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# Sleeping Better

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 04/03/2024 | Recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 26/03/2024 | Ongoing | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 17/11/2026 | Mental and Behavioural Disorders | [X] Record updated in last year |

## Plain English summary of protocol

Background and study aims

“I have now got the motivation to go out and start showing people what I can do. I have signed up to go back to college to go back into education and learn again.” Toby (after sleep therapy)

Most people with psychosis report sleep problems that are troubling for them, that exacerbate affective and psychotic symptoms, and that make thinking and everyday functioning more difficult. We want to follow through on the implications of what patients are telling us: that sleep problems are a problem in their own right and that successful treatment will bring numerous additional benefits. We aim therefore to conduct the first definitive test of the idea that psychological therapy can help people with psychosis to enjoy greatly improved sleep and that this will lead to gains in many other aspects of people’s lives.

Our team has pioneered the treatment of sleep problems in psychosis, conducting feasibility trials with patients at ultra-high risk of psychosis, with patients diagnosed with psychosis, and with people admitted to psychiatric hospital. In each trial the eight-session intervention has achieved large effect size improvements in sleep.

Who can participate?

1. Participants at ultra-high risk of psychosis - people aged 14 years and above who have difficulties sleeping, and who are attending NHS mental health services for difficulties such as worries about other people or hearing voices.

Or

2. Participants with a diagnosis of (non-affective) psychosis - adults (aged 16 years+) who have difficulties sleeping, and who are attending NHS mental health services for conditions such as schizophrenia.

What does the study involve?

To find out whether the Sleeping Better therapy works, half of the people who take part will have the sleep therapy and half will not. Whether a person has the therapy is decided randomly decided by a computer. The sleep therapy is provided in around eight sessions over 12 weeks. The research team then see how people have got on with and without the therapy. Everyone will meet a research assistant to conduct the assessments to find out if things have changed. These assessments will be at the beginning and then after 12 and 24 weeks.

What are the possible benefits and risks of participating?

The research team do not think there are any major risks in taking part in the study. Taking part

will not affect a person's usual NHS care. It is hoped that the sleep therapy will help people’s sleep and that will lead to improved mood, concentration, and thinking.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
September 2023 to September 2028

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
1. Miss Natalie Rouse, natalie.rouse@psy.ox.ac.uk
2. Prof. Daniel Freeman, daniel.freeman@psy.ox.ac.uk
3. Dr Felicity Waite, felicity.waite@psy.ox.ac.uk

# Contact information

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Scientific

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## Additional identifiers

### Integrated Research Application System (IRAS)
330747

### Central Portfolio Management System (CPMS)
57022

### Protocol serial number
226718/Z/22/Z

## Study information

### Scientific Title
A randomised controlled trial testing the effects of treating sleep difficulties in patients at ultra-high risk of psychosis and patients diagnosed with non-affective psychosis (Sleeping Better)

### Study objectives
This study aims to demonstrate the effects on psychiatric symptoms (mood and psychotic experiences) and cognition of treating sleep and circadian rhythm problems (such as insomnia, hypersomnia, circadian rhythm disorder, nightmares) that are common in individuals at ultra-high risk of psychosis and individuals with diagnosed non-affective psychosis. We will conduct separate tests of the effects of sleep treatment for people at ultra-high risk of psychosis and a diagnosis of non-affective psychosis.

For patients at ultra-high risk of psychosis and patients with a diagnosis of non-affective psychosis who have sleep difficulties can a brief sleep therapy, added to treatment as usual, compared to treatment as usual, improve sleep? The primary time-point is 12 weeks (end of treatment) from randomisation. The outcome measure is the Insomnia Severity Index.

Compared to treatment as usual, does sleep therapy at the end of treatment (12 weeks) lead to improvement in psychiatric symptoms (mood, psychotic experiences) and cognitive functioning? Mood will be depression scores (PHQ-9), psychotic experiences will be persecutory ideation (R-GPTS Part B), and cognitive functioning will be a composite score from subtests of the MATRICS Consensus Cognitive Battery.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 01/02/2024, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8021; southyorks.rec@hra.nhs.uk), ref: 24/YH/0018

## Primary study design
Interventional

## Study design
Randomized; Interventional; Design type: Treatment, Psychological & Behavioural

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Sleep difficulties in patients at ultra-high risk of psychosis and patients diagnosed with non-affective psychosis

## Interventions
A multi-centre two-arm randomised controlled trial testing the addition of the sleep therapy to treatment as usual (TAU) against TAU. There will be two cohorts within the trial, with 554 patients at ultra-high risk of psychosis and 554 patients diagnosed with psychosis. Assessments will be conducted by research assistants blind to group allocation at 0, 12 (end of treatment), and 24 weeks. Moderation and mediation tests are built into the trial design.

A screening meeting will be conducted with referred patients to assess suitability. Following the provision of informed consent, the baseline assessment will be carried out. The assessments will take about two hours each and will involve the completion of questionnaires on, for example, sleep, mood, and activities, and tasks assessing memory, concentration, and problem-solving. After the baseline assessment participants will be randomly allocation to receive sleep therapy in addition to their usual care or to continue with their usual care. The sleep therapy is a type of cognitive behavioural therapy (CBT) and will be delivered in approximately eight sessions over 12 weeks. The treatment is personalised and the number and length of sessions may vary according to a person’s need. The treatment aims to achieve regular sleep at the correct time of day.

## Intervention Type

Other

### Primary outcome(s)
Sleep is measured using the Insomnia Severity Index at 0, 12 (primary end point), 24 weeks

### Key secondary outcome(s)
Measured at 0, 12 and 24 weeks:
1. Psychiatric symptoms (mood, psychotic experiences) and cognitive functioning measured using PHQ-9, R-GPTS Part B, a composite MATRICS score (mean T-score of administered tests)
2. Sleep assessed using Consensus Sleep Diary
3. Cognitive functioning measured using Bell Lysaker Emotion Recognition Task (BLERT) (emotion recognition)
4. Subjective measures of cognitive abilities and functioning: the self-report Scale to Investigate Cognition in Schizophrenia (SSTICS-Brief)
5. Functioning measured using the Time Use Survey, capturing time spent in structured activity including work, education, housework, and leisure, Work and Social Adjustment Scale, actigraphy to capture physical movement
6. Psychiatric symptoms:
6.1. Anxiety measured using GAD-7
6.2. Suicidal ideation measured using the Beck Scale for Suicide Ideation (BSS-5)
6.3. Hallucinations measured using Cardiff Anomalous Perceptions Scale – hallucination items
6.4. Negative symptoms measured using Self-assessment of Negative Symptoms (SNS)
6.5. Comprehensive Assessment of At-Risk-Mental-States-23 (CAARMS) (in UHR group only)
7. Quality of life measured using EQ-5D-5L, ReQol, Warwick-Edinburgh Mental Well-being Scale

### Completion date
30/09/2028

## Eligibility

### Key inclusion criteria
1. Aged 14 years or above
2. Patient of mental health services (at the time of referral to the trial), or for young people at UHR seeking help
3. Have a clinical diagnosis of schizophrenia spectrum psychosis (i.e. non-affective psychosis) (ICD-10 codes F20–29) or meet diagnostic criteria for ultra-high risk of psychosis on the Comprehensive Assessment of At-Risk-Mental-States (CAARMS)
4. Experiencing current sleep problems (score > 14 on the Insomnia Severity Index) and would like help to improve sleep
5. Willing and able to give informed consent (or assent with parent/guardian consent for participants aged 14 to 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
120 Years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Likely primary diagnosis of sleep apnoea (using the STOP-BANG screen [Chung et al, 2016])
2. A primary diagnosis of another mental health condition (e.g. substance use disorder) that would be the first clinical priority to treat
3. In forensic settings or Psychiatric Intensive Care Unit (PICU)
4. Command of spoken English inadequate for engaging in the trial
5. Current receipt of significant other psychological therapy or significant change in medication or in another intervention study
6. A participant may also not enter the trial if there is another factor (for example, current active suicidal plans that need to the focus of intervention), which, in the judgement of the investigator, would preclude the participant from providing informed consent or from safely engaging with the trial procedures. Reason for exclusion will be recorded.

### Date of first enrolment
20/05/2024

### Date of final enrolment
31/03/2028

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Warneford Hospital**
Warneford Lane
Headington
Oxford
England
OX3 7JX

### Study participating centre

**Berkshire Healthcare NHS Trust Headquarters**
Skimped Hill Lane
Bracknell
England
RG12 1LH

**Study participating centre**
**Northamptonshire Healthcare NHS Foundation Trust**
St Marys Hospital
77 London Road
Kettering
England
NN15 7PW

**Study participating centre**
**Central and North West London NHS Foundation Trust**
Trust Headquarters
350 Euston Road
Regents PLACE
London
England
NW1 3AX

**Study participating centre**
**Avon and Wiltshire Mental Health Partnership NHS Trust**
Bath NHS House
Newbridge Hill
Bath
England
BA1 3QE

**Study participating centre**
**Gartnavel Royal Hospital**
1055 Great Western Road
Glasgow
Scotland
G12 0XH

**Study participating centre**
**St Nicholas Hospital (newcastle upon Tyne)**
Jubilee Road, Gosforth

Newcastle upon Tyne
England
NE3 3XT

**Study participating centre**
**Sussex Partnership NHS Foundation Trust**
Trust Hq
Swandean
Arundel Road
Worthing
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BN13 3EP

# Sponsor information

**Organisation**
University of Oxford

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

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Wellcome Trust

**Alternative Name(s)**
Wellcome, WT

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

Requests, accompanied by a study summary, for sharing of de-identified data will be considered by the Chief Investigator (daniel.freeman@psy.ox.ac.uk) and the team. The intent is to share data for reasonable requests. Data will be made available to external researchers subject to the constraints of the consent under which data were collected, with an appropriate data sharing agreement, and after publication of the main study report.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 17/11/2026 | No | No |