Study Protocol for a Pilot High Intensity Interval Training Intervention in Inpatient Mental Health Settings: A Two-Part Study Using a Randomised Controlled Trial and Naturalistic Study Design

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Abstract

Background: Severe mental illnesses (SMI), including schizophrenia spectrum disorder, bipolar disorder and major depressive disorder are associated with physical health comorbidities and premature mortality. Physical activity and structured exercise have a beneficial impact on cardiometabolic risk and ameliorate mental health symptomology and cognition. This protocol describes a feasibility study for a high intensity interval training (HIIT) intervention amongst inpatients with SMI, to improve their physical and mental health.

Methods: The feasibility study follows a two-part design owing to Covid-19 related adaptations to project design: a) A non-blinded randomized controlled trial (RCT) of 12 weeks of bicycle-based HIIT, delivered twice weekly in a face-to-face, one-to-one setting, compared to treatment as usual (TAU). b) A naturalistic study of inpatient HIIT; eligible participants will be invited to two sessions of HIIT per week, delivered by the research team remotely or in person. Additionally, participants may use the bike to conduct self-directed sessions of their chosen length and intensity. We will measure feasibility and acceptability of the HIIT intervention as primary outcomes, alongside secondary and tertiary outcomes evaluating the physical, mental and cognitive effects of HIIT. The study aims to recruit 40 patients to the RCT and 6-8 patients to the naturalistic design.

Discussion: Exercise is a modifiable lifestyle barrier that can reverse cardiometabolic disease risk. If HIIT is found to be feasible and acceptable in inpatients with SMI there would be scope for large scale work to evaluate the clinical, cost and implementation effectiveness of HIIT in inpatient mental health settings.

Trial registration: ClinicalTrials.gov, registration no: NCT03959735, registered 22/05/2019, https://clinicaltrials.gov/ct2/show/NCT03959735

1. Background

Severe mental illnesses (SMI), including schizophrenia spectrum disorder, bipolar disorder and major depressive disorder (MDD) are leading causes of years lived with disability, affecting approximately 3–5% of the population (1–3). Along with the impact of the mental health symptoms and reduced daily functioning, SMIs are associated with physical health comorbidity and an associated premature mortality amounting to 13–20 years (4, 5). Cardiometabolic diseases, including the metabolic syndrome, diabetes mellitus, obesity, and coronary heart disease are two-fold higher in people with SMI (6, 7). In addition, people with SMI typically experience cognitive impairment, socio-occupational difficulties and reduced quality of life (QoL) which may worsen over time (8–11).

The newly published WHO guidelines report that frequent physical activity and structured exercise have a beneficial impact on cardiometabolic and cardiovascular disease risk, and ameliorate symptoms and QoL for those living with these complications (12). Further, regular exercise can improve mental health, cognition and sleep quality, in both the general population and those with severe mental health conditions (13–16), and may aid smoking cessation in the long term (17, 18). Acute exercise bouts can

also have immediate effects on appetite and cigarette cravings (19–21), cognitive functioning (22), and positive wellbeing in healthy and clinical populations (22–24). This said, people with SMI engage in significantly less moderate and vigorous intensity exercise than the general population and are less likely to meet physical activity guidelines of 150 minutes of exercise per week (25). Thus, low levels of physical activity are recognised as contributing towards physical, mental and cognitive ill health in this population group (13), along with higher levels of tobacco consumption and antipsychotic induced weight gain. Physical activity is a modifiable lifestyle risk factor; thus, a focus of current research is to increase levels of physical activity in people with SMI and to promote uptake of structured exercise interventions (26). For example, the recent European Psychiatric Association (EPA) guidance draws on 20 past systematic reviews in SMI population and suggests physical activity should be used as an adjunctive treatment in SMI to improve mental health symptoms, physical health, cognition and quality of life (13).

High intensity interval training (HIIT) is a type of exercise characterised by alternating short bursts (typically 30 seconds to 4 minutes) of high intensity exercise interspersed by similar length periods of light exercise or rest, repeated for typically 10-25minutes. This popular fitness approach yields positive effects on physical and mental health in the general population and may be more beneficial in terms of improvements in cardiometabolic health when compared to traditional moderate intensity continuous training (MICT) approaches (27). Preliminary work has sought to establish the effectiveness of HIIT in people with schizophrenia spectrum disorders (28–34), major depressive disorders (35–38), and adults with self-reported psychiatric problems (39) in interventions of duration 12 days to 6 months. This work has been summarised in two recent meta-analyses, whereby significant improvements in depressive symptoms and cardiorespiratory fitness were reported post HIIT intervention, and there was a suggestion that HIIT may be more beneficial in terms of improvements in depressive symptoms when compared to MICT (40, 41). Further, HIIT may improve cognitive measures including verbal learning and overall neurocognition (34). This said, there is inconsistency concerning the effects of HIIT on psychopathology, social and global functioning, and anthropometric measures, which is hampered by small sample sizes and a paucity of clinical trials. Total number of participants with an SMI allocated to HIIT ranges from 8 (39) to 43 (28, 34) across trials, and meta-analysis data summarised findings from just 366 participants with SMI, including comparison groups. To add, previous work in people with SMI has reported a low rate of adverse events (AE) including no acute injuries or cardiovascular events, completion rates of approximately 71% and a mean attendance at sessions of 74%, suggesting good feasibility and acceptability, although these measures have only been reported in roughly half of HIIT trials in people with SMI to date (40, 41).

To add, two trials have sought to establish the acute effects of HIIT in those with a mental illness (42, 43). In patients with schizophrenia and depression, there was an improvement in positive affect and wellbeing, and a reduction in psychological distress and state anxiety from pre-training to 15 minutes post HIIT (42). In adolescents hospitalised with MDD, suicidal ideation, stress and anxiety disorders, there was a suggestion that acute bouts of HIIT may improve inhibitory control for up to 30 minutes post exercise (43).

Despite the initial evidential support for HIIT in people with SMI, little work has been undertaken with patients receiving treatment on psychiatric wards, in particular in those with schizophrenia spectrum disorders. To date, four papers have assessed the effect of HIIT in inpatients with MDD (35–38), one has assessed HIIT in inpatients with schizophrenia (31), and another has looked at the acute effects of a single bout of HIIT in adolescents receiving inpatient mental health treatment (43), highlighting a need for further research in this population and setting. Moreover, a recent qualitative analysis explored perspectives on implementing HIIT interventions in inpatient mental health settings (44). Across seven focus groups, in inpatients with SMI, carer and staff groups, HIIT was seen positively, with beliefs that it would help inpatients feel more relaxed, build their fitness, and provide a break from the monotony of ward environments. This said, concerns were noted related to patient motivation, safety, especially for those with chronic physical health comorbidities, and practical logistical factors, including having access to the right sports clothing and staff availability to supervise (44).

1.1. Aims

The primary aim of the study, therefore, is to determine whether HIIT is acceptable and feasible amongst inpatients with a broad range of severe mental illnesses, and the secondary aim is to investigate if the HIIT intervention improves mental health symptoms, including psychiatric symptoms, depression, anxiety, stress, sleep and mental wellbeing; cognition; and physical activity measures including increases in weekly physical activity, motivation to engage in exercise and anthropometric measures. The tertiary aim is to determine whether a single bout of HIIT leads to acute changes in psychological states and appetite and cigarette cravings.

2. Methods/ Design

2.1. Design

The pilot study follows a two-part design owing to Covid-19 related adaptations to project design (and subsequent social restrictions).

1. a) A parallel non-blinded randomized controlled trial (RCT) of HIIT compared to treatment as usual (TAU). Participants allocated to HIIT will received 12 weeks of HIIT twice weekly, delivered in a face-to-face setting. Participants assigned to TAU will be instructed to maintain their usual dietary habits, no restrictions will be applied to their current level of physical activity.
2. b) A naturalistic study of HIIT uptake. All eligible participants will be invited to take part in two sessions of HIIT per week, delivered by the research team remotely or in person depending on Covid-19 social restrictions. Additionally, patients will be able to use the bike to conduct self-directed sessions of their own chosen length and intensity. No time limit for participation will be applied.

The novel two-part design is based on the need to adapt to Covid-19 restrictions and is thus a strength.

The pilot design (Part A) is registered online (ClinicalTrials.gov Identifier: NCT03959735) and has been reported in accordance with the CONSORT for reporting of pilot and feasibility trials (45), and the SPIRIT guideline for main trials was consulted (46). Ethical approval was obtained from London Bloomsbury Ethics Committee (IRAS ID: 263996, REC reference 19/LO/0901) for part A of the research and governance approval was granted from local National Health Service (NHS) bodies for part B of the research (Lewisham and Croydon NHS governance teams). A flow diagram of the study design is provided in Figs. 1–2, and the schedule of enrolment, interventions and assessments is provided in Fig. 3.

2.2. Setting

Participants will be recruited from adult inpatient settings operating in one large London mental health National Health Service (NHS) Trust, South London & Maudsley NHS Foundation Trust (SLaM), which provides inpatient and community mental health care for people residing in London boroughs of Lambeth, Southwark, Lewisham and Croydon, along with National Specialist services. The HIIT intervention will be conducted, face to face, in the hospital Physiotherapy department for those recruited to the RCT design. The HIIT intervention will be conducted, remotely or face to face, on the inpatient ward for those recruited to the naturalistic design dependant on Covid-19 social restrictions.

2.3. Participants

Participants will be recruited from adult inpatient settings operating in SLaM, through adverts and presentations at ward-based community meetings for patients, and via clinician referral. Additionally, posters will be displayed on wards with a request that anyone with an interest in taking part should contact the research team. All those who display an interest will be given written information on the study and invited to take part, providing they meet study eligibility criteria.

Individuals will be eligible for the study if they meet the following criteria: 1) a service user receiving inpatient care in the participating NHS Trust for a severe mental health condition (including schizophrenia, MDD and bipolar disorder); 2) sufficient command of spoken English; 3) able to provide written informed consent. Exclusion criteria include: 1) a medical condition that impedes exercise (e.g., chronic back pain); 2) an eating disorder (e.g., anorexia nervosa, bulimia nervosa) characterised by excessive exercise; 3) pregnancy. Additionally, in Part A of the research design eligibility will be limited to those aged 18–60 years old.

We aim to recruit 40 participants to the RCT phase, 20 in the intervention and 20 in the control group over a 1-year period. This number is based on recruiting a big-enough sample to assess the feasibility of the study and on the resources available (47). We aim to recruit 6–8 participants to the naturalistic phase of the study. This reduced sample considers Covid-19 related challenges to recruitment, including reduced referrals and admissions to inpatient mental health wards during the pandemic.

2.4. Procedure

Participants who satisfy eligibility criteria will be screened using the Physical Activity Readiness Questionnaire (PAR-Q)(48) to determine readiness to exercise. Participants will be deemed eligible to

exercise according to the PAR-Q if they do not: a) experience chest pain during exercise; b) have a bone or joint problem (for example, back, knee or hip) or a heart condition that could be made worse by a change in physical activity; or c) lose balance due to dizziness. In Part A of the study design participants will be asked to give written informed pre-consent before completing the PAR-Q.

Following satisfaction that the participant is ready to exercise according to this screening tool, participants will meet with a member of the research team to obtain written informed consent for study participation and complete baseline assessments.

2.4.1 RCT Design: Part A

Participants will complete a sociodemographic questionnaire, mental health assessments, a cognitive test, anthropometric measures, lifestyle assessments and the bicycle YMCA submaximal fitness test (49). The YMCA fitness test is used to predict the maximum rate of oxygen consumption (VO2max) during incremental exercise via measuring heart rate changes in response to an increase in resistance. It is an extrapolation method