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Light-dark and activity rhythm therapy for sleep: a study to explore the practicality of delivering the therapy, and participant's experiences and views of whether the intervention is acceptable, in people with schizophrenia spectrum disorders

Submission date
13/01/2020

Recruitment status
No longer recruiting

Registration date
17/02/2020

Overall study status
Completed

Last Edited
14/11/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The researchers have been looking at existing evidence and surveying the views of relevant experts on how to improve sleep-wake patterns in people with schizophrenia and related disorders. From this work they have designed a therapy, with the help and involvement of people with relevant lived experience along the way. The aim of this study is to test whether they can deliver the therapy as planned, how acceptable people find it, and how much they are able to stick to it.

Who can participate?
People aged over 18 with a diagnosis of schizophrenia spectrum disorder (schizophrenia, schizoaffective disorder, delusional disorder, schizotypal disorder), who also have problems with falling asleep, staying asleep, sleep timing, or sleep quality.

What does the study involve?
An occupational therapist sees each participant for 6-9 sessions plus 3-6 phone calls to give Light-Dark and Activity Rhythm Therapy (L-DART). L-DART focuses on light exposure patterns across the day, the type of activities people are doing and when, and when people go to bed and get up. It includes education about sleep and the body clock, homework activities, using wearable technology to track and alter light exposure and activity timing, and making changes to the home environment. The researchers measure things that they hope to possibly improve through the intervention, like sleep, daytime functioning, wellbeing, and mental health symptoms, but the main purpose in this study is to see how acceptable and practical the sleep therapy is to deliver and test. A big part of this will be based on individual interviews with participants after they have received the intervention.

What are the possible benefits and risks of participating?
Payment is offered for time spent completing measures on three occasions (3 x £10), up to 45 minutes each. The researchers can't pay travel expenses, but can come to participants or meet somewhere convenient for them. There may be no benefit to participants. The aim is that this research will help others with similar problems in future. Participants will receive an activity tracking watch, a wake-up light alarm, and a light box if relevant (if they find these helpful they can keep them at the end of the study). Participants receive blackout curtains and net curtains if they need them (which they can keep). It is hoped that L-DART will help participants improve their sleep, but the researchers don't currently have evidence to say that this therapy will improve sleep because it is new. It is hoped that even if L-DART doesn't improve sleep, that participants might be pleased with some of the changes they make to their daytime activity routines. It is possible that answering questions about their sleep could cause participants to think about or discuss something distressing. They can take a break at any time, or ask for support. It is possible that by making changes designed to improve their sleep in the long term, might mean that participants get less sleep in the short term. Using light therapy boxes can give some people a feeling of eye strain or a headache, this should go away if they stop using the light box. Some people get used to the light box so that it no longer causes them discomfort, or sit farther away to reduce the brightness. Light therapy boxes don't cause sunburn, but the sun can. The researchers will talk about how to avoid sunburn when they talk about going outside more. Shortening time in bed and increasing light exposure could possibly cause mania, so far research shows this is rare, but the researchers will monitor this especially if the participants have had mania before. The opposite - too long in bed and too little light - can contribute to low mood and low energy, so there is a balance to be struck. Pushing participants outside of their usual routine can feel risky or anxiety provoking, but the researchers think this is positive risk taking. They will support participants to choose the right level of challenge and to set goals which suit them, so that risks and effort are more worth it. The researchers have some smartphones they can lend to people who need them. Participants don't have to be very technical to use the app, as it just shows activity graphs.

Where is the study run from?
1. Greater Manchester Mental Health NHS Foundation Trust (UK)
2. Pennine Care NHS Foundation Trust (UK)
3. University of Manchester (UK)

When is the study starting and how long is it expected to run for?
September 2019 to July 2022 (updated 04/03/2022, previously: March 2022; updated 05/01/2021, previously: January 2021)
The survey begins recruiting in January 2021 and intervention study in April 2021 (added 05/01/2021)

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

Who is the main contact?
Sophie Faulkner
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Study website
http://sleepot.org/L-DART-FitSz/

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
268874

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44512, IRAS 268874

Study information

Scientific Title
Light-dark and activity rhythm therapy for sleep: feasibility and acceptability in schizophrenia spectrum disorders (L-DART FitSz)

Acronym
L-DART FitSz

Study objectives
To explore the feasibility and acceptability of delivering and larger scale testing the intervention Light-Dark and Activity Rhythm Therapy for sleep (L-DART) in schizophrenia spectrum disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/03/2020, Greater Manchester South REC (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8063; gmsouth.rec@hra.nhs.uk), ref: 20/NW/0059

Study design
Mixed methods single-group feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
http://sleepot.org/L-DART-FitSz/

Health condition(s) or problem(s) studied
Sleep problems in people with schizophrenia spectrum disorders

Interventions
An occupational therapist will see each participant for 6-9 sessions plus 3-6 phone calls to give Light-Dark and Activity Rhythm Therapy (L-DART). L-DART focuses on light exposure patterns across the day, the type of activities people are doing and when, and when people go to bed and get up. It includes education about sleep and the body clock, homework activities, using wearable technology to track and alter light exposure and activity timing, and making changes to the home environment.

Intervention Type
Behavioural

Primary outcome measure
Acceptability, adherence and feasibility of delivery based on data triangulated from the following sources:
1. Qualitative interview data (pre and post intervention)
2. Satisfaction Likert ratings (weekly throughout intervention)
3. Therapy adherence (completion of homework tasks, adherence to light and activity recommendations goals and agreements) (completed by therapist throughout)
4. Therapy delivery fidelity log (completed by therapist after sessions)
5. Attendance logs (% attendance) (completed by therapist after sessions)
6. Recruitment rates (% of those eligible and approached who consent, total number recruited by end of study)
7. Reasons for declining participation
8. Attrition (% of participants who consent to participate that remain in the study until the end of therapy, and until the end of follow up)

9. Reasons for attrition (e.g. therapy-related, study measure related, other reasons, no reason given)

Secondary outcome measures
1. Sleep disturbance measured by Insomnia Severity Index (ISI) & PROMIS-SD 8a (Sleep Disturbance)
2. Sleep-related impairment of functioning measured by PROMIS-SRI 8a (Sleep-Related Impairment)
3. Wellbeing and quality of life measured by Warwick–Edinburgh Mental Wellbeing Scale (WEMWBS) & EQ 5D-5L (5-level EQ-5D version, EuroQol)
4. Social and occupational functioning measured by PROMIS-AP 8a (Ability to Participate in social roles and activities)
5. Psychiatric symptoms measured by Clinical Global Impression-Schizophrenia (CGI-SCH)

The above will be measured at week 1 (pre-intervention), week 17 (post intervention), and week 29 (follow up). PROMIS-SD 8a will also be used each week during therapy to track change over time.

Overall study start date
02/09/2019

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Diagnosis of non-affective psychosis: Schizophrenia, Schizotypal disorder, Delusional disorder, Schizoaffective disorder (ICD-10 F20, F21, F22, F25, F28 / DSM 295.*, 297.1)
2. Open to secondary care mental health services in Greater Manchester Mental Health and NHS Foundation Trust (GMMH) or Pennine Care NHS Foundation Trust (Pennine Care)
3. Aged over 18 years
4. Expresses dissatisfaction with their sleep (length of time to fall asleep, amount of sleep, subjective sleep quality, broken sleep, unrefreshing sleep, difficulty waking up, unsatisfactory timing of sleep)
5. Interested in receiving the intervention

Staff survey sub-study sample:
The person is a member of staff, a student, or a volunteer at GMMH or Pennine Care, or at a third sector service and working with service users of GMMH or Pennine Care (the person is a potential referrer or potential future referrer)

(added 05/01/2021) Anonymous service user survey sub-study:
The person is a service user at GMMH or Pennine Care, or at a third sector service and working with service users of GMMH or Pennine Care (the person is a service user or potential service user of GMMH or Pennine). No specific diagnosis inclusion criteria

Participant type(s)
Mixed

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10 feasibility study participants (+250 staff survey participants, +250 anonymous service user survey participants)

Total final enrolment
347

Key exclusion criteria
1.1. Change of medication within the last 1 month
1.1. Discharged from hospital within the last 1 month
1.3. Current inpatient or acuity of illness requiring home treatment team
1.4. Actively suicidal (expressing suicidal plans or intent)
1.5. Risk to others prevents lone visiting
2.1. Known untreated significant sleep apnoea (AHI Index >20, or symptomatic)
2.2. Primary complaint is of sleep apnoea, sleep related movement disorder or parasomnia
2.3. Diagnosis of narcolepsy or REM sleep behaviour disorder
3. Co-morbid learning disability, dementia, or moderate to severe neurological impairment
4. Alcohol or substance dependent (unsuitable if using heavily every day and/or not able to be sober for sessions).
5. No fixed abode
6. Does not have capacity to give informed consent

There are no exclusion criteria for the staff survey

(added 05/01/2021) There are no exclusion criteria for the anonymous service user survey, but staff recruiting will be advised not to ask anyone who would find completing a brief survey confusing or distressing (although no sensitive topics are covered)

Date of first enrolment
09/01/2021

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old St
Ashton-under-Lyne
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Study participating centre
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Sponsor type
University/education

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
The researchers will publish the results in a scientific journal, and in more accessible forms, including sending participants summaries of the research findings.

Intention to publish date
15/12/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Results article		04/12/2023	27/12/2023	Yes	No