

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

Submission date 07/09/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 08/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/07/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

felicity.waite@psych.ox.ac.uk

Study website

<https://www.psych.ox.ac.uk/research/oxford-cognitive-approaches-to-psychosis-o-cap/projects-1/sleepwell>

Contact information

Type(s)

Scientific

Contact name

Dr Felicity Waite

ORCID ID

<https://orcid.org/0000-0002-2749-1386>

Contact details

Department of Psychiatry

Warneford Hospital

Oxford

United Kingdom

OX3 7JX

+44 (0)1865 618192

felicity.waite@psych.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

281235

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

See study outputs table

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 $<21/\geq 22$) 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 measure

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

Secondary outcome measures

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

Overall study start date

01/06/2020

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

Age group

Mixed

Lower age limit

14 Years

Upper age limit

25 Years

Sex

Both

Target number of participants

40

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

England

United Kingdom

Study participating centre

Oxford Health NHS Foundation Trust

Warneford Hospital

Warneford Lane

Headington

Oxford

United Kingdom

OX3 7JX

Study participating centre

Berkshire Healthcare NHS Foundation Trust

Fitzwilliam House

Skimped Hill Lane

Bracknell

United Kingdom

RG12 1JX

Sponsor information

Organisation

University of Oxford

Sponsor details

Clinical Trials & Research Governance

Research Services

Oxford

England

United Kingdom

OX3 7GB

+44 (0)1865 289885

ctrng@admin.ox.ac.uk

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

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

Publication and dissemination plan

1. Once the study has been registered with ISRCTN the protocol will be submitted for publication. Once the protocol is published, a copy will be added to the ISRCTN record.
2. The results of the trial will be published in a peer-reviewed journal and made open access. An anonymised version of the main outcome data will be available from the trial team on reasonable request after publication of the main results paper.

Intention to publish date

01/12/2023

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?
Participant information sheet	version V1.1	17/08/2020	08/09/2020	No	Yes
HRA research summary			28/06/2023	No	No
Results article		04/08/2023	14/08/2023	Yes	No
Protocol article		10/11/2020	03/12/2024	Yes	No
Other publications	Peer methods qualitative evaluation	06/07/2025	07/07/2025	Yes	No