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# Treating sleep problems in young people at ultra-high-risk of psychosis

**Submission date**
07/09/2020

**Recruitment status**
No longer recruiting

**Registration date**
08/09/2020

**Overall study status**
Completed

**Last Edited**
07/07/2025

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
New evidence has shown that poor sleep is a causal factor in the development of many mental health problems, including psychosis. Psychosis can have major consequences on psychological wellbeing, physical health, relationships, education, and employment. As disrupted sleep has proven to be a major causal factor of psychosis, researchers have developed a psychological sleep treatment. This has been tested in a small study with 12 young people. The results are highly promising. This trial is a feasibility study, which will test the study procedures and develop the treatment further before the researchers conduct a larger study to test if the sleep treatment works.

Who can participate?
People aged 14-25 years who have difficulties sleeping and other difficulties, including worries about other people or hearing voices

What does the study involve?
Participants will be randomly allocated to receive sleep therapy in addition to their usual care or just continue with their usual care. The sleep therapy involves up to eight meetings with a clinical psychologist (therapist) to work on improving sleep and takes place over about 12 weeks. Participants who do not get the sleep therapy will be offered a one-off session with a therapist at the end of the study to talk about ideas to improve their sleep. Everyone who takes part will be asked to meet with a research assessor at the beginning of the study, after 3 months and after 9 months. During these meetings they will be asked to complete questionnaires about sleep, how they've been feeling, and any other concerns they may have. At the end of the study some participants will be invited to take part in an interview with a research worker to talk about their experiences of the study. The interview will take about 45 minutes.

What are the possible benefits and risks of participating?
It is hoped that the sleep therapy will help people sleep better. It is also expected to increase people’s activity levels and improve mood. There are no notable risks of taking part but the questionnaires do ask about sleep and mental health, which may be considered a sensitive topic.

Where is the study run from?
Oxford Health NHS Foundation Trust and the University of Oxford (UK)

When is the study starting and how long is it expected to run for?
June 2020 to January 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Felicity Waite
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Felicity Waite

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
281235

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
IRAS 281235, CPMS 46331

# Study information

### Scientific Title

Treating sleep problems in young people at ultra-high-risk of psychosis: a single-blind parallel-group randomised controlled feasibility trial (SleepWell)

## Acronym
SleepWell

## Study objectives
The primary objective is to assess the feasibility and acceptability of a targeted sleep intervention to prevent psychosis in young people at ultra-high-risk in order to establish the key parameters for a definitive RCT. The secondary research objective is to gather data on clinical outcomes to provide a preliminary indication of the clinical efficacy of the sleep intervention (SleepWell) for young people attending NHS mental health services with sleep problems who are at ultra-high-risk of psychosis.

The hypotheses related to clinical outcomes are:
1. Compared to usual care, the SleepWell therapy added to usual care will reduce insomnia and other sleep disruption (post treatment).
2. Compared to usual care, the SleepWell therapy added to usual care will reduce psychotic experiences (a key marker of psychosis risk) and rates of transition to psychosis (post treatment).
3. Compared to usual care, the SleepWell therapy added to usual care will reduce psychiatric symptoms (depression, anxiety, worry, suicidal ideation), increase activity and social functioning, improve physical health, and enhance quality of life (post-treatment).
4. Treatment effects will be maintained at follow-up.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 19/08/2020, NHS South Central - Oxford A Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8048; oxforda.rec@hra.nhs.uk), ref: 20/SC/0281

## Study design
Prospective parallel-group feasibility randomized controlled trial with single-blind assessment

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Young people (14-25 years) attending NHS mental health services with sleep problems who are at ultra-high-risk of psychosis

## Interventions
Participants are randomised (1:1) to the sleep therapy (SleepWell) added to treatment as usual or treatment as usual.

Participants will be randomised once they have completed the baseline assessment. Participants will be allocated to one of the trial arms using a 1:1 allocation ratio. Randomisation will be

carried out by a validated online system, Sortition, designed by the University of Oxford Primary Care Clinical Trials Unit. Allocation will be carried out using a non-deterministic minimisation algorithm to ensure balance across groups with respect to severity of sleep disturbance (Insomnia Severity Index score <21/≥22) and referring service (early intervention in psychosis team (EIP), child and adolescent mental health services (CAMHS), improving access to talking therapies service (IAPT)).

SleepWell is a psychological intervention designed for young people that precisely targets the key mechanisms which regulate sleep: circadian rhythm, sleep pressure, and hyperarousal. The intervention is delivered on an individual basis in up to eight 1-hour sessions over 12 weeks.

Participants who do not get the sleep therapy will be offered a one-off session with a therapist at the end of the study to talk about ideas to improve their sleep.

Everyone who takes part will be asked to meet with a research assessor at the beginning of the study, after 3 months and after 9 months. During these meetings they will be asked to complete questionnaires about sleep, how they've been feeling, and any other concerns they may have. At the end of the study some participants will be invited to take part in an interview with a research worker to talk about their experiences of the study. The interview will take about 45 minutes.

## Intervention Type
Behavioural

## Primary outcome(s)
The primary outcome measures relate to the feasibility and acceptability of the trial procedures and intervention. The primary clinical outcome is insomnia measured on the Insomnia Severity Index (ISI) at baseline, 3 months, and 9 months.

Feasibility markers measured at baseline, 3 months and 9 months:
1. Recruitment and retention: number of patients identified, recruited, declined and retained
2. Referral procedure: number of referrals made per site, and per service type, per month
3. Service provision and comparator: level and type of service use as measured on the Client Service Receipt Inventory (CSRI)
4. Data collection methodology: completion rate of each assessment measure, including wearable-teach devices, and time taken to complete each assessment
5. Acceptability of the intervention: location and attendance at treatment sessions; content covered in treatment sessions; feedback from qualitative interviews; treatment acceptability score (AARP)
6. Health economic data collection: service use data completeness, and time taken to collect service use data

## Key secondary outcome(s))
Measured at baseline, 3 months and 9 months:
1. Sleep disturbance measured using ISI; SLEEP-50 CRD subscale; sleep diary; actigraphy; fatigue scale
2. Attenuated psychotic experiences measured using CAARMS; SPEQ-H; R-GPTS; CEFSA
3. Psychiatric symptoms measured using DASS-21; CSSRS; DWQ; BCSS
4. Activity and social functioning measured using time budget; WASA; SROBAT; actigraphy
5. Physical health measured using BMI; step-count; BESAA; PHQ15; MAP

6. Quality of life measured using QPR; ReQoL; EQ5D
7. Service use measured using CSRI and medication
8. Participant ranking of clinical outcome variables

### Completion date
31/01/2023

## Eligibility

### Key inclusion criteria
1. Aged 14-25 years
2. Patient of mental health services (at the time of referral to the study)
3. Meet diagnostic criteria for ultra-high-risk of psychosis on the Comprehensive Assessment of At-Risk-Mental States
4. Experiencing current sleep problems (defined as a score >15 on the Insomnia Severity Index)
5. Would like help to improve sleep
6. Participant is willing and able to give informed consent (or assent with parent/guardian consent for participants aged 14-15 years) for participation in the trial

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
14 years

### Upper age limit
25 years

### Sex
All

### Total final enrolment
40

### Key exclusion criteria
1. Diagnosis of a primary severe mental health problem (including psychosis, bipolar disorder, personality disorder)
2. A primary diagnosis of alcohol/substance dependency, organic syndrome or learning disability
3. Likely primary diagnosis of sleep apnoea (established using the STOP-BANG screen)
4. Current engagement in any other individual psychological therapy
A participant may also not enter the trial if there is another factor (for example, current active suicidal plans, high risk for severe course of COVID-19), which, in the judgement of the investigator, would preclude the participant from providing informed consent or from safely engaging with the trial procedures

**Date of first enrolment**
01/11/2020

**Date of final enrolment**
31/01/2022

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Oxford Health NHS Foundation Trust**
Warneford Hospital
Warneford Lane
Headington
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**Study participating centre**
**Berkshire Healthcare NHS Foundation Trust**
Fitzwilliam House
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RG12 1JX

# Sponsor information

**Organisation**
University of Oxford

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**

Government

### Funder Name
National Institute for Health Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Felicity Waite (felicity.waite@psych.ox.ac.uk) after the publication of the main trial outcomes.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 04/08/2023 | 14/08/2023 | Yes | No |
| Protocol article | | 10/11/2020 | 03/12/2024 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Other publications | Peer methods qualitative evaluation | 06/07/2025 | 07/07/2025 | Yes | No |
| Participant information sheet | version V1.1 | 17/08/2020 | 08/09/2020 | No | Yes |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |