepressants/anxiolytic

To make sure there was no amplification of sleeping pills, antidepressants, sleep and anxiolytic medications will be converted to flunitrazepam equivalents[32] and antidepressants to fluoxetine equivalents.[33] Differences in flunitrazepam and imipramine equivalent doses between the groups at each time point will be analysed (independent t-tests). If any participant reduces or discontinues these medications at weeks 0, 4, 8 or 12, the mean changes in the doses will be compared (paired t-tests). The number and proportion of participants who reduce or discontinue their medications will also be determined.

Adverse events and dropout rates

Throughout the 12-week study period, any changes or increases in sleep medication will be recorded. Adverse events will be monitored and documented at weeks 0, 4, 8 and 12. The total number of adverse events will be calculated, and the incidence rates for each group will be determined. Moreover, the overall dropout rate during the study period will be calculated.

Criteria for discontinuing the allocated interventions

The intervention will be discontinued if any of the following criteria are met:

1. A physician determines that continued intervention is inappropriate because of the patient's worsening physical or mental symptoms.
2. The patient requests to discontinue the intervention. If a participant's symptoms worsen, the primary physician will adjust the medication as appropriate; however, the participant will not be excluded from the study unless the discontinuation criteria are met.

Criteria for withdrawing from the study

The patient will be withdrawn from the study (ie, will not be asked for further evaluations) if any of the following criteria are met:

1. A physician determines that continued assessment is inappropriate because of the patient's worsening physical or mental symptoms.
2. The patient requests to withdraw from the study and have no further assessments.

ETHICS AND DISSEMINATION

This study has been approved by the Ethics Committee for Clinical and Epidemiological Research of Toyama University (no. R2023152). Therapists will explain the purpose of the study to interested patients using written materials, emphasising their voluntary participation and assuring their anonymity.

Data collection and aggregation will be conducted using the REDCap system managed by the Clinical Research Management Center of Toyama University. All data will be anonymised using unique identifiers. Any adverse events observed during the study will be reported to the GP, who will decide the intervention and necessary treatments. Serious adverse events will also be reported to the Ethics Committee. If any modifications to the protocol are necessary, they will be reviewed and approved by the Ethics Committee for Clinical and Epidemiological Research of Toyama University. This study is registered with the University Hospital Medical Information Network Clinical Trials Registry (no. UMIN000052911). The study will be reported according to the Consolidated Standards of Reporting Trials recommendations[21] and will be published in international academic journals, regardless of the results.

Patient and public involvement

The patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this study.

DISCUSSION

This study aims to address the gap in CBT-I implementation by evaluating th efficacy of a feasible programme that maintains treatment effectiveness while significantly reducing session duration and frequency, focusing on SR and SC.[7 12] The findings of this study will provide evidence for developing implementable BBTI and establishing treatment algorithms.

One potential limitation is the reliance on subjective ISI and sleep diary assessments. While objective measures, such as polysomnography, could provide independent measures, their relevance is being questioned,[34 35] and their use is costly and burdensome for participants. Therefore, this study adopts the ISI and sleep diary as

recommended by the European insomnia treatment guidelines.[6] Reducing the time required for CBT-I is a crucial strategy to enhance its accessibility. The results of this study will be expected to contribute to treatment strategies of insomnia treatment.

This study aims to target time-related barriers as an entry point to improving access to CBT-I. Nonetheless, whether such a brief intervention can be effectively implemented in routine care remains uncertain; its success may depend on additional contextual factors that warrant further exploration.

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Competing interests MS is employed by the donation from City of Nagoya. MS reports a personal fee from SONY outside the submitted work. SN has received research funding from S'UIMIN for another study. All other authors have no completing interest to declare.

