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An online exercise intervention for young adults in early intervention for psychosis services

Submission date 06/04/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/04/2023	**Overall study status** Completed	
Last Edited 20/04/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims

People with mental illness experience drastic inequalities in physical health, having a 2-3 fold risk of cardiometabolic diseases, and a ~15 years reduced life expectancy compared to the general population. This is mostly due to a lack of access to sufficient health care, side effects of psychotropic medications, and heightened risk of adverse health behaviours observed in mental health populations. While there is an increasing amount of investment, research and innovation around using digital technologies to improve the health behaviours and physical fitness of the general population, the uses of such technologies for improving physical health in mental health populations are not widely studied. If this vulnerable population continues to be 'left behind' from technological advances in health promotion, this could ultimately result in even greater health disparities arising for people with mental illness over time. To begin addressing this gap, this study will examine the acceptability, feasibility and outcomes of using digital technology to support a remotely-delivered exercise and lifestyle intervention in young adults receiving treatment for a severe mental illness - specifically, First Episode Psychosis (FEP).

Who can participate?

Current service users of Early Intervention in Psychosis services, aged 18-35 years old

What does the study involve?

For this study, ~32 participants with FEP will be recruited from Early Intervention Services (EIS) in the NHS. All participants will be provided with a Fitbit Inspire wearable device for the duration of the study (8 weeks), and access to the FitBit premium app. A non-randomised crossover design will be used to assign participants to either the FitBit-only control condition or the 'Remote Exercise and Lifestyle' (REAL) intervention group (which receives twice-weekly supervised online exercise sessions). Participants' physical activity levels and their engagement with the intervention will be measured, alongside survey-style questions on their physical and mental well-being.

What are the possible benefits and risks of participating?
The possible benefits are increasing health through physical activity. Possible risks are injuries from engaging in physical activity.

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

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

Who is funding the study?
1. National Institute for Health Research (NIHR) UK Research and Innovation (UK)
2. Medical Research Council (UK)

Who is the main contact?
Dr Joseph Firth, joseph.firth@manchester.ac.uk (UK)

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
322359

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55670, IRAS 322359

Study information

Scientific Title
Exploring the feasibility of a remote exercise and lifestyle (REAL) intervention for early psychosis: a mixed-methods study

Acronym
REAL

Study objectives
Providing home exercise sessions via teleconferencing will be feasible and acceptable to young adults using Early Intervention in Psychosis services

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approval pending, Cornwall & Plymouth REC (Ground Floor, Temple Quay, House 2, The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8071, (0)207 104 8278, (0)207 104 8141; cornwallandplymouth.rec@hra.nhs.uk), ref: 322359

Study design
Non-randomized interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home, Hospital, Internet/virtual, Telephone, University/medical school/dental school

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Physical health in young people with psychosis

Interventions
This is a mixed-methods study employing a range of methods to explore the acceptability, feasibility, and potential benefits of an online fitness intervention for young people with psychosis. Potential participants will either contact the research team spontaneously after seeing the advertisements in clinics/online, or they will be identified by members of the EIS clinical team. Potential participants will be identified by members of their clinical care team, and subsequently alerted to the study by their care teams (e.g. care coordinators and physical health support workers), to be asked if they would be interested in participating.
Those service users who are interested in participating can agree to have their details passed over to the research team.
Following this, the research team will arrange to conduct an initial telephone screening over the phone (to determine eligibility) and provide further information about the study.
Alternatively, potential participants may opt to complete an online self-referral form (either on their own, or with their care team) to provide their contact details to the research team, or even contact the research team directly, via email or phone/text, who will then arrange their screening, enrolment, and informed consent. For all self-referrals, a notice of their enrolment will be provided to their clinical teams, to confirm their status as a service user and suitability for the study. Following the completion of study enrolment, participants will be asked to complete the baseline questionnaire, which captures data on demographic information and clinical characteristics (i.e. age, gender, ethnicity, education, diagnosis, medications), health behaviours, physical health, mental health and quality of life. Finally, the clinical teams of the participants will also be informed of their successful recruitment to the study after the enrolment process is

completed, but prior to commencing the live exercise sessions.
On completing baseline measures, participants will be assigned to either the 'FitBit-only Control' or 'REAL Intervention'. Rather than randomisation, assignment to groups will be batched based on the timing of entry to the study, whereby the first 16 individuals recruited will be assigned to the REAL Intervention, while the other 16 will be in the FitBit-only control.
In this cross-over study, all participants will have to opportunity to complete both the Control Group and REAL Intervention conditions, lasting 16 weeks in total (8 weeks each).
Alongside this, all participants will be followed up at 6 months (24 weeks) post-intervention where possible, to assess sustained adherence to physical activity over time.
During the whole time, all participants will be provided with a wearable physical activity tracker (Fitbit) as an objective measure of physical activity for the study, and act as an ongoing control intervention in its own right Participants assigned to the REAL intervention group will also receive access to twice-weekly online group sessions, delivered via Zoom, to groups of 6 – 8 participants. Sessions will be 45 minutes in length, and hosted by an RW. The 45-minute-long sessions will consist of (i) a 10–15-minute introduction, and Q&A/Discussion session among group members to discuss staying active daily, home exercise and maintaining other aspects of a healthy lifestyle (sleep, diet, etc) with the group and (ii) a structured home workout video, up to 30 minutes in length using bodyweight and aerobic exercises with minimum equipment.
Participants in the REAL intervention will also receive email reminders prior to the live session commencing, and access to recordings of the workout section after each session has concluded. In the recorded videos, only the video workout will be visible (rather than the participants), and the discussion/Q&A session will not be included. Participants will repeat the baseline assessments at 8 weeks and 16 weeks, to collect post-intervention/control follow-up outcome data, and again 6 months post-intervention as a longitudinal follow-up. These will take part in assessments via telephone or online. Participants will be reimbursed and thanked for their time with a £20 shopping voucher at each assessment period.
Participants will also have the option to participate in the qualitative interviews and use the wearable device for passive data gathering.
The qualitative interviews will be conducted online (via Zoom or Teams) by trained researchers experienced in qualitative methods using a semi-structured interview schedule. They will last no more than 60 minutes, and all participants will be compensated with a further £20 voucher for their time. To maintain anonymity each participant will be assigned a study number. The interviews will be audio recorded and transcribed verbatim (which will be completed by a member of staff from the University of Manchester or an approved transcribing service, "1st Class transcription"). Recording of the interviews will be conducted and saved to encrypted University laptop audio-recorded software. The audio recordings will be deleted as soon as the transcription is complete.
Passive data involves the data collected from the Fitbit wearable device, which will be transferred automatically to the research team from the participants' device are regular intervals during the study and saved to secure servers under the participant's pseudo-name. The passively collected data will include: 1) Physical activity levels: (i) Amounts of physical activity (across three different intensity levels: lightly, fairly and very active) in minutes per day; (ii) length of time individuals spent sedentary per day; (iii) step count per day. 2) Sleep: (i) minutes asleep; (ii) minutes in bed; (iii) efficiency.
3) Heart rate: Resting Heart Rate (RHR) and Heart Rate Variability (HRV). Those participating in passive data collection for the duration of the study will be compensated with a further £20 on return of the device.
During the enrolment, baseline and follow-up assessments, participants will be made aware that their engagement with the intervention itself has no bearing on reimbursement (as this is provided entirely for completing the assessments), although compensation for wearable usage will be provided on return of the device.

Intervention Type
Behavioural

Primary outcome measure
Self-report measures of physical and mental health will all be administered as survey /questionnaire measures at pre-intervention and post-intervention (8-weeks) and 6-month follow-up.
These measures will include:
1. Exercise Preferences Questionnaire [baseline only]; based on a shortened version of a general survey administered in previous exercise studies in this population, asking about individual's motivations and preferences around exercise/physical activity
2. Self-Reported Physical Activity measured using the International Physical Activity Questionnaire (IPAQ). The IPAQ has been well-validated against objective measures for providing a reliable indication of an individual's daily physical activity levels, including light, moderate, and vigorous activity along with total amounts of sedentary behaviour
3. Mental Well-being measured using the Kessler Psychological Distress Scale (K10) – a 10-item measure of depression and anxiety validated in numerous populations
4. Social Functioning measured using the Personal and Social Performance (PSP) scale – a 20-item assessment of an individual's engagement with daily living and social activities, which provides a reliable indication of social functioning in people with schizophrenia
5) Loneliness measured using the UCLA 3-Item Loneliness Scale (ULS-3) to provide a brief but relatively accurate assessment of an individual's feelings of loneliness

Device-Collected Data from the Fitbit wearable device will be used to examine how engaging with the REAL intervention and FitBit-only control conditions are associated with changes in participants. For each day that participants remain in the study, the following data items will be collected:
1. Physical activity levels:
1.1. Amounts of physical activity (across three different intensity levels: lightly, fairly and very active) in minutes per day
1.2. Length of time individuals spent sedentary per day
1.3. Step count per day
2. Sleep:
2.1. Minutes asleep
2.2. Minutes in bed
2.3 Efficiency
3. Heart rate: Resting Heart Rate (RHR) and Heart Rate Variability (HRV).

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
10/01/2023

Completion date
30/03/2025

Eligibility

Key inclusion criteria

1. Aged between 18 – 35 years old (inclusive)
2. A current service user of Early Intervention Services (defined as having a designated care coordinator within the service).
3. Interested in participating in an online group exercise class
4. Confident in their ability to use Zoom, Teams or any other video-conferencing software on any smart device

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
Planned Sample Size: 32; UK Sample Size: 32

Key exclusion criteria
1. Inability to use tablet/mobile phone devices for the purpose of video-conferencing
2. Inability to give informed consent (as assessed during recruitment)
3. Currently has an eating disorder or a physical health condition which could act as a contraindication to exercise

Date of first enrolment
05/05/2023

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Prestwich Hospital
Bury New Road
Prestwich

Manchester
United Kingdom
M25 3BL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Study participating centre
University of Manchester
Division of Psychology and Mental Health
3.005 Jean Macfarlane Building
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Sponsor information

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Sponsor type
University/education

Website
http://www.manchester.ac.uk/

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Conference presentation

3. Publication on website
4. Other. The main results will be disseminated via usual academic channels (i.e. peer-reviewed journals, conference presentations, etc.). Alongside this, A ‘lay summary’ of the findings will be presented on the UoM website and social media channels and healthcare providers' social media and website for participants who would like to know the study outcome.

Intention to publish date
30/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from PI Joseph Firth, Joseph.firth@manchester.ac.uk. Only anonymised data will be available. This data will be made available in this way to other research teams based at academic institutions from 2 years after fellowship completion; allowing time for the exclusive use of data by the research team for publication and innovation, prior to making the data available for broader usage. Consent for data to be shared in this way will be gained from participants during enrolment to the study.

IPD sharing plan summary
Available on request