

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

Submission date 11/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/04/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/09/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

295193

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

BMI calculated from weight and height measured at baseline and 8 weeks

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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

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

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly 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
Results article		01/04/2022	04/09/2023	Yes	No
Results article		26/04/2022	04/09/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes