Greater Manchester Mental Health NHS Foundation Trust

Motiv8: A randomized feasibility trial of a weight management intervention for adults on secure forensic mental health inpatient units

[Protocol Version 2.0; 16 09 2021]

Chief Investigator: Dr Rebekah Carney

Research Reference Numbers

IRAS: 299909
SPONSOR: GREATER MANCHESTER MENTAL HEALTH NHS FOUNDATION TRUST
SPONSOR REFERENCE: x533s
FUNDER: RfPB NIHR201482
ISRCTN: ISRCTN13539285
UKCRN:
RfPB: NIHR201482

Key Study Contacts

Chief Investigator	Dr Rebekah Carney
Clinical Lead GMMH	Dr Hany El-Metaal
Co-investigators	Dr Sophie Parker, Dr Heather Law, Siobhan Savage, Ingrid Small, Andrew Macdonald, Dr Mark Hann, Dr Gemma Shields, Dr David Shiers, James Farrell.
Sponsor	Greater Manchester Mental Health NHS Foundation Trust (GMMH NHS FT), Research and Innovation, Bury New Road, Prestwich, Manchester, M25 3BL
Funder(s)	National Institute of Health Research – Research for Patient Benefit Competition 40
Key Protocol Contributors	Dr Rebekah Carney (Rebekah.carney@gmmh.nhs.uk)
Committees	R&I Department GMMH
TSC	Trial Steering Committee Chair: Dr Brendon Stubbs Trial Steering Committee Members: Dr Joseph Firth, Dr Emily Peckham, Dr Jenna Hudson, Dr Ceu Mateus

Confidentiality Statement: This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

Funding and Support in Kind

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
NIHR Research for Patient Benefit – Competition 40 NIHR201482	£248,162.00
Greater Manchester Clinical Research Network (Service Support Costs)	

Role of Study Sponsor and Funder

The sponsor will review the protocol and study materials to ensure they are in line with the research governance requirements of the trust. The sponsor will approve the research team to work on the study and recruit from the trust. The sponsor has not contributed to the design, conduct, data management and analysis, interpretation and dissemination of the study.

Table of Contents

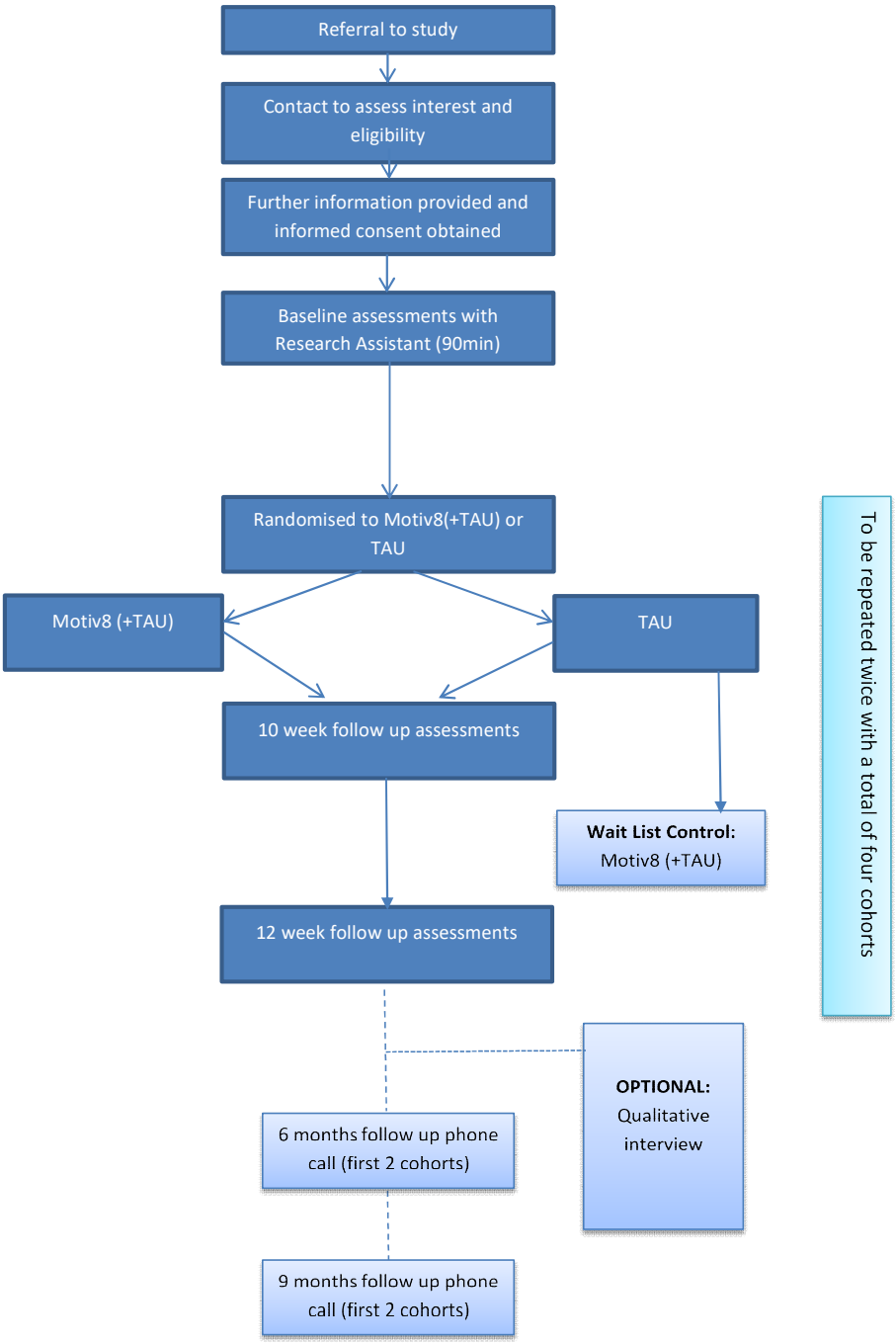
Study Summary

Study Title	Motiv8: A randomized feasibility trial of a weight management intervention for adults on secure forensic mental health inpatient units	
Internal ref. no. (or short title)	Motiv8 RCT	
Study Design	Randomised Controlled Trial	
Study Participants	Adults in low/medium secure services	
Planned Sample Size	32	
Planned Study Period	24 months	
Research Question/Aim(s)	Objectives	Outcomes
Primary	To assess acceptability and feasibility of the research trial, associated processes including the intervention, and assessments.	Measured by: - Recruitment rates - Follow-up retention and questionnaire/outcome response rates - Attendance at sessions - Experience of involvement in the trial - Assessment of safety (SAES - Development of a manualised intervention
Secondary	Physical Health: Body composition, blood pressure, cardiovascular fitness, health status Mental Health: Wellbeing, depression, anxiety, negative symptoms Behavioural: Physical activity, occupational functioning, diet, sleep	Physical Health Measures: BMI, BP, Hip/Waist/Chest/Neck circumference, Fitness test. Mental Health Measures: WEMWEBS, HADS, SNS Behavioural Measures: SIMPAQ, MOHOST, 24HR Diet Recall, PROMIS SD Short-Form, PROMIS SRI Short Form. Measures to Support Economic Evaluation: EQ-5D-5L, ReQOL, Engagement in care, LUNSERS, and ward activity.
Tertiary	Clarify training needs for delivering Motiv8 via a MDT care team, prior to the commencement of a definitive trial.	- Qualitative Interview - Adherence Checklists - Feedback forms and interviews with facilitators - M-BacK Assessment and ESSEN- CES with clinical staff

Key Words: forensic, inpatient, secure services, physical health intervention, mental health, physical health, qualitative, physical activity, diet, health promotion, exercise.

Study Flow Chart

Study process flow chart



Research Team

This protocol has been approved and agreed within the study team.

Name	Role	Contact Details
Dr Rebekah Carney	Chief Investigator	Rebekah.carney@gmmh.nhs.uk 0161 358 6595
Dr Hany El-Metaal	Co-Investigator Clinical Lead and Consultant Psychiatrist	hany.el-metaal@gmmh.nhs.uk 0161 358 3332
Dr Sophie Parker	Co-Investigator Senior Clinician and Consultant Clinical Psychologist	sophie.parker@gmmh.nhs.uk 0161 358 1417
Dr Heather Law	Co-Investigator Experienced trial manager, PPI lead and qualitative researcher	heather.law@gmmh.nhs.uk 0161 358 1402
Ms Siobhan Savage	Co-Investigator and Facilitator Senior Occupational Therapist	Siobhan.savage@gmmh.nhs.uk 0161 358 4709
Ms Ingrid Small	Co-Investigator and Facilitator Clinical Lead Dietitian	ingrid.small@gmmh.nhs.uk 0161 358 7485
Mr Andrew McDonald	Co-Investigator Senior Advanced Practitioner	andrew.mcdonald@gmmh.nhs.uk 0161 357 1772
Dr Mark Hann	Co-Investigator Expert Statistician	mark.hann@manchester.ac.uk
Ms Gemma Shields	Co-Investigator Health Economist	gemma.shields@manchester.ac.uk
Dr David Shiers	Co-Investigator Expert PPI Consultant	david.shiers@doctors.org.uk
Mr James Farrell	Co-Investigator Expert PPI Consultant	n/a
Dr Richard Jones	Facilitator Consultant Clinical Psychologist	richard.jones2@gmmh.nhs.uk 0161 358 8242
Ms Lisa Nuttall	Facilitator Practice Nurse	Lisa.Nuttall@gmmh.nhs.uk 0161 271 0323
Mr Douglas Ainsworth	Facilitator Sports and Recreation Assistant and Exercise Lead	douglas.ainsworth@gmmh.nhs.uk
Mr James Ryan	Facilitator Technical Instructor and Exercise Lead	james.ryan@gmmh.nhs.uk

Abbreviations

AE	Adverse Event
BART	Bipolar At Risk Trial
BMI	Body Mass Index
BP	Blood Pressure
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DoB	Date of Birth
ESSEN-CES	ESSEN Climate Evaluation Schema
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GMMH NHS FT	Greater Manchester Mental Health NHS Foundation Trust
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HRA	Health Research Authority
IATTp	Investigation of Attention Training Technique for Psychosis
IG	Information Governance
LUNSERS	Liverpool University Neuroleptic Side Effect Rating Scale
M-BACK	Metabolic-Barriers, Attitudes, Confidence and Knowledge Questionnaire
MOHOST	The Model Of Human Occupation Screening Tool
NHS	National Health Service
NICE	National Institute for Care and Excellence
NIHR	National Institute for Health Research
PHE	Public Health England
PI	Principle Investigator
PID	Participant Identifiable Data
PIS	Participant Information Sheet
PPE	Personal Protective Equipment
PPI	Public and Patient Involvement
PROMIS SD	Patient Reported Outcome Measurement Information Centre Sleep Disturbance
PROMIS SRI	Patient Reported Outcome Measurement Information Centre Sleep Related Impairment
RA	Research Assistant
REC	Research Ethics Committee
ReQoL	Recovering Quality of Life
RfPB	Research for Patient Benefit
SAE	Serious Adverse Event
SIMPAQ	Simple Physical Activity Questionnaire
SMI	Severe Mental Illness
SNS	Self-evaluation of Negative Symptoms
TAU	Treatment As Usual
TSC	Trial Steering Committee
WEMWBS	Warwick Edinburgh Mental Wellbeing Scale

Protocol of Study

1. Background & Rationale

Secure mental health services (or forensic units) treat and support people with some of the most severe and enduring mental illnesses, who may pose an imminent risk to themselves and others. Secure mental health services have a dual purpose; to treat mental illness and address offending behaviour (Roesch & Cook, 2017; McInerny & Minne, 2004). A quarter of the total mental health funding budget is allocated to secure services, however research is scarce compared with other clinical populations. Approximately 6000 people reside in secure services in the UK (Public Health England, 2016), and inpatient admissions usually exceed 5 years, with 20% of people staying for longer than 15 years, often in receipt of high doses of medication (Public Health England, 2016; Care Quality Commission, 2016; Davoren et al., 2015; Duke, Furtardo, Guo, & Völlm, 2018). However, there is a lack of high-quality research in secure services, particularly in relation to physical health. This is despite the fact that those on inpatient units have fewer opportunities to be active, due to increased restrictions on leave, interaction with community services and higher levels of containment during admission (Daroven et al., 2015; Duke et al., 2018). More research is needed to identify ways to improve people's lifestyle and reduce the likelihood of iatrogenic harm.

It has been well established that people with SMI have poor physical health (De Hert, Schreurs, Vancampfort & Van Winkel, 2009). They are more likely to develop cardiovascular disease/obesity, receive substandard physical health care, and live an unhealthy lifestyle, resulting in a 25-year reduction in life expectancy (De Hert et al., 2009; Correll et al., 2017; Brown, Kim, Mitchell & Inskip, 2010). Improving physical health of people with SMI is a national and international priority, reflected in the recent Lancet commission for physical health care in mental health services (Firth et al., 2019), and Public Health England (PHE) guidance to reduce mental health inequalities (Pubic Health England, 2016). This issue is labelled a national scandal (Public Health England, 2018; Shiers, Bradshaw & Campion, 2015; Thornicroft, 2011), and individuals in secure services remain at even higher risk.

Despite a strong evidence-base for the use of exercise interventions for a range of mental health conditions (Ashdown-Franks et al., 2020), there have been relatively few well-conducted physical health studies in this setting. Our previous work has led us to this current study. This includes the development of a weight management intervention (Motiv8). Motiv8 was co-developed, co-produced and co-facilitated with service users. Four cohorts have taken place in an internal pilot which has allowed us to develop and refine the intervention. Initial pilot data suggests a reduction in weight and change in waist circumference. Participants also reported increased fitness, energy, better sleep and improved sense of mental health and wellbeing. The work conducted to date has been an open trial, and therefore, no conclusions can be made as to the scientific feasibility of the programme under randomised conditions.

We aim to conduct a randomised waitlist-controlled feasibility trial of a lifestyle intervention (Motiv8)+TAU for individuals on secure mental health services, to investigate the acceptability, feasibility and potential effectiveness of this intervention to supplement standard secure care.

2. Research Questions and Aims

Several questions remain which need to be addressed by the research: can we recruit to the number required to demonstrate feasibility? Can we retain service users across a follow-up period to test outcome? Can we recruit and retain participants with an assessment battery which collects data required for a definitive trial? Can the treatment be delivered by staff ideally placed to increase physical activity and promote physical health on inpatient units?

The main research question is:

Is a weight management intervention feasible to implement for adults on secure forensic mental health inpatient units within a randomised wait-list controlled trial?

The main aim of this study is to conduct a randomised waitlist-controlled feasibility trial of a lifestyle intervention (Motiv8)+TAU for individuals on secure mental health units, to investigate the acceptability, feasibility and potential effectiveness of this intervention to supplement standard secure care.

Our **aims** are to assess feasibility via:

1. Recruitment, randomisation and retention rates
2. Adherence to a lifestyle intervention delivered in NHS secure services (Motiv8)
3. Acceptability of assessments (e.g. questionnaires, fitness tests, health checks)
4. Identification of a primary outcome measure for a definitive trial
5. Development of a manualised intervention, to be used within NHS secure services
6. Development of a national network of experts for a definitive trial

Our **objectives** are:

Aim 1: assess recruitment/retention rates (including willingness to be randomised to a waitlist)

Aim 2: assess adherence, engagement with intervention, attendance, dropout rates and withdrawal

Aim 3-4: assess completion rate of measures, descriptive analyses and qualitative interviews

Aim 5: examine the appropriateness, feasibility and acceptability of the intervention, refine the protocol and procedure for a definitive trial

Aim 6: host a national stakeholder event (dissemination)

3. Study Procedures

All study procedures are described below.

3.1 Design

Study 1 will be a single (rater) blind feasibility study with two conditions; Motiv8 plus treatment as usual vs. TAU waitlist control (with Motiv8 delivered after the study period).

Study 2 will be a nested qualitative study that will explore the subjective experience of taking part in Motiv8.

3.2 Setting

The study will be conducted in one site at Greater Manchester Mental Health NHS Foundation Trust (GMMH NHS FT). The Edenfield Centre and Lowry Unit combined, provide 226 inpatient beds forming part of the adult forensic mental health service. The Edenfield Centre and Lowry Unit provide medium and low secure treatment respectively for men and women in Greater Manchester.

The service provides individualised care and treatment for people with severe and enduring mental health disorders. A wide range of treatment is available including psychological and pharmacological therapies. Clinical teams are comprised of consultant psychiatrists, nurses, psychologists, occupational therapists and social workers, and they work collaboratively with the service user towards their recovery and discharge. Service users have access to a wide range of activities to support their recovery including a fully equipped gym, a large sports hall, workshop, and Recovery Academy. As service users make progress, they are supported to access community facilities as part of their recovery and in preparation for discharge.

3.3 Sample & Recruitment

Individuals will be recruited from medium and low secure services in Greater Manchester Mental Health NHS Foundation Trust. The inclusion and exclusion criteria are as follows:

Inclusion

- Adult inpatient (at least 18 years old) at mental health medium or low secure unit at Greater Manchester Mental Health NHS Foundation Trust
- Mental health diagnosis requiring treatment from secure services
- Capacity to consent to taking part in the study

Exclusion

- Inability to provide informed consent in line with ethical requirements
- Previous Motiv8 participant from the pilot study
- Insufficient command of English or communication difficulties which prevents engagement in written informed consent, validity of research assessments or understanding of the programme

A total of four cohorts of eight individuals (n=32) will be recruited and randomised (n=16 Motiv8+TAU, n=16 TAU). Each cohort will contain a maximum of 8 individuals from the same ward and will consist of 2 active Motiv8+TAU groups (n=16) and 2 waitlist control groups who will receive the intervention after the assessments have been completed (n=16). The randomised clusters will run consecutively. If more than 8 people from the same ward are willing to take part in the programme, they will be placed on a waitlist to complete the Motiv8 programme at the end of the study. Sample size is based on practical limitations within secure services requiring groups are small to allow staff to deal with complex needs of individuals. The procedure will be as follows:

3.4 Participant Identification

The research team will liaise with clinicians and care co-ordinators on the units to identify potential participants. Ward managers will indicate whether they are willing to take part and if so, all individuals and staff will be informed of the study. Staff members will be made aware of the eligibility criteria and asked to inform the research team of any eligible people of interest. They will be asked to speak with individuals they feel might be suitable and inform the research team if there is any reason why they should not take part, for example severe anorexia or eating disorder posing a significant risk to their physical health. Information sheets will be left within the service so that people can self-refer in the instance that a staff member has not been in touch. All staff members on the participating wards will be approached to take part in a brief questionnaire study to assess the effect of Motiv8 on the ward environment.

3.5 Recruitment

Research assistants will be responsible for recruitment of participants, supervised by Dr Carney and clinical leads. Following on from the successful pilot study, ward managers and clinicians will be approached to identify eligible individuals. Information sheets will be left within the service and offered to individuals. Potential participants will discuss taking part with their care co-ordinator and will provide verbal consent to be contacted by a researcher. Researchers will also present the study at any community groups or directly to people on the wards at the discretion of the ward manager. Potential participants will be contacted via a mode of their choice; email, phone, text or via care team to offer further information and tell them that their participation is voluntary and there is no obligation to take part. Only limited information will be collected at this stage (name, dob). Potential participants will have the information for a minimum of 24 hours prior to meeting with a researcher to discuss the study. Clinicians will be asked for feedback on the reasons provided for those deemed ineligible for the study or those who have declined to take part, but only if this has been offered up voluntarily.

Wards must have 8 referrals (maximum amount of each in each Motiv8 group) to be eligible for randomisation (which will take place by ward). Each cohort will aim to contain people from the same ward to avoid conflict between patients and avoid contamination of the control groups; this decision is based on previous work in secure units and the internal pilot. Individuals from the pilot phase and PPI consultations (October 2019) claimed being from the same unit is beneficial as it reduces anxiety being with people they know and avoids conflict between wards. In the instance that fewer than 8 people from one ward are interested, two wards may be combined to make up the cohort. This will be discussed within the study team. A distress protocol will be adhered to throughout which will be developed with PPI input. In the pilot, the physical health team referred individuals to Motiv8 facilitators and people were placed on a waiting list for the next cohort, therefore, a waitlist control design will be used (to avoid ethical issues around withholding an intervention) and all individuals will ultimately receive the intervention. Recruitment will take place at two timepoints, for 1-month at the start of the study period, and another towards the end of the first two cohorts. Staff completing the questionnaires regarding ward environment will be provided with a consent form which will be signed and collected back by the study team.

We will adopt the same approach to recruitment we have used in previous successful studies where the recruitment phase is stopped when the maximum target is reached (e.g IATTp, BART). This will involve being clear with clinicians about targets during the liaison period about the recruitment targets. If there are additional people who contact the research team who cannot take part in Motiv8, they will be placed on a waiting list to be considered at the next stage (e.g. definitive trial). This was standard practice within services for the pilot phase of Motiv8. If we do not get 8 people from the same unit to form a cohort, we may implement the contingency plan at the discretion of the Trial Steering Committee and co-investigators, which may involve mixing people from different units to form a group of 8.

3.6 Screening and Booking Baseline/Eligibility

Once identified and verbal consent to contact has been obtained, potential participants will be approached to provide consent. Researchers will ask some preliminary questions related to the inclusion/exclusion criteria to ensure they are eligible. Eligibility will be confirmed in discussion with the Chief Investigator and/or the clinical lead. Should researchers require any further information regarding eligibility, this will be obtained from the care co-ordinator. Potential participants will be provided with a participant information sheet if they have not already received one for them to read prior to informed consent taking place. The Eligibility Form will be completed and signed off by the research assistant and Chief Investigator at this point.

3.7 Informed Consent

The care co-ordinator and lead clinician will assess ability to provide informed consent. The researcher will liaise with clinical teams and arrange to meet with interested individuals in a private room on trust premises. Relevant NHS lone worker policies will be adopted to ensure the safety of the researcher. Written informed consent will be obtained upon the first visit in line with Good Clinical Practice guidance and the initial baseline assessments will take place. Participants will be assigned a Case ID number to maintain anonymity and permit removal of data if consent is withdrawn. Participants will be informed of the confidentiality agreement

and that this will only be broken if they reveal information to suggest they themselves, or somebody else is at immediate risk of harm. In this case the relevant professional body will be informed (care co-ordinator, social worker etc). Participants will be informed that their NHS number will be stored (on a separate password protected document stored on a secure server) and they will provide informed consent for this. This is so that they can be traced for follow ups, in the instance that they have been discharged from the inpatient unit. Their GP will also be informed of their participation via a letter sent from the research team following their consent, and this will also be recorded on the clinical notes system.

3.8 Baseline

The baseline assessment will be performed by the research assistant and will take place on trust premises in a private room. The aim of this is to provide a baseline measurement prior to intervention of all outcome measures. Blinded RAs will conduct assessments, which will last approximately 90 minutes, and multiple appointments will be offered if needed. The assessments will be in a private room, and safety procedures will be adhered to. Physical health and fitness assessments will be conducted by the physical health team within the first and final sessions and so will not be blinded. This is because it forms part of the intervention and enables the team to assess fitness levels and ability for safety reasons.

The assessments performed at the Baseline Assessment will include:

- **Physical Health Assessments**
  BMI (Height/Weight), Blood Pressure, Pulse Rate, Hip/Waist/Chest/Neck Circumference, Cardiorespiratory fitness (using a vo2 sub max proxy test 6 minute walk, and standing jump test)

- **Mental Health Assessments**
  Warwick Edinburgh Mental Wellbeing Scale (WEMWBS; Tennant et al., 2007), Depression and Anxiety (Hospital Anxiety and Depression Scale; Zigmond & Snaith, 1983), Negative Symptoms (SNS, Dolfus, Mach & Morello, 2016)

- **Behavioural Assessments**
  Physical Activity (SIMPAQ; Rosenbaum & Ward, 2016), Model of Human Occupation Screening Tool for nutrition sessions (MOHOST; Parkinson, Forsyth & Kielhofner, 2006), 24-hr diet recall (Nelson, Erens, Bates, Church & Boshier, n.d.), Sleep (PROMIS SD Short Form 8-item; PROMIS SRI Short form 4-item; Cella et al., 2010; Buysse et al., 2010; Yu et al., 2012)

- **Clinical and Socioeconomic Demographics**
  Such as age, gender, ethnicity, illness factors, duration of illness, treatment (medication and dosage), any additional treatments, any physical health conditions, and length of stay.

- **Measures to Support Future Economic Evaluation**
  Health status (EQ-5D-5L; Herdman et al., 2011), Quality of Life (ReQoL; Keetharuth et al., 2018), the Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS; Day, Wood, Dewey, & Bentall, 1995), Engagement with ward activities

and health care. ESSEN-Climate Evaluation Schema (ESSEN-CES; Schalast et al., 2008)

3.9 Randomisation and Blinding

Individuals will be cluster randomised by cohort, using minimisation to ensure balanced distribution. Following written consent, cohorts will be randomised using a free web-based system (www.sealedenvelope.com). Allocation is communicated to the CI, study management team and facilitators but not the research assistants. Participants will be informed of their randomisation status by letter or via their clinicians on the unit, communicated via the administrator.

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). Maintaining rater-blindness to treatment allocation is crucial, and the Trial Steering Committee (TSC) will regularly monitor unblinding and implement corrective action if necessary.

3.10 Follow-Up Assessments

Follow-up assessments will be performed by research assistants and will take place in an area of mutual convenience, such as a private room on trust premises. All participants will be assessed at 10-weeks following baseline assessment (regardless of whether they will have received Motiv8+TAU or TAU), and 12 weeks following the 10-week assessment (regardless of whether they have received Motiv8 or TAU). The same assessments will be conducted as described in section 3.8. The 12 week follow up was decided based on PPI input and previous research which shows positive effects sustained at three months, which continues to predict long-term behaviour change (Martin, Chater & Lorencatto, 2013; Tobi, Estacio, Yu, Renton & Foster, 2012). This feasibility study was also bound by financial limitations of the funding competition.

3.11 Additional Contact / Subsequent Visits

The first cohort will be contacted at two additional follow up points:

1. 6 months following the end of the intervention.
2. 9 months following the end of the intervention.

Participants will be contacted by a researcher who will ask them if it were a definitive study, would they be willing to complete assessments at this timepoint. This will be done to establish proof of concept for a definitive study, to judge whether people could be followed up over a longer period.

To maximise involvement and retention of participants several additional procedures will be adopted, based on our previous work with service user reference groups in the Psychosis Research Unit and the Youth Mental Health Research Unit. This includes intermittent contact with both clinical teams and participants via newsletters and cards (e.g. thank you cards). PPI input will be used to inform this contact with participants, and although not pre-specified we

will ensure that this will not amount to more than 4 additional contacts. Consent to send this information will be ascertained at the start, and participants will be told that trial participation will not be contingent on this.

3.12 Assessments

Assessments will occur at baseline (immediately before the intervention), at 10-weeks (post-intervention) and 12-weeks after the intervention has finished. To assess feasibility, data will be recorded in line with the 'Consolidated Standards of Reporting Trials, (CONSORT; Schulz, Altman & Moher, 2010) 2010 Statement: extension to randomised pilot and feasibility trials', showing attrition rates and loss to follow up. Participants will complete a range of physical and mental health assessments before and after the intervention. The following measures will be completed at each timepoint.

3.12.1 Proposed Primary Outcome Measure for a Definitive Trial

The proposed primary outcome is weight. We will also assess alternative proposed primary outcome measures for a definitive trial such as physical activity levels, cardiorespiratory fitness, and wellbeing. This will be informed by the acceptability of the measures (completeness, retention, change from baseline and satisfaction), qualitative feedback from the trial and input from experts by experience PPI group.

3.12.2 Secondary Outcome Measures

Outcome measures will be collected to determine suitability for use in a definitive trial:

1. **Physical Health**
   BMI (height, weight); BP/Pulse; Hip/Chest/Waist/Neck Circumference; Cardiorespiratory Fitness using a proxy of Vo2 Submax (such as standing jump test or 6-min walk).

2. **Mental Health**
   Warwick Edinburgh Mental Wellbeing Scale (WEMWBS, Tennant et al., 2007; Depression and Anxiety (Hospital Anxiety and Depression Scale, Zigmond & Snaith, 1983); Self-Evaluation of Negative Symptoms (SNS, Dollfus et al., 2016).

3. **Behavioural**
   Physical Activity (SIMPAQ; Rosenbaum & Ward, 2016); Model of Human Occupation Screening Tool for Nutrition Sessions (MOHOST, Parkinson et al., 2006); Dietary intake (24-Hour Recall, Nelson et al., n.d.); Sleep (PROMIS SD Short Form 8-item and PROMIS SRI Short Form 4-item, Cella et al., 2010; Buysse et al., 2010; Yu et al., 2012)

In addition, a range of demographic and clinical information will be collected from demographics forms and clinical notes such as age, gender, ethnicity, illness factors (diagnosis, physical health, duration of illness, treatment, length of stay), incident rates, side effects of medication (LUNSERS; Day et al., 1995). Measures to inform future economic evaluation will be collected including health status indicators (EQ-5D-5L; Herdman et al.,

2011), quality of life (ReQoL; Keetharuth et al., 2018), engagement with ward activities and health care.

3.12.3 Staff Evaluation

Staff on participating wards will complete the M-Back Questionnaire (Metabolic-Barriers, Attitudes, Confidence and Knowledge Questionnaire, Watkins et al., 2017), and the ESSEN-CES (Schalast et al., 2008), before and after the interventions. All staff will be approached to complete the questionnaires, regardless of whether they were present at the start of the intervention. They will be provided with a participant information sheet, and consent form to sign before they complete any questionnaires. We will also be administering anonymous feedback forms to the staff on participating wards to gather information about the intervention and the effect it has had on the ward environment/ward culture and atmosphere e.g., incident rates, behaviour of other service users (non-participants). These will be developed with PPI input during the study.

3.12.4 Fidelity Outcomes

Fidelity to the intervention will be ascertained using adherence checklists developed with facilitators. Adherence checklists will allow the facilitator to record whether they have completed the key parts of the session. Attendance at sessions will be recorded using sign in sheets and be collected by the CI to be stored in a fidelity database. Participation in sessions will be recorded by attendance sheets and engagement will be assessed by facilitators.

Facilitators will also meet on a regular basis before and during the delivery of the intervention, to ensure fidelity. The facilitators will receive regular supervision throughout the study period. Any instances where the intervention cannot be delivered as planned will be discussed with the clinical lead and the CI and will be recorded in the fidelity database.

3.13 Discontinuation/ Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. In addition, the Chief Investigator may discontinue a participant from the study at any time if the Chief Investigator considers it necessary for any reason, including withdrawal of consent or loss of capacity. If this occurs the reason for withdrawal will be recorded in the CRF.

3.14 Study Management

The study will be managed internally by the research team who have experience of managing and conducting a range of research projects including large randomised clinical trials, cohort studies, service evaluations, clinical audits and both qualitative and quantitative studies. The research team will continue to meet regularly to discuss the ongoing running of the study, ensure recruitment is up to date and any issues are resolved within the team. There will be a local PI, responsible for the overseeing of any site related activities and ensure local policy is being adhered to. The analysis will be conducted as described above, with the advice and guidance from a statistician and discussed during the regular meetings.

3.15 Additional Feasibility Considerations

Facilitators will complete feedback forms at the end of the study which will assess their experiences of delivering the intervention, and provide detailed information on any difficulties they had, or what they thought went well. This will be developed by members of the study team who are not involved in delivering the intervention, with input from the TSC and PPI representatives.

3.16 End of Study

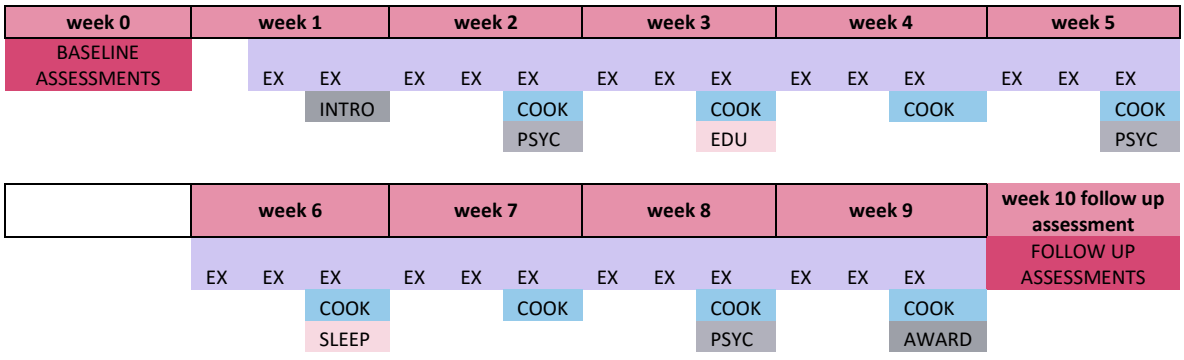
The end of study is the date of the last visit of the last participant.

4. Interventions

4.1 Treatment Arm – Motiv8 plus Treatment As Usual

Those randomised to receive Motiv8 (N=16), will receive the intervention alongside any treatment as usual (TAU) on a group basis. Motiv8 is a programme co-produced and co-developed with service users to improve the cardiovascular health of people on secure units. Motiv8 seeks to increase activity levels, improve diet and use psychological guidance to maintain good health in long stay units. It is a multidisciplinary intervention which focuses on increasing activity levels, improving dietary intake, and looking after physical health, whilst establishing a sense of community on the units. Motiv8 has been successfully piloted, and 32 individuals have taken part in the initial cohorts. Pilot work suggests Motiv8 may be feasible and beneficial to service users on secure units. Participant feedback from this pilot work has been used to refine the intervention and gather information on the potential efficacy of the programme.

Individuals randomized to receive the intervention will take part in a 9-week structured programme of physical activity, motivational sessions, and healthy diet/cooking skills. This structure has been piloted within the services and 9-weeks has been an acceptable amount of time for individuals to engage with the programme. It runs as follows:



KEY: INTRO: Introduction; EX: Exercise Sessions; COOK: Nutrition Sessions; EDU: Physical Health Education; PSYC: Psychology Sessions; SLEEP: Sleep Session; AWARD: Awards Session.

Motiv8 is delivered by a multidisciplinary team of occupational therapists, dietitians, psychologists, psychiatrists, pharmacists, sports and recreation instructors, nursing staff and support workers; all employed within secure services in GMMH NHS FT. Service users assist with the delivery by providing extra support during activity sessions e.g., motivational support, encouragement, working 1:1 with people, demonstrating activities. Interventions delivered by professionals have been shown to have fewer dropouts and higher levels of adherence.

4.1.2 Introduction to Programme

An introductory session is held at the start of the programme to equip participants with the intervention schedule and inform them of the content of Motiv8. Participants will be encouraged to introduce themselves to each other and to ask any questions to facilitators. They will be given intervention materials (e.g. workbooks, information packs) in this session and informed what will be expected of them throughout the programme and provided with a schedule.

4.1.3 Exercise Sessions

Exercise sessions will be delivered by sports and recreation instructors and supported by NHS Support workers. The sessions will last one hour each and will be conducted 2 times per week in the first week, followed by 3 times per week for the following 8 weeks. They will take place in the onsite gym facilities and/or outdoor spaces. The first session will include a baseline fitness test. The content of the sessions will vary each week and gradually build on fitness. This will include a mixture of cardio and strength-based exercises, with the aim of reaching 150 minutes of moderate intensity exercise per week, based on Department of Health Guidelines. The aim of the sessions is to provide guidance and encouragement and work on gradually increasing fitness levels, stamina and duration of activity over the course of the programme. The activities offered will vary, and depend on the initial fitness level, ability and preferences of the group. This may include activities such as circuit training, moderate sporting activities, use of resistance and cardio machines and active games. Individuals will be invited to monitor their activity outside of the sessions using activity trackers if they wish however this is not mandatory. Attendance will be stamped in their booklets and duration of exercise will be recorded.

4.1.4 Cooking Sessions

Cooking sessions will last approximately 90-minutes per week and will be co-facilitated by dietitians and occupational therapists and will take place in the cooking facilities available on site (kitchen and catering area). The goals of the sessions are to improve cooking skills and knowledge about nutrition, portion sizes, healthy food choices, and encourage consumption of a healthy diet through practical sessions and activities. The sessions will be user-informed and guided by the interest of the group. A selection of recipes will be decided at the start of the programme, depending on preferences and needs of the group e.g. low fat, vegetarian, halal. Individuals will each follow a recipe from preparation of ingredients, through to cooking the meal. Throughout this, participants will be encouraged to engage in conversation with facilitators regarding their own food choices, and beliefs about food and discuss potential food swaps. Once the food is cooked, participants and facilitators are encouraged to eat together

and try each other's dishes facilitating a safe and shared dining experience. These sessions will take place over a lunchtime and so will replace the usual mealtimes from the ward.

4.1.5 Physical Health Sessions

A baseline, midpoint and end of programme physical health check by the physical health team is completed to confirm and monitor physical health and decide the appropriate level of initial activity. A one-hour physical health education session will take place midway through by a physical health nurse with a focus on health literacy and discussions on how to live a healthy lifestyle. This session aims to provide information on the impact of having poor physical health (e.g. implications of obesity). The session is open for discussion and is guided by the needs of the participants and their knowledge levels. The physical health nurse will take a collection of NHS approved information leaflets (such as live well plate) and visual aids and will use these to prompt discussions with the group to provide an interactive and educational session.

4.1.6 Pharmacy Review

A pharmacist will review the medication of everyone involved in the study and will provide advice back to the lead psychiatrist during the cohort. This will involve assessing whether any changes need to be made to people's medication, or any additional medications need to be provided and will offer guidance on obesogenic medication. This may be done on an individual basis via the person's care team if necessary or discussed in the physical health sessions. Any information on changes/reductions in medication dosage will be collected during the study.

4.1.7 Psychology Sessions

A total of 3 psychology sessions will be delivered for 1 hour by a clinical psychologist which are based on psychological theories of motivation and behaviour change. Individuals will be encouraged to challenge their thinking about food, exercise, and health, and set goals for the week with a focus on using evidence-based behaviour change techniques. Positive changes will be reinforced to encourage autonomy and barriers to change are discussed, along with any difficulties the person may be having. A peer support worker with lived experience will co-facilitate these sessions and act as a mentor.

4.1.8 Sleep

An additional session is delivered by the Occupational Therapy team which focuses on sleep. During this session participants are provided with information on the importance of sleep hygiene in relation to their physical health and how to achieve good quality sleep. This is an interactive session and participants are encouraged to discuss their own needs and behaviours.

4.1.9 Awards Ceremony

The final session will include an awards ceremony where the participants are presented with a certificate of attendance. Facilitators and participants will meet to discuss progress and will discuss strategies for long-term adherence.

4.2 Waitlist Control – Treatment As Usual (Followed by Motiv8)

The control groups (N=16) will receive TAU and will complete assessments at baseline and 12 weeks. They will be able to access the usual gym facilities but given no additional guidance above standard routine care. They will still be encouraged to exercise and eat healthily in line with NICE guidelines for treatment of patients in secure services. Clinicians will be informed not to withhold any treatments to individuals or prevent them for engaging in any additional programmes offered outside of the study. Participants will complete assessments at the same time-points as those receiving the intervention. Any assessments which identify risk to self or others will be discussed with the clinical teams.

After receiving TAU and completing the (pre/post) assessments, individuals in this cohort will then receive the Motiv8 intervention (thus putting them on a waitlist). This represents an enhancement over routine care since this includes comprehensive and regular monitoring of mental state through research assessments, in addition to participation in the future cohort of Motiv8. The participants will complete assessments after receiving motiv8 to allow a pre-post comparison to be made.

All additional treatments in both conditions will be monitored using a Treatment Documentation Sheet.

5. Statistics and Analysis

5.1 Description of Statistical Methods

A detailed statistical analysis plan will be produced by the study statistician (Hann) prior to examination of the data.

Quantitative analysis will be conducted using intention-to-treat principles. Data will be reported according to CONSORT guidelines, for randomised pilot and feasibility studies (Eldridge et al., 2016), including the numbers of prospective participants who were approached, deemed eligible and subsequently consented. We will also report the number of participants who received their intended treatment (including which elements of it) and were assessed at follow-up.

As this is a feasibility study, the primary focus will be on tabulated and graphical summaries of key indicators of success of the study, e.g. recruitment, engagement, retention, satisfaction with the Motiv8 intervention (participant and facilitator). Where applicable these will be reported with a 95% confidence interval. We will also report any adverse events. We will summarise the baseline demographic and clinical characteristics of each cohort by trial arm.

In order to determine if the Motiv8 intervention 'shows promise', we will fit an appropriate regression model, using our intended primary outcome weight, with trial arm as a covariate controlling for gender and ward type. We will not report p-values as this study is not designed to test effectiveness – instead, we will report 70, 80 and 90% confidence intervals for the difference in weight between Motiv8 and TAU. We will also explore alternative proposed primary outcomes such as cardiovascular fitness, physical activity and wellbeing.

As Motiv8 is delivered in cohorts, a degree of intra-cohort correlation will exist in the outcomes. A sample size calculation for a definitive trial will require an estimate of the intra-cohort

correlation. We will investigate the correlation in this study, but the number of cohorts is likely to be too small to obtain an accurate estimate. We will use descriptive statistics to inform the design of the economic components of the definitive trial.

5.2 Participants

The number of participants will be 32. This will be made up of four cohorts (n=8) from wards at GMMH NHS FT. Sample size is based on practical limitations within secure services, requiring groups are to be kept small to allow staff to deal with complex needs of individuals. This is based on staff experience of conducting groups in secure services and informed by service user input. NIHR guidelines for feasibility studies recommend a sample of at least 12 per group is adequate for preliminary studies (Sim & Lewis, 2012; Lancaster, Dodd & Williamson, 2004; Billingham, Whitehead & Julious, 2013). Given the aim is to investigate feasibility of the intervention and not effectiveness, this is an adequate figure to obtain reliable sample estimates and is in line with the practical limitations of the setting.

6. Nested Qualitative Sub-study

A qualitative study will explore the subjective experience of taking part in Motiv8. This will have input from service-user representatives who will assist with developing the interview schedules, refinement of procedures and analysis of outcomes. The interview schedule and study documents will be created at a later stage and will be informed by the conduct of the study

6.1 Qualitative Methods

We will interview approximately 10 participants, seeking a maximum variable sample across key variables e.g., engagement, symptoms, demographics. Qualitative interview guides will be developed with PPI input in the latter stages of the trial. Semi-structured interviews will explore:

- Participant experiences and views of intervention / recruitment
- Randomisation
- Acceptability and satisfaction with the intervention
- Barriers/Challenges to taking part
- Factors affecting engagement
- Participation in a group activity

Individuals will select whether they are willing to be contacted for the additional study at the time of consent. The interviews will be conducted after the follow up assessments have been completed (post-intervention). Relevant confidentiality and lone worker policies will be adhered to. Written informed consent will be obtained and the interview will take place. Interviews may be face-to-face or conducted over the phone if an individual is unavailable to meet. In this instance written informed consent will still be sought using posted consent forms, or alternative methods of obtaining consent. Participants will be assigned a case ID number to maintain anonymity and permit removal of data if consent is withdrawn.

Interviews will last no longer than 60 minutes and participants will be informed that they can take a break or stop at any time. Participants are under no obligation to complete the study and are free to withdraw at any time. They are also informed that they can still take part in the main study, even if they do not want to take part in the interview. They will be informed that they will be able to withdraw their data from the study should they choose, but only for a period of 3 weeks after the interview at which point their data will have been transcribed and mixed in with other data. As a token of gratitude, they will be given a £10 voucher for a high-street retailer. This is a reasonable reimbursement without acting as a financial incentive. All interviews will be recorded using an NHS encrypted Dictaphone and transcribed verbatim. Participants will be assigned pseudonyms to maintain anonymity and the data will be stored on secure NHS servers.

6.2 Qualitative Analysis

Qualitative analysis will be conducted with the help of nVivo software. Thematic analysis will be conducted according to the five-phase procedure described by Braun & Clarke (2006):

1. Familiarisation
2. Initial code generation
3. Searching and identifying themes
4. Reviewing themes
5. Defining and naming themes

An 'inductive' or 'bottom-up' approach will be taken to analyse the data and will begin during the transcription stage. The analysis team will familiarise themselves with the data by reading each of the transcripts. Transcripts will initially be coded by re-reading line by line to identify concepts, meanings and initial themes or patterns in the data. Each segment will be labelled in a way that captures the semantic meaning, using participants' own words where possible. The transcripts will be constantly re-read to identify any underlying themes and whether those established sit within the larger context. As coding develops and different themes emerge, these will be grouped into overarching concepts and constructs. This will be an iterative process involving revisiting the data supporting each theme and adding, removing, subdividing or collapsing themes where necessary, before returning to the data. This will be done within the research team during a series of analysis meetings and any discrepancies carefully resolved through discussion. Finally, themes will be named in order to represent each theme/topic and verbatim quotes will be selected based on their ability to represent the essence of each theme. Field notes will be kept throughout the coding process and memos made to ensure reflexivity and describe the rationale behind each construct.

7. Safety Reporting

No adverse events were reported during the initial pilot. All research staff will adhere to policy on reporting adverse events throughout the study period.

7.1 Definition of Adverse Events

An adverse event (AE) is commonly understood to be an event that occurs during treatment with a drug or device. However, the definition can also be applied to any "untoward

occurrence" that occurs in any clinical trial. To reflect what is clinically and scientifically relevant to this study the following definition will be used to classify what is an adverse event:

"*Any unfavourable, unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome, or disease that occurs during the study, having been absent at baseline, or—if present at baseline—appears to worsen*."

As well as broadly defined 'medical events' including self-harm, and worsening of symptoms which were present at baseline, adverse event recording will also include capturing information about the occurrence of non-medical events such as violence to others, which may be contributing factors to an AE or may indicate that an AE has occurred.

7.2 Reporting Procedures of Adverse Events

Information related to the adverse event as defined above will be captured in the AE Case Report Form (CRF) and will be recorded within the AE database and regularly monitored by the trial management group in line with Good Clinical Practice Guidelines.

7.3 Definition of Serious Adverse Events

A serious adverse event (SAE) is either any untoward medical occurrence that:

- results in death
- is life-threatening (including suicide attempts)
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity

Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences plus any serious violent incidents, movement from low to medium secure services, or formal complaints about the intervention.

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe, e.g. attempt to take an overdose which is not followed through.

7.4 Reporting of Serious Adverse Events

SAEs occurring to a participant should be reported to the REC that gave the favourable opinion of the study where in the opinion of the independent chair of the TSC the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs should be submitted within 15 working days of the Chief Investigator becoming aware of the event, using the HRA report of serious adverse event form (see HRA website).

Additionally, all serious adverse events as defined above will be reported to the responsible clinical team, the sponsor and the trial steering committee (TSC). The response to an adverse incident will be determined on a case-by-case basis and will be in line with local policies and procedures.

8. Data Management

8.1 Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

8.2 Data Recording and Record Keeping

Each study participant will be assigned a unique trial identification number (as described in section 10.5) at the start of the assessment process. This number will be written on all clinical assessment forms/datasheets and databases used to record data on study participants. A hard copy of a record sheet linking participant identity, contact details and trial identification number for all participants will be placed securely in a locked filling cabinet or will be stored electronically, separate from datasheets.

Data will be entered onto Case Record Forms (CRFs) or assessment packs prior to entry onto the database. The CRFs will be designed to record the outcome assessments in a manner that reduces chance of error (e.g. forced entry format such as DD.MM.YYYY). Data will be entered onto the central database, stored on secure NHS servers. All such data will be checked for errors within the appropriate statistical package. Training on CRF completion, use of databases and storage for site staff listed on the delegation of responsibilities log will be provided in addition to supervision and refresher training; all of which have a continual focus on accurate assessment completion, documentation and use of the database in line with the relevant procedures and policies.

Data collection, data entry and any queries raised by a member of the trial team will be conducted in line with the trial specific working practice documents. Identification logs, screening logs and enrolment logs will be kept at the trial site in a locked cabinet within a secured room. Trial team members will receive trial protocol training. All data will be handled in accordance with the Data Protection Act 1998. Audio recordings of qualitative interviews will be stored on an encrypted NHS network, until they are transcribed and then they will be disposed of.

All trial documentation and data will be retained for a minimum of 5 years, as stated in Clinical Trials Regulations. Personal data will be stored for over 3 years so that it can be independently scrutinised if required at any point during the trial.

9. Quality Assurance Procedures

The sponsor will permit monitoring and audits by the relevant authorities in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures. The investigator, in line with responsibilities set out in the Research Governance Framework, will allow monitoring and audits by these bodies and by the sponsor and provide direct access to source data and documents to perform source data verification and data completeness checks. A general check of the continued sustainability of the site will also be performed.

10. Ethical and Regulatory Considerations

The Chief Investigator will ensure that this study is conducted in accordance with the relevant regulations, policies, and procedures in mind and only with the appropriate approvals. The CI will regularly monitor the study and review any ethical issues.

10.1 GCP

The CI will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice. Refreshers will be completed with any team members who do not have a recent GCP certificate. GCP will be updated every 2 years by members of the research team.

10.2 Approvals

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to the Research Ethics Committee (REC), and HRA for written approval. Greater Manchester Mental Health NHS Foundation Trust will be the sponsor for the study and will review all documents prior to the study commencing.

The CI will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents. Local research governance approvals will be sought from the participating NHS Trust via Health Research Authority approval processes.

10.3 Reporting

The CI will submit Annual Progress Reports to the Funder and HRA/Sponsor (on request). An End of Study notification and final report will be submitted to the same parties.

10.4 Informed Consent

Researchers seeking consent will be trained in information governance (IG) and Good Clinical Practice (GCP) and have experience gaining informed consent from people with a range of mental health difficulties. The research team is made up of experienced clinicians and academics who will provide regular supervision to ensure capacity to consent is being adhered to. The care co-ordinator will primarily be responsible for assessing the ability to provide informed consent, but the research team will also check when individuals are providing written consent. The issues that will be covered will be to ensure the person: understands the purpose and nature of the research; understands what the research involves; the possible benefits, risks, and burdens; and is able to retain and recall this information in order to make a rational decision. Individuals will all be made aware they do not have to take part and are able to withdraw at any time; before, during or after.

10.5 Participant Confidentiality

All participants will be allocated a unique study number which will be used to identify participant information and ensure confidentiality. Each participant will be given an ID number

and data will be matched to this number and not to any names. Any personally identifiable information will be kept in a locked filing cabinet (paper copies) in secure NHS property, or stored securely on a password protected NHS server, to which only the research team will have access. The study team will ensure that the participants' anonymity is maintained. Participants will be identified by their unique ID number on all study documents and on electronic databases. All documents will only be accessible by the study team and authorised personnel. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so. Electronic files will be stored securely on NHS computers and will be password protected. If required, regulatory authorities or the NHS will have access to relevant sections of the participant's medical records for audit purposes or to verify and cross check data.

Both intervention facilitators and research assistants who are NHS employees will have access to some of the participant's personal data during the study so they can undertake their assessments and intervention sessions. Both intervention facilitators and research assistants receive direct supervision from either the CI or a qualified clinician. The NHS code of confidentiality and the Data Protection Act will be adhered to by all involved in the research study. This will be ensured by all staff receiving initial and ongoing training e.g. GCP, information governance.

Medical records will be examined by those who would not normally have access (e.g Research Assistants). Informed consent will be gained from the participants regarding access to their medical records. The participants will be made aware on the participant information sheet, consent form and in the first intervention session (where relevant) who would have access to their medical records and the reasons why such people might need access e.g. to collect information on service use. Members of the research team or clinical team may document participation in research activities throughout the course of the study, should this be a requirement of the local research department. This may involve the addition of progress notes or data to their clinical notes.

The qualitative sub-study may involve publication of direct quotes from participants', but individuals will not be identifiable from these. All qualitative interviews will be audio taped with the participants consent. As soon as these tapes have been transcribed verbatim, they will be deleted and the word document password protected.

Participants will be informed that their responses are kept confidential within the study team unless they disclose information indicating that they themselves, or somebody else, is at immediate risk of harm. This is also the case for physical health assessments, and immediate risk will be shared with clinical teams. If this occurs this information will be shared with the relevant professional body (e.g. care co-ordinator, social services) and the participant will be made aware of that. This will also be the case if there are any abnormal results from any of the physical health assessments which will be discussed in clinical supervision of the research assistants. Any abnormal or out of range assessments will be shared with the care team and the participant will be made aware of this.

10.6 Risks & Benefits

Risks

A distress protocol developed with service user input will always be adhered to. Physical health assessments and questionnaires that will be used are non-invasive and not intended to induce distress. Physical health measures that will be used are common in general practice and a usual part of the standard health-checks individuals receive in mental health units and have typically been conducted as part of the Motiv8 pilot. The research assistants will be fully trained to administer outcome measures and will be supervised within the clinical teams. They will adhere to local policy guidelines for conducting physical health assessments and will relay all physical health data back to the clinical teams where the lead clinician/GP will be responsible for managing their care. There is the chance that people may feel uncomfortable or embarrassed having their physical health checked by a researcher they do not know. However, all participants will be informed they do not have to do anything they do not feel comfortable with and that they are free to stop at any time without having to provide a reason. Should the participant become distressed at any time the researcher will offer to discontinue the outcome assessments and encourage the individual to speak to their care co-ordinator. If there is significant deterioration of a person's physical health they will be made aware that this information will be passed on to their clinician and GP.

As the intervention consists of physical activity sessions, there is a risk of injury to participants, or risk of delayed onset muscle soreness. This will be mediated by facilitators being trained to lead physical activity sessions, following procedures such as warming up prior to exercise and supervising all sessions with participants. There is also the low risk of injury during the cooking sessions due to equipment being used such as knives, ovens and stove tops which may cause accidental injury if used improperly. This risk is mediated by all sessions being supervised by senior dietitians and occupational therapists.

Additionally, the research team is made up of highly experienced and trained researchers and clinicians who have professional experience to recognise when an individual may be experiencing distress or discomfort during any of the sessions or assessments. The research team will work closely with the clinical team regarding the participants' wellbeing. The research team will guide care co-ordinators to take special consideration if referring people at the start of their admission for whom it may be too soon to consent to the study.

Benefits

The benefits to taking part in the study include individuals having a physical health check at multiple timepoints during the study. All participants (even the control group) will receive access to a multi-disciplinary intervention which has the potential to improve physical and mental health. This is in addition to the standard of care available to people in the units. The research team will provide individuals a summary of their physical health should they wish, which may be useful for some people. They will also be providing an important contribution to new information in physical health care in mental health services, and service improvement, and may find some benefit in the knowledge of this. The information will enable us to optimise physical health care for adults admitted to secure inpatient units.

Participants will receive a £20 payment at the baseline appointment and at the end of the follow-up visits (£60 in total). This will be offered since participating in the research study may

require some effort and take up the participants' time. All participants will also receive a certificate of achievement and any materials from the intervention will be free for the participants to keep (eg. workbooks, water bottles).

10.7 Patient and Public Involvement

There has been extensive PPI which has underpinned this study. Motiv8 is co-developed and co-produced with service user input, from conception and ongoing iterative updates have been used to incorporate feedback from previous cohorts. Service users will assist with facilitating Motiv8, as will our PPI co-investigators. The study has been reviewed at PPI discussion groups and contributed to the development of this protocol. We also have two PPI co-investigators on the study team who will work throughout to ensure the research is appropriate and sensitive to the needs of service users. We will set up a PPI group to advise on all aspects of the study as we progress.

10.8 Peer Review

This protocol has undergone extensive peer review. The scientific quality and requirement for the study has been reviewed internally within the research team during a series of meetings, and externally by academics and clinicians at all potential and included sites. The funding application underwent a highly competitive review process to obtain funding from the NIHR and has undergone external review prior to being accepted. The sponsor (Greater Manchester Mental Health NHS Foundation Trust) has critically reviewed and approved the protocol.

10.9 Covid-19 Contingency Planning

This protocol was developed prior to the Covid-19 pandemic. The research team are hopeful that this research will be conducted according to the protocol. However, in the instance that the UK remains in a partially 'locked down' situation, or re-enters a 'full lockdown' the research team will adhere to all national and local guidelines and policies, such as reducing face-to-face contact, maintaining social distancing, wearing of personal protective equipment, conducting assessments virtually or over the phone, maintaining hygiene standards and monitoring of own health status, to avoid putting any participant at risk. The research assistants will be trained in local policy and provided with adequate support from line management and the local NHS trust/university. More information can be found in the appendix.

11. Finance and Insurance

11.1 Funding

This study is funded by the National Institute of Health Research (NIHR) Research for Patient Benefit (RfPB) Programme (Grant Reference Number NIHR201482). Main and Sub-Contracts attached to the funding are drawn up in separate documents.

11.2 Insurance

Greater Manchester Mental Health NHS Foundation Trust will act as the sponsor for this study and as such the NHS indemnity scheme will apply.

12. Dissemination & Publication Policy

Dissemination will occur with researchers, staff, service users and PPI representatives. Results will be disseminated via multiple modalities to ensure maximum reach within the healthcare networks.

The main aims of the feasibility study are to obtain evidence for the acceptability for a weight management intervention to inform a definitive study, this will be delivered via descriptive data and analysis of the data. This will include reporting data in line with the CONSORT 2010 Statement. There will be additional reporting of qualitative data. These findings will be written up for publication in high impact peer-reviewed journals as open access. Additional outputs include the development of a protocol and manualised intervention, and training materials to deliver the intervention. We will also present the findings at national and international conferences, as well as service user / voluntary sector organisations and networks and their newsletters and websites. Participants involved in the study will be encouraged to participate in dissemination should they wish.

The study will be registered on a public registry, International Standard Randomised Controlled Trial Number Registry when ethics approval is granted. This will ensure that information about the protocol is publicly available, and contact details are provided for the CI. This will be updated on a regular basis and results will be made available within 1 year of finishing the study.

A publication policy will be drawn up and agreed within the research team. The CI will have lead authorship on any academic papers arising from the study, and all members of the research team will be invited as co-authors on any further published papers. The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by National Institute for Health Research. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

13. References

Ashdown-Franks, G., Firth, J., Carney, R., Carvalho, A. F., Hallgren, M., Koyanagi, A., ... & Stubbs, B. (2020). Exercise as medicine for mental and substance use disorders: a meta-review of the benefits for neuropsychiatric and cognitive outcomes. *Sports Medicine*, *50*(1), 151-170.

Billingham, S. A., Whitehead, A. L., & Julious, S. A. (2013). An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. *BMC medical research methodology*, *13*(1), 1-6.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology*, *3*(2), 77-101.

Brown, S., Kim, M., Mitchell, C., & Inskip, H. (2010). Twenty-five year mortality of a community cohort with schizophrenia. *The British journal of psychiatry*, *196*(2), 116-121.

Buysse, D. J., Yu, L., Moul, D. E., Germain, A., Stover, A., Dodds, N. E., ... & Pilkonis, P. A. (2010). Development and validation of patient-reported outcome measures for sleep disturbance and sleep-related impairments. *Sleep*, *33*(6), 781-792.

Care Quality Commission. (2016) Monitoring the Mental Health Act in 2015/2016. *Care Quality Commission.*

Cella, D., Riley, W., Stone, A., Rothrock, N., Reeve, B., Yount, S., ... & PROMIS Cooperative Group. (2010). The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. *Journal of clinical epidemiology*, *63*(11), 1179-1194.

Correll, C. U., Solmi, M., Veronese, N., Bortolato, B., Rosson, S., Santonastaso, P., ... & Stubbs, B. (2017). Prevalence, incidence and mortality from cardiovascular disease in patients with pooled and specific severe mental illness: a large-scale meta-analysis of 3,211,768 patients and 113,383,368 controls. *World Psychiatry*, *16*(2), 163-180.

Davoren, M., Byrne, O., O'Connell, P., O'Neill, H., O'Reilly, K., & Kennedy, H. G. (2015). Factors affecting length of stay in forensic hospital setting: need for therapeutic security and course of admission. *BMC psychiatry*, *15*(1), 1-15.

Day, J. C., Wood, G., Dewey, M., & Bentall, R. P. (1995). A self-rating scale for measuring neuroleptic side-effects: validation in a group of schizophrenic patients. *The British Journal of Psychiatry*, *166*(5), 650-653.

De Hert, M., Schreurs, V., Vancampfort, D., & Van Winkel, R. (2009). Metabolic syndrome in people with schizophrenia: a review. *World psychiatry*, *8*(1), 15.

Dollfus, S., Mach, C., & Morello, R. (2016). Self-evaluation of negative symptoms: a novel tool to assess negative symptoms. *Schizophrenia bulletin*, *42*(3), 571-578.

Duke, L. H., Furtado, V., Guo, B., & Völlm, B. A. (2018). Long-stay in forensic-psychiatric care in the UK. *Social psychiatry and psychiatric epidemiology*, *53*(3), 313-321.

Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., & Lancaster, G. A. (2016). CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *bmj*, *355*.

Firth, J., Siddiqi, N., Koyanagi, A., Siskind, D., Rosenbaum, S., Galletly, C., ... & Stubbs, B. (2019). The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness. *The Lancet Psychiatry*, *6*(8), 675-712.

Herdman, M., Gudex, C., Lloyd, A., Janssen, M. F., Kind, P., Parkin, D., ... & Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research*, *20*(10), 1727-1736.

Keetharuth, A. D., Brazier, J., Connell, J., Bjorner, J. B., Carlton, J., Buck, E. T., ... & Barkham, M. (2018). Recovering Quality of Life (ReQoL): a new generic self-reported outcome measure for use with people experiencing mental health difficulties. *The British Journal of Psychiatry*, *212*(1), 42-49.

Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies: recommendations for good practice. *Journal of evaluation in clinical practice*, *10*(2), 307-312.

Martin, J., Chater, A., & Lorencatto, F. (2013). Effective behaviour change techniques in the prevention and management of childhood obesity. *International journal of obesity*, *37*(10), 1287-1294.

McInerny, T., & Minne, C. (2004). Principles of treatment for mentally disordered offenders. *Crim. Behav. & Mental Health S43*, *14*.

Nelson, M., Erens, B., Bates, B., Church, S., & Boshier, T. 24-hour recall instructions. *London: Kings College London*.

Parkinson, S., Forsyth, K., & Kielhofner, G. (2006). *A User's Manual for the Model of Human Occupation Screening Tool (MOHOST),(Version 2.0)*. Model of Human Occupation Clearinghouse, Department of Occupational Therapy, College of health and Human Development Sciences, University of Illinois at Chicago.

Public Health England. Working Together to Address Obesity in Adult Mental Health Secure Units. Public Health England. (2016). Available from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/591875/obesity_in_mental_health_secure_units.pdf (accessed 17.07.17).

Public Health England. (2018). Health matters: reducing health inequalities in mental illness.

Roesch, R. and Cook, A.N. eds., (2017). *Handbook of forensic mental health services.* Taylor & Francis.

Rosenbaum, S., & Ward, P. B. (2016). The simple physical activity questionnaire. *The Lancet Psychiatry*, *3*(1), e1.

Schalast, N., Redies, M., Collins, M., Stacey, J., & Howells, K. (2008). EssenCES, a short questionnaire for assessing the social climate of forensic psychiatric wards. *Criminal Behaviour and Mental Health*, *18*(1), 49-58.

Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *Trials*, *11*(1), 1-8.

Shiers, D., Bradshaw, T., & Campion, J. (2015). Health inequalities and psychosis: time for action. *The British Journal of Psychiatry*, *207*(6), 471-473.

Sim, J. and Lewis, M. (2012). The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *Journal of clinical epidemiology, 65(3), pp.301-308.*

Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S., ... & Stewart-Brown, S. (2007). The Warwick-Edinburgh mental well-being scale (WEMWBS): development and UK validation. *Health and Quality of life Outcomes*, *5*(1), 1-13.

Thornicroft, G. (2011). Physical health disparities and mental illness: the scandal of premature mortality. *The British Journal of Psychiatry*, *199*(6), 441-442.

Tobi, P., Estacio, E. V., Yu, G., Renton, A., & Foster, N. (2012). Who stays, who drops out? Biosocial predictors of longer-term adherence in participants attending an exercise referral scheme in the UK. *BMC Public Health*, *12*(1), 1-7.

Watkins, A., Rosenbaum, S., Ward, P. B., Patching, J., Denney-Wilson, E., & Stein-Parbury, J. (2017). The validity and reliability characteristics of the M-BACK questionnaire to assess the barriers, attitudes, confidence, and knowledge of mental health staff regarding metabolic health of mental health service users. *Frontiers in public health*, *5*, 321.

Yu, L., Buysse, D. J., Germain, A., Moul, D. E., Stover, A., Dodds, N. E., ... & Pilkonis, P. A. (2012). Development of short forms from the PROMIS™ sleep disturbance and sleep-related impairment item banks. *Behavioral sleep medicine*, *10*(1), 6-24.

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta psychiatrica scandinavica*, *67*(6), 361-370.

Appendix

Appendix A – Amendment History

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

Appendix B – COVID-19 Contingency Plan

Amendments during the Covid 19 pandemic to be made for remote working – summary of key points

1. Recruitment to study:
   Due to the ongoing restrictions we may not able to meet teams face to face to discuss the study, this might make it more difficult to recruit as it is easy for clinical teams to forget about the study. Researchers will attend meetings virtually where appropriate and present the study to the teams. Information sheets and packs may be emailed or sent via internal post to the wards.

2. Taking referrals:
   This will be done remotely, and researchers will obtain electronic consent to contact, before taking down the referrer details using an electronic version of the referral form (password protected). This may be done over the phone or via password protected emails. A recent risk assessment should be obtained over the phone, or over a video call from clinicians before the potential participant is contacted.

3. First contact:
   The first contact with the potential participant will be done virtually in a way which works best for them eg. over the phone, or using a virtual platform. The PIS will be provided along with any other information via either posting paper copies to the care teams or by emailing these to clinicians to give to their service users. The researcher will only meet face to face with the participant if the ward manager, local research department and study lead approves this.

4. Informed Consent:
   Participants will be offered several ways to provide their informed consent to take part in the study including paper copies passed back to the research team from the care team, providing verbal consent over the phone which is recorded by the researcher, or sending electronically signed and dated consent forms via email to the researcher. All methods will comply with GDPR and will need to be stored separately from any personal identifiable data (eg. encrypted recordings saved in a different folder, password protected emails and word documents).

5. Collecting outcome measures:
   Due to restrictions on face-to-face contact with service users, researchers may be unable to collect any physical measurements. This means that facilitators of the intervention will need to complete these measures within the initial sessions. All other outcome measures will be collected via virtual methods such as over the phone, over a video call or via electronically completed forms. This will be done from home or from a designated office space and the researcher will complete the CRF. All PID will be stored securely and saved in password protected documents.

6. Delivering the intervention
   There may be restrictions on clinical staff being able to deliver their sessions face to face. Therefore, some sessions may need to be delivered remotely (eg. psychology sessions). However, as facilitators are based within the clinical teams, we will hope to deliver sessions safely on the wards. This may affect the content of the sessions e.g the amount of people who can be in the kitchen at the same time. If the sessions cannot be delivered as planned and there are restrictions on who can be on the wards, we will revisit this with the TSC to discuss delaying or pausing the study.

7. Payment:
   This can be done either virtually with the use of electronic gift vouchers, or with hard copies sent out or dropped off at the units. All gift vouchers (regardless of delivery) will need to be logged and recorded.

8. PPE and Social Distancing:
   During the pandemic, the researcher will only be able to meet face-to-face with participants and clinical services with the approval of the local PI, the ward management, and the local research and development department. All parties must adopt local and/or national policies in place at the time, such as wearing of adequate PPE (personal protective equipment), maintaining social distancing and meeting in a place large enough to accommodate this, following local policy for track and trace, and ensuring hygiene procedures are adopted.