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REFERENCES

1 Roth T, Coulouvrat C, Hajak G, *et al*. Prevalence and perceived health associated with insomnia based on DSM-IV-TR; International Statistical Classification of Diseases and Related Health Problems, Tenth Revision; and Research Diagnostic Criteria/International Classification of Sleep Disorders, Second Edition criteria: results from the America Insomnia Survey. *Biol Psychiatry* 2011;69:592–600.
2 Itani O, Kaneita Y, Munezawa T, *et al*. Nationwide epidemiological study of insomnia in Japan. *Sleep Med* 2016;25:130–8.
3 Ge L, Guyatt G, Tian J, *et al*. Insomnia and risk of mortality from all-cause, cardiovascular disease, and cancer: Systematic review and meta-analysis of prospective cohort studies. *Sleep Med Rev* 2019;48:101215.
4 de Almondes KM, Costa MV, Malloy-Diniz LF, *et al*. Insomnia and risk of dementia in older adults: Systematic review and meta-analysis. *J Psychiatr Res* 2016;77:109–15.
5 Hertenstein E, Feige B, Gmeiner T, *et al*. Insomnia as a predictor of mental disorders: A systematic review and meta-analysis. *Sleep Med Rev* 2019;43:96–105.
6 Riemann D, Espie CA, Altena E, *et al*. The European Insomnia Guideline: An update on the diagnosis and treatment of insomnia 2023. *J Sleep Res* 2023;32:e14035.
7 Edinger JD, Arnedt JT, Bertisch SM, *et al*. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med* 2021;17:255–62.
8 Sun J, McPhillips MV, Chen K-C, *et al*. Primary care provider evaluation and management of insomnia. *J Clin Sleep Med* 2021;17:1083–91.
9 Everitt H, McDermott L, Leydon G, *et al*. GPs' management strategies for patients with insomnia: a survey and qualitative interview study. *Br J Gen Pract* 2014;64:e112–9.
10 Morin CM, Benca R. Chronic insomnia. *Lancet* 2012;379:1129–41.
11 Furukawa Y, Sakata M, Furukawa TA, *et al*. Initial treatment choices for long-term remission of chronic insomnia disorder in adults: a systematic review and network meta-analysis. *Psychiatry Clin Neurosci* 2024;78:646–53.
12 Furukawa Y, Sakata M, Yamamoto R, *et al*. Components and Delivery Formats of Cognitive Behavioral Therapy for Chronic Insomnia in Adults: A Systematic Review and Component Network Meta-Analysis. *JAMA Psychiatry* 2024;81:357–65.
13 Baglioni C, Altena E, Bjorvatn B, *et al*. The European Academy for Cognitive Behavioural Therapy for Insomnia: An initiative of the European Insomnia Network to promote implementation and dissemination of treatment. *J Sleep Res* 2020;29:e12967.
14 Takaesu Y, Sakurai H, Aoki Y, *et al*. Treatment strategy for insomnia disorder: Japanese expert consensus. *Front Psychiatry* 2023;14:1168100.
15 Board of Education of the Japanese Society of Sleep Research. Manual of cognitive behavioral therapy for insomnia. Tokyo: Kongo Publishing Co, 2020.
16 Buysse DJ, Germain A, Moul DE, *et al*. Efficacy of brief behavioral treatment for chronic insomnia in older adults. *Arch Intern Med* 2011;171:887–95.
17 Falloon K, Elley CR, Fernando A, *et al*. Simplified sleep restriction for insomnia in general practice: a randomised controlled trial. *Br J Gen Pract* 2015;65:e508–15.
18 Pigeon WR, Funderburk J, Bishop TM, *et al*. Brief cognitive behavioral therapy for insomnia delivered to depressed veterans receiving primary care services: A pilot study. *J Affect Disord* 2017;217:105–11.
19 Kyle SD, Siriwardena AN, Espie CA, *et al*. Clinical and cost-effectiveness of nurse-delivered sleep restriction therapy for insomnia in primary care (HABIT): a pragmatic, superiority, open-label, randomised controlled trial. *Lancet* 2023;402:975–87.
20 Nagai M, Oe Y, Horikoshi M, *et al*. Evaluation of a Japanese brief CBT-I administered by a nurse: a pilot study. *Prim Health Care Res Dev* 2022;23:e42.
21 Chan A-W, Tetzlaff JM, Altman DG, *et al*. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
22 Hoffmann TC, Glasziou PP, Boutron I, *et al*. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:bmj.g1687.

23 American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed, vol 17. Washington DC: American Psychiatric Association 2013, 2021:263–98.
24 Bastien CH, Vallières A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Med* 2001;2:297–307.
25 Kyle SD, Madigan C, Begum N, *et al*. Primary care treatment of insomnia: study protocol for a pragmatic, multicentre, randomised controlled trial comparing nurse-delivered sleep restriction therapy to sleep hygiene (the HABIT trial). *BMJ Open* 2020;10:e036248.
26 Edinger JD, Wohlgemuth WK, Radtke RA, *et al*. Dose-response effects of cognitive-behavioral insomnia therapy: a randomized clinical trial. *Sleep* 2007;30:203–12.
27 Harvey AG, Bélanger L, Talbot L, *et al*. Comparative efficacy of behavior therapy, cognitive therapy, and cognitive behavior therapy for chronic insomnia: a randomized controlled trial. *J Consult Clin Psychol* 2014;82:670–83.
28 Spitzer RL, Kroenke K, Williams JBW, *et al*. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006;166:1092–7.
29 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9. *J Gen Intern Med* 2001;16:606–13.
30 Brooks R. EuroQol: the current state of play. *Health Policy* 1996;37:53–72.
31 Edinger JD, Arnedt JT, Bertisch SM, *et al*. Behavioral and psychological treatments for chronic insomnia disorder in adults: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med* 2021;17:263–98.
32 The Japanese Society of Psychiatric Rating Scale. Equivalent conversion of anti-anxiety and sleeping pills. Available: http://jsprs.org/toukakansan/2022ver/index.php [Accessed 23 Aug 2024].
33 Hayasaka Y, Purgato M, Magni LR, *et al*. Dose equivalents of antidepressants: Evidence-based recommendations from randomized controlled trials. *J Affect Disord* 2015;180:179–84.
34 Harvey AG, Tang NKY. (Mis)perception of sleep in insomnia: a puzzle and a resolution. *Psychol Bull* 2012;138:77–101.
35 Maltezos A, Perrault AA, Walsh NA, *et al*. Methodological approach to sleep state misperception in insomnia disorder: Comparison between multiple nights of actigraphy recordings and a single night of polysomnography recording. *Sleep Med* 2024;115:21–9.