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Exploring how sleep and activity information can support patients, carers, family members and clinical teams during inpatient stays on mental health wards

Submission date
11/01/2024

Recruitment status
No longer recruiting

Registration date
02/07/2024

Overall study status
Completed

Last Edited
02/08/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Although there are links between sleep and mental health, it is difficult to measure someone's sleep without disturbing them. This study will explore whether prototype contact-free sleep measurement software, and contact-free activity metrics, can be useful to patients, their carers and family members, and clinicians in understanding patterns of sleep and activity during inpatient mental health care.

Who can participate?
People aged 18 years or older can take part if they are adult patients on an inpatient mental health ward where a contact-free monitoring system is already used as part of routine care. They will only be approached about the study if they have capacity to decide whether to take part and if their care team feel that taking part in the study will have no negative effects for the patient.

What does the study involve?
If a patient gives written informed consent to take part in the study, data from their stay in the hospital will be processed by new software to generate prototype reports showing patterns of sleep and activity. These prototype reports will be shown to the patient so that they can give feedback on the reports and whether or not they would find them useful (for example in understanding how their sleep patterns may change during a stay in hospital).
The patient can choose whether the reports are shown to one of their carers or family members, to ask for their feedback.
The reports will also be shown to the clinical team on the ward to gather their feedback.
The patient will leave the study at the end of their stay on the ward, or they can choose to leave the study any time before then.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part in the study, although patients may find it interesting to give their feedback on the prototype reports. The study is designed to have no effect on the

patient’s usual care (such as the patient’s treatment, routine usage of the contact-free monitoring system by staff, or how long the patient stays in hospital).

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

When is the study starting and how long is it expected to run for?
October 2023 to August 2025

Who is funding the study?
Oxehealth Limited (UK)

Who is the main contact?
Prof. Dan Joyce, d.joyce@liverpool.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
337784

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 337784, CPMS 60339

Study information

Scientific Title
Sleep and activity patterns to support mental health inpatient care

Acronym
SAP

Study objectives
This study will investigate whether prototype contact free sleep and activity reports might be useful to support patients, their carers or family members, and clinicians in inpatient settings. It will also explore the relationships between patterns of sleep and activity and psychiatric conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/04/2024, South Central - Oxford C Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London , E20 1JQ, United Kingdom; +44 (0)207 104 8271; oxfordc.rec@hra.nhs.uk), ref: 24/SC/0055

Study design
Exploratory cohort observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Inpatient mental health

Interventions
Patients on mental health inpatient wards will be approached about the study, with the permission of their care team and if they have capacity to decide whether to take part. If a patient gives written informed consent to take part in the study, prototype sleep and activity reports will be generated for the period of their stay on the ward. The patient will be asked to give feedback on the prototype reports. With the patient's permission, a carer or family member may also be approached about the study and, if they give written informed consent, asked for feedback on the prototype reports. The clinical team on the ward will also be asked for feedback on the prototype reports.

Intervention Type
Other

Primary outcome(s)
The utility of prototype sleep and activity reports for patients, their carers and clinicians is measured using semi-structured interviews to gather qualitative data. Each participant will

undertake one interview towards the end of their participation in the study. The outcome will be measured by identifying and summarising key themes from the interview responses.

Key secondary outcome(s))
1. Patterns of sleep and activity measured by processing anonymised data for the duration of their stay on the ward, when written informed consent to participate is provided by a patient.
2. Patient diagnoses, symptoms, treatment or stage of recovery measured by extracting anonymised information from the patient records, for the duration of their stay on the ward, when written informed consent to participate has been given. As part of standard care, these data are recorded in the patient records whenever new information is gathered by the care team.
3. Occurrences of sleep disturbance on the ward (such as night-time visits by staff conducting periodic observations) measured using the sleep and activity data generated by processing anonymised data as above for the duration of the patient's stay on the ward, to be measured at the time of discharge.

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Adult (aged 18 years or older)
2. Currently an inpatient on a ward where the Oxevision system is already in routine clinical use
3. The Oxevision system has been used during their routine care (dependent on Trust policies)
4. Able to understand the study (patient information sheets and informed consent process)
5. Has the capacity to make an informed decision about whether to take part and to decide whether to withdraw consent at any later stage
6. Able to give written informed consent if they wish to take part

Participant type(s)
Health professional, Carer, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. On the basis of clinical expert opinion of the multidisciplinary team, being approached and/or taking part in the study might cause additional anxiety or distress to the patient or be unhelpful to their recovery

Date of first enrolment

29/07/2024

Date of final enrolment
15/04/2025

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Oxehealth Limited

Funder(s)

Funder type
Industry

Funder Name
Oxehealth Limited

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available to ensure that the confidentiality of participants is maintained.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes