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Increasing physical activity in a medium secure service

Submission date
26/05/2021

Recruitment status
No longer recruiting

Registration date
28/05/2021

Overall study status
Completed

Last Edited
08/08/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
People with severe mental health problems find it more difficult to live healthy lifestyles. They have a shorter life span by about 10-20 years and obesity rates up to four times higher than the general population. Maintaining a healthy lifestyle is more difficult for people in medium secure mental health units. This type of service provides care and treatment to adults with severe mental health problems, who present a serious risk of harm to others and to themselves, and who are prevented from leaving the hospital. There is a need to develop interventions for improving physical activity in these settings. This study aims to work with service users and professionals in two NHS medium secure units to design and evaluate a way of improving the levels of physical activity for service users.

Who can participate?
In-patients in medium secure services

What does the study involve?
Service users will co-design and complete a questionnaire to help understand what helps or hinders their participation in physical activities. Discussion groups will then occur between service users and stakeholders to develop a physical activity intervention. Service users in the two study sites will then use the intervention and data will be collected for 3 months about their participation, body weight, physical activity, mood, mental well-being, and motivation. The researchers will interview all service users and some staff at the end.

What are the possible benefits and risks of participating?
The service users may experience increases in physical health, self-esteem, quality of life and psychosocial health. Risks related to the intervention are minimal and no other risks have been identified in the study.

Where is the study run from?
Durham University and South West Yorkshire Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2019 to December 2023

Who is funding the study?
NIHR Research for Patient Benefit (RfPB) Programme (UK)

Who is the main contact?
Prof. Tammi Walker
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
297420

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49039, IRAS 297420

Study information

Scientific Title
Increasing physical activity in a medium secure service: the development and feasibility of a physical activity intervention (IMPACT)

Acronym
IMPACT

Study objectives
1. Can an evidence-based intervention aimed at increasing physical activity in medium secure services be coproduced?
2. Can this co-produced evidence-based intervention be implemented in medium secure services?
3. What are medium secure service users' and staffs' perceptions and experience of the physical activity intervention?
4. Is the intervention sufficiently developed to be evaluated in a future pilot randomised control trial?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/04/2021, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ, UK; +44 (0)207 1048091; newcastlenorthtyneside2.rec@hra.nhs.uk), REC ref: 21/NE/0080

Study design
Non-randomized; Both; Design type: Treatment, Prevention, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Physical, Active Monitoring, Validation of investigation /therapeutic procedures

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Physical activity of people in medium secure mental health units

Interventions
This is a 24-month mixed-methods project that will follow the Medical Research Council (MRC) framework Developing and Evaluating Complex Interventions as it provides guidance for the systematic development and testing of complex health interventions. A phased iterative approach consisting of development, feasibility and piloting, evaluation and implementation will be applied.

The study has four complementary phases to address the objectives. Phases 1-2 will gather the information required to develop an evidence-based intervention in Phase 3. The feasibility of evaluating and testing the intervention for a future pilot study of this intervention will be assessed in Phase 4.

The theoretical framework that will guide the intervention development is the Behaviour Change Wheel (BCW) which evolved from a synthesis of 19 behaviour change frameworks and provides a comprehensive approach to aid behaviour change intervention design. This framework is underpinned by the Capability, Opportunity, Motivation, Behaviour (COM-B) model which proposes people need capability (C), opportunity (O) and motivation (M) to perform a

behaviour (B). This model guides understanding of behaviour in context and develops behavioural targets as a basis for intervention design. It proposes that for someone to engage in a particular behaviour (B) at a given moment they must be physically and psychologically able (C) and have the social and physical opportunity (O) to do the behaviour and, in addition, want or need to do the behaviour more than any other competing behaviours at that moment. This inclusive definition of motivation (M) covers basic drives and automatic processes such as habit and impulses as well as reflective processes such as intention and choice.

Methodology

Phase 1: To identify the barriers and facilitators in medium secure care to increased physical activity; the researchers will co-produce a questionnaire for all service users to complete in two NHS medium secure units (N=90; N=102) and conduct staff focus groups at each unit (6-10 in each group, 12-20 in total).

Phase 2: To identify views on designing, delivering, establishing engagement and maintaining a commitment to attend physical activity interventions, the researchers will conduct a focus group with service users and key stakeholders with expertise in promoting physical activity and behavioural change within medium secure environments (6-10 participants).

Phase 3: To co-produce a physical activity intervention, the researchers will conduct an intervention development group with service users, our patient and public representatives, staff from Phase 1 and service users and key stakeholders from Phase 2 (6-10 participants). The researchers will produce guidelines for training to facilitate consistent intervention delivery and replication.

Phase 4: 15-20 medium secure service users from each medium secure unit will participate in this phase. Using a quasi-experimental one arm, pre-test post-test design the researchers will assess physical activity levels pre and post-intervention. Pre-test, basic demographic data, information on current medication, body weight, physical activity, mood functioning; mental well-being and motivation will be collected. The researchers will repeat measures after 3 months and then at follow up at 1 month and 3 months post-intervention. Qualitative data will be collected on acceptability, and pilot recruitment, participation, retention and causes of drop-out, data collection, and outcome measure to inform a future pilot randomised control trial.

All participants will receive an information sheet and will be asked to provide written consent prior to participation. All qualitative data will be guided with a topic guide schedule, will take place face to face or online, be digitally recorded and transcribed verbatim. A debrief sheet will be provided to all participants.

Quantitative Analysis:
Phase 1 quantitative data will be using Statistical Package for the Social Sciences (SPSS) and descriptive and inferential statistics will be performed. Phase 4 quantitative data will be analysed using SPSS. Baseline characteristics including physical and mental health conditions of all participants will be tabulated. The analysis plan is to quantify study parameters using descriptive statistics as the aim is to develop and refine study procedures and the intervention for testing in a future pilot study in medium secure units

Qualitative Analysis:
The interviews and focus groups will be analysed using framework analysis following the methods set out by Gale et al (2013). Framework analysis is designed to be used in applied health and policy research and it seeks to systematically identify commonalities and differences

within qualitative data sets, examining the relationship between different parts of the data, and resulting in descriptive or explanatory conclusions clustered around themes. The main purpose of framework analysis is to describe and interpret what is happening among a pre-designed sample (e.g., medium secure service users) with a set of a priori issues. It is particularly useful when a multi-disciplinary team are working on the analysis and facilitates constant comparative techniques. The analysis will be completed in NVivo using their framework matrices facility.

Evaluating the intervention using the RE-AIM framework
The RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework will be used to determine the feasibility and acceptability of the intervention using the five-dimension indicators: Reach into the target population; Effectiveness of the intervention; Adoption by target settings, institutions and staff; Implementation, including consistency; and Maintenance of intervention effects over time. For example, REAIM's efficacy and maintenance components of participants' behavioural change will be based on quantitative outcome comparisons between baseline, 1 month and 3 months maintenance phase, as well as qualitative interview narratives.

Intervention Type
Behavioural

Primary outcome(s)
All measured at the completion of the study:
1. Participant recruitment rate: the proportion of eligible patients who accept the invitation to participate in the research study
2. Retention and adherence: the proportion of participants who complete the study and the proportion of intervention sessions completed
3. The acceptability of the intervention, study design and outcome measures as well as participants' and staff experiences with the intervention, assessed qualitatively using focus group and interview data for patient and staff groups analysed using framework analysis
4. Descriptive statistics for each outcome measure at week 0, 12, 16 and 28

Key secondary outcome(s))
1. Body Mass Index, body fat and muscle measured using the Tanita weight machine at week 0, 12, 16 and 28
2. Resting pulse rate (beats per minute) measured using the Home Step test at week 0, 12, 16 and 28
3. Perceived exertion measuredusing the Borg ten-point scale at week 0, 12, 16 and 28
4. Cardiac and metabolic health measured using the Lester Tool at week 0, 12, 16 and 28
5. Review of prescribed Medication and Diagnosis record and compared against reported side-effects as documented within the British National Formulary and a discussion with service users at week 0, 12, 16 and 28
6. Motivational profile of exercise and training measured using the Behaviour Regulation in Exercise Questionnaire-2 (BREQ-2) at week 0, 12, 16 and 28
7. Three dimensions of physical activity (frequency, duration, and intensity) over the past 7 days measured using the New Zealand Physical Activity Questionnaire Short form (NZPAQ-SF) at week 0, 12, 16 and 28
8. Number of steps, distance, active minutes, and calories burned measured using a Fitbit Zip activity tracking device at week 0, 12, 16 and 28

Completion date
21/12/2023

Eligibility

Key inclusion criteria

Phase 1: Service user questionnaire and staff focus groups

Service users:
1. Aged 18+ years
2. Have mental capacity to give informed consent (through discussion with the multi-disciplinary team)
3. Sufficient command of English to complete the questionnaire

Staff:
1. Aged 18+ years
2. Qualified and unqualified staff from both study sites that have worked in the service for at least 3 months

Phase 2: Stakeholder and service user focus group

Service users:
1. Aged 18+ years
2. Have mental capacity to give informed consent (through discussion with the multi-disciplinary team)
3. Sufficient command of English to participate in a focus group

Staff:
1. Aged 18+ years
2. Qualified and unqualified staff from both study sites that have worked in the service for at least 3 months
3. Professionals with expertise in interventions to promote physical activity and behaviour change interventions

Phase 3: Intervention development group

Service users:
1. Aged 18+ years
2. Have mental capacity to give informed consent (through discussion with the multi-disciplinary team)
3. Sufficient command of English to participate in a focus group

Staff and stakeholders:
1. Aged 18+ years
2. Qualified and unqualified staff from both study sites that have worked in the service for at least 3 months
3. Professionals with expertise in interventions to promote physical activity and behaviour change interventions

Phase 4: Feasibility study with service users and staff

Service users:
1. Aged 18+ years
2. Have mental capacity to give informed consent (through discussion with the multi-disciplinary

team)
3. Sufficient command of English to participate, complete the assessments (alone or with help of researcher) and complete interviews
4. Is an in-patient for 12 months or more

Staff:
1. Aged 18+ years
2. Qualified and unqualified staff from both study sites that have had direct contact with participants who received the treatment intervention
3. Exercise and occupational therapists who deliver the intervention at each study site

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
215

Key exclusion criteria
Phase 1: Service user questionnaire and staff focus groups

Service users:
1. Age under 18 years
2. Unable to provide informed consent
3. Insufficient command of English to complete a questionnaire
4. Pose a significant risk to self and/or others

Staff:
1. Age under 18 years
2. Qualified and unqualified staff from both study sites that have not worked in the service for at least 3 months

Phase 2: Stakeholder and service user focus group

Service users:
1. Age under 18 years
2. Unable to provide informed consent
3. Insufficient command of English to participate in a focus group
4. Pose a significant risk to self and/or others

Staff:
1. Age under 18 years
2. Qualified and unqualified staff from both study sites that have not worked in the service for at least 3 months
3. Professionals with no expertise in interventions to promote physical activity and behaviour change interventions

Phase 3: Intervention development group

Service users:
1. Age under 18 years
2. Unable to provide informed consent
3. Insufficient command of English to participate in a focus group
4. Pose a significant risk to self and/or others

Staff and stakeholders:
1. Age under 18 years
2. Qualified and unqualified staff from both study sites that have not worked in the service for at least 3 months
3. Professionals with no expertise in interventions to promote physical activity and behaviour change interventions

Phase 4: Feasibility study with service users and staff

Service users:
1. Age under 18 years
2. Unable to provide informed consent
3. Insufficient command of English to participate
4. Pose a significant risk to self and/or others
5. Is an in-patient for less than 12 months

Staff:
1. Age under 18 years
2. Qualified and unqualified staff from both study sites that have not had direct contact with participants who received the treatment intervention
3. Exercise and occupational therapists who did not deliver the intervention at each study site

Date of first enrolment
25/11/2021

Date of final enrolment
09/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Arnold Lodge
Cordelia Close
Leicester
United Kingdom
LE5 0LE

Study participating centre
Newton Lodge
Ouchthorpe Ln
Wakefield
United Kingdom
WF1 4AH

Sponsor information

Organisation
South West Yorkshire Partnership NHS Foundation Trust

ROR
https://ror.org/02m7qex15

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201176

Results and Publications

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 01/11/2021:
The datasets generated during and/or analysed during the current study are not expected to be made available due to the data protection policies of Durham University. The collected data includes sensitive data.

Previous individual participant data (IPD) sharing statement :
The datasets generated during and/or analysed during the current study are not expected to be

made available due to the data protection policies of Teesside University. The collected data includes sensitive data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/07/2025	08/08/2025	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results		19/08/2024	23/08/2024	No	Yes