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Motiv8: A weight management intervention for adults in secure mental health inpatient services

Submission date
06/10/2021

Recruitment status
No longer recruiting

Registration date
07/10/2021

Overall study status
Completed

Last Edited
03/12/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Being overweight is a common issue in mental health services and it can lead to many health problems. For example, people with severe mental illness (SMI) are more likely to die 20-25 years earlier than people in the general population. We want to improve the poor physical health of people with SMI who use forensic mental health services. These services provide treatment for people with SMI who have committed (or risk committing) a criminal offence. These people often experience more physical health problems, due to things like less freedom to exercise, higher doses of medication which increase weight gain, and eating unhealthy foods. At Greater Manchester Mental Health NHS (GMMH), service users worked with staff to create a new programme called Motiv8. It is a 9-week weight management programme which aims to improve physical health. Motiv8 includes cooking classes, physical health education, group exercise, a medication review and psychology sessions delivered by a team of occupational therapists, dietitians, psychologists, psychiatrists, pharmacists, sports and recreation instructors, nursing staff and support workers. Many of the standard treatments already used in services are helpful for mental health disorders but may not help people's physical health which is why we are looking at Motiv8. Motiv8 seeks to improve both mental and physical health and address this gap in healthcare. We are going to see if we can run Motiv8 in the NHS and see if it helps people.

Who can participate?
Adults over 18 years old who are being treated at secure forensic services at GMMH, who have not taken part in a Motiv8 group before and who have no communication difficulties and a good understanding of English

What does the study involve?
Patients will give verbal consent to their care team to be contacted by a researcher and asked to sign a consent form if they want to take part. All participants will fill in some assessments at the start (called baseline assessments) which involve questionnaires about their mental and physical health, their exercise, diet and sleeping habits. Participants will then be put in one of two groups. One group will get Motiv8 straightaway. The other group will carry on with normal treatment and be put on a waiting list where they will receive Motiv8 after the first group has finished. Each group will be made up of 8 people from the same ward (where possible). The researcher will not know which group participants have been assigned to. After 10-weeks has

passed (and the first group has completed a course of Motiv8), a researcher will carry out the same assessments as a follow-up for both groups. 12-weeks after this another follow-up assessment will be done. This is to see if we can collect information on people's physical and mental health over time so we can compare one group to another and see if Motiv8 is beneficial. Participants in the first two groups may be contacted at six and nine months to see if we can keep in touch with people over a longer period of time. The participants will also be asked if they want to take part in an optional interview to talk more about their experiences of Motiv8.

What are the possible benefits and risks of taking part?
Researchers have been trained to ask questions sensitively to avoid participants feeling embarrassed and all assessments used have been chosen as they are unlikely to upset participants. Assessments can also be completed over more than one session if they need to. Physical health checks are procedures most participants will be used to doing as part of their usual care on inpatient mental health units. Research staff and facilitators will offer to stop any sessions or assessments if the participant is becoming upset and will encourage them to talk to their care team.

There is risk that participants injure themselves by doing exercises or handling cooking equipment incorrectly. To reduce these risks all sessions will be supervised by specialist staff (physical health professionals, dieticians, and occupational therapists).
Every participant who takes part will get to do Motiv8! All participants are going to get support with their physical health as it will be checked on more frequently and will have access to the Motiv8 programme. As the Motiv8 study is asking for time and effort, all participants will receive a £20 voucher after completing their first round of assessments and when they complete follow-up assessments (receiving £60 in total) as a thank you.

Where is the study run from?
Low and medium secure adult forensic services in Greater Manchester Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2021 to September 2023

Who is funding the study?
National Institute for Health Research (UK) Research for Public Benefit (RfPB) programme (UK)

Who is the main contact?
Dr Rebekah Carney, Rebekah.Carney@gmmh.nhs.uk

For more trial information:
http://www.juicementalhealth.org
@GMMH_Motiv8

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
299909

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 299909, CPMS 49921, NIHR201482

Study information

Scientific Title
Motiv8: A randomised feasibility trial of a weight management intervention for adults on secure forensic mental health inpatient services

Acronym
Motiv8

Study objectives
The overall aim of this study is to conduct a waitlist randomised controlled trial of a weight management intervention (Motiv8) plus Treatment As Usual (TAU) compared with TAU for adults on low and medium secure forensic units to test its feasibility and acceptability. This allows testing of the key questions about recruitment, retention and adherence, provide a test of the protocol and will gather information about Motiv8 including training and supervision needs of those providing it. Information about acceptability and feasibililty will be used to develop an application for a definitive trial to test the effectiveness of Motiv8 for use in adult secure services. This study will enable a robust definitive trial by giving information for sample size and a finalised protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/10/2021, London - Bromley Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8105; bromley.rec@hra.nhs.uk), ref 21/LO/0658

Study design
Cluster randomized waitlist controlled feasibility trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Physical health of people with severe mental illness in secure forensic services

Interventions
Study Arm 1 – Motiv8
People randomised to Motiv8 (Study Arm 1) will receive Motiv8 straight away, along with any treatment as usual. Motiv8 is a programme co-produced with service users and staff at secure services designed to improve the cardiovascular health of people on secure units. It is delivered on a group basis by a multidisciplinary team of facilitators including occupational therapists, dietitians, psychologists, psychiatrists, sports and recreation instructors, nursing staff and support workers. It is a 9-week programme which consists of guided exercise sessions, cooking and nutrition focussed sessions, physical health education, psychological guidance and problem solving for living a healthy lifestyle and setting goals, and a medication review by pharmacy /psychiatry. Motiv8 aims to improve physical health and wellbeing for people in secure services whilst supplementing usual care.

Study Arm 2 – Waitlist
People randomised to Study Arm 2 will be placed on a waitlist to receive Motiv8 but will act as a control group during this time. They will receive treatment as usual and be able to access usual facilities (such as gym/sports hall) as usual but will be given no additional guidance above standard routine care. Treatment will not be withheld for participants in either group and participants can take part in other programmes if they are offered (which will be monitored throughout). Participants will complete pre-post assessments at the same time. After completing assessments at 10 weeks, individuals will receive the Motiv8 intervention, which is an enhancement of routine care. Participants will complete assessments again after Motiv8.

Follow-Up Assessments
Follow-up assessments will be conducted at the same time points for both arms. All participants will complete a baseline assessment prior to randomisation to either Motiv8 or waitlist. Participants will then complete follow-up assessments at 10 weeks (following Motiv8 for the first study arm, and treatment as usual for waitlist), then again 12 weeks later (following treatment as usual for first study arm and Motiv8 for the waitlist control group. The first two cohorts will be contacted via phone at 6 and 9 months following the start of the study to establish proof of concept for a longer follow up in a definitive trial.

Randomisation Process
Individuals will be cluster randomised by cohort. Following written consent, cohorts will be randomised using a free web-based system (www.sealedenvelope.com) by an unblinded administrator. Allocation will be communicated to the CI, study management, facilitators, participants and ward staff, but not the research assistants. This will be done via letter, phone call or secure communication such as internal NHS email. Blinding of allocation will be maintained for research assistants until all outcome measures for all subjects have been collected. Blindness will be maintained using a range of measures (e.g. separate offices for facilitators and researchers, protocols for answering phones, message taking and secretarial support, and security for electronic randomisation information).

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes:
1. Recruitment as measured by number of referrals and number consenting and randomised. Timepoint: Baseline
2. Retention as measures by percentage follow-up and completion of measures. Timepoint: baseline, 10 weeks (post intervention), and 12 weeks (post follow up).

Key secondary outcome(s))
1. Attendance at intervention sessions, adherence to Motiv8 programme as measured by the number of sessions attended and participated in measured using patient records at 9 weeks.
2. Physical Health Measures including body composition (height (cm), weight (kg), BMI (kg/m^2), hip/waist/chest/neck circumference (cm)), blood pressure (mmHg) and pulse (bpm), fitness (such as 6-minute walk and/or standing jump test) at baseline, 10 weeks, and 3 months.
3. Mental Health Assessments including WEMWEBS, HADS, SNS at baseline, 10 weeks, and 3 months.
4. Behavioural Assessments including SIMPAWQ, MOHOST, 24Hr Diet Recall, PROMIS SD Short-Form, PROMIS SRI Short-Form at baseline, 10 weeks, and 3 months.
5. Measures to support Economic Evaluation including EQ-5D-5L, ReQOL, Engagement with Ward Activity, LUNSERS at baseline, 10 weeks, and 3 months.
6. Staff measures including M-BACK Questionnaire, ESSEN-CES before and after Motiv8 intervention is delivered.
7. Qualitative feedback on participant experiences of taking part in the study at the end of the study.

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Adult inpatient at medium or low secure unit at Greater Manchester Mental Health NHS Foundation Trust
2. Mental health diagnosis requiring treatment from secure services
3. Capacity to consent taking part in the study
4. >18 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
29

Key exclusion criteria
1. inability to provide informed consent in line with ethical requirements
2. Previous Motiv8 participant from the pilot study as this will confound the outcomes of the study as the individual will have previously completed the programme, and this may affect the feasibility criteria of attendance/adherence
3. Insufficient command of English or communication difficulties which prevents engagement in written informed consent, validity of research assessments (eg English language standardised assessments), understanding of the programme and communication with the research and clinical teams without interpreters or additional support workers. This is due to the fact that the research assessments used are validated in English, for adult populations with an assumed standard literacy level.

Date of first enrolment
01/12/2021

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Prestwich Hospital
Edenfield Centre
Greater Manchester Mental Health NHS Foundation Trust
Bury New Road
Prestwich

United Kingdom
M25 3BL

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?

Results article		02/03/2024	04/03/2024	Yes	No
Results article		18/11/2024	03/12/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet			27/11/2023	No	Yes
Participant information sheet	Participant information sheet version 2	11/11/2025	11/11/2025	No	Yes
Protocol file		16/09/2021	13/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes