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Well-Track: Wearable activity/sleep tracker for health & wellbeing

Submission date
11/02/2021

Recruitment status
No longer recruiting

Registration date
19/04/2021

Overall study status
Completed

Last Edited
04/09/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Poor sleep hygiene and low levels of physical activity are linked to poor mental and physical health in people experiencing psychosis. People with experience of psychosis are more likely to have low levels of physical activity and high levels of sedation and sleep disorders are common (80% of people with psychosis). Low levels of psychical activity and poor sleep in psychosis are thought to be connected.

Regular physical activity has a beneficial impact on well-being and is an effective preventative strategy against many chronic medical conditions. For people with psychosis, engaging in physical exercise is associated with improved symptoms of psychosis, quality of life, functioning, and physical health. In patients with mental health disorders sleep problems should be assessed, monitored, and treated, and sleep hygiene advice for sleep problems in psychosis may be beneficial.

Studies have shown that people with serious mental illness find wearing a Fitbit activity/sleep tracker to be acceptable, motivating, and useful for enabling goal setting and healthier lifestyles. Using a Fitbit tracker and providing sleep hygiene advice and training and physical exercise advice and opportunities could improve wellbeing and physical health in people with psychosis.

This study aims to investigate the impact of using a Fitbit tracker and providing sleep and physical exercise advice on sleep, physical activity, wellbeing, and health in people with psychosis. The study will also explore how best to integrate similar advice and use of technology in mental health services.

Who can participate?
Early psychosis service patients aged 18 to 65 years

What does the study involve?
Participants who are in an early psychosis service will be offered the use of a Fitbit, sleep hygiene advice/training, and physical exercise advice/opportunities for an 8 week period with the aim of enhancing wellbeing and physical health. All participants receive the same

programme. If participants are identified as having sleep problems they will also be offered the 'Sleepio' on-line sleep hygiene training programme, which has demonstrated significant reductions in insomnia, paranoia, and hallucinations.

In-depth interviews will be used to explore participant experiences of the programme, factors influencing physical activity and sleep, and to gain an understanding of how participants can best use technology, sleep hygiene and physical exercise advice.

What are the possible benefits and risks of participating?
Participants may find the Fitbit, sleep and exercise advice, and engagement useful, as it may improve sleep, mental health, and physical health. Participants may benefit from having the opportunity to describe their experiences and so be able to make sense of and process these with a receptive listener. They may find it therapeutic or useful to enable reflection or feel affirmed from recalling what has been good about their experiences. They may feel a sense of contribution as their feedback and ideas may improve care and treatment for others.

Having a Fitbit, completing brief assessments, providing feedback, and being interviewed is not considered to have a high risk of harm. Participants may find discussing issues related to mental and physical health, physical exercise, and sleep uncomfortable or distressing.

Where is the study run from?
Northamptonshire Healthcare NHS Foundation Trust

When is the study starting and how long is it expected to run for?
From January 2021 to December 2021

Who is funding the study?
The project is funded by UK Research and Innovation (UKRI) through the University of York 'Closing the Gap' Network (UK)

Who is the main contact?
Dr. Chris Griffiths, chris.griffiths@nhft.nhs.uk

Study website
https://www.york.ac.uk/healthsciences/closing-the-gap/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295193

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V1, IRAS 295193

Study information

Scientific Title
The Well-Track project: mental health service integration of wearable activity and sleep trackers for improving health and wellbeing in early psychosis

Acronym
Well-Track

Study objectives
The study will ask:
1. What is the impact of the intervention on sleep, physical activity, weight, wellbeing, and mental health?
2. What are the links between patient factors, measures of sleep, physical activity, weight, wellbeing, and mental health?
3. What are the experiences and feedback of patients?

The aims of the study are that:
1. Participants will be empowered to have improved control over their sleep, physical activity, health, and wellbeing
2. Participants will have better sleep, physical fitness, health, and wellbeing
3. The study team will gain an understanding of how people with experience of psychosis can best use technology, sleep hygiene, and physical exercise advice/opportunities
4. The study team will gain an insight into how participants involve friends, carers, family, and professionals in staying fit and healthy
5. The study team will gain an understanding of how project intervention can be integrated into services and benefits can be maximised

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2021, Leicester South REC (Health Research Authority, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8115; helen.poole@hra.nhs.uk), REC ref: 21/EM/0047

Study design
Single-site mixed-method design non-randomized study with no control, employing pre and post measures

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
First or early psychosis

Interventions
The study involves an 8 week intervention using a Fitbit, sleep hygiene advice/training and physical exercise advice/opportunities for patients in an early psychosis service. If people are identified as having sleep problems they will be offered the 'Sleepio' on-line sleep hygiene training programme, which has demonstrated significant reductions in insomnia, paranoia and hallucinations.

Intervention Type
Mixed

Primary outcome measure
BMI calculated from weight and height measured at baseline and 8 weeks

Secondary outcome measures
1. Physical activity measured using steps and intensive activity collected by the Fitbit between baseline and 8 weeks
2. Sleep measured using the duration of sleep and wake after sleep onset (WASO) collected by the Fitbit between baseline and 8 weeks
3. Well-being measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) collected at baseline and 8 weeks
4. Positive and negative affect measured using the Positive and Negative Affect Schedule (PANAS) collected at baseline and 8 weeks

Overall study start date
01/01/2021

Completion date
06/12/2021

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years
2. Patient of early psychosis service
3. Understands written and oral English
4. Based in the community

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
41

Key exclusion criteria
1. Unable to wear a watch-like device on their wrist
2. Do not have capacity to consent

Date of first enrolment
01/03/2021

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Mary's Hospital
Kettering
United Kingdom
NN15 7PW

Sponsor information

Organisation
Northamptonshire Healthcare NHS Foundation Trust

Sponsor details
Berrywood Hospital
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Sponsor type
Hospital/treatment centre

Website
https://www.nhft.nhs.uk/

ROR
https://ror.org/0358tcd02

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings will be disseminated through peer-review journals, media sources and conferences.

Intention to publish date
01/02/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/02/2022	08/02/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/04/2022	04/09/2023	Yes	No
Results article		26/04/2022	04/09/2023	Yes	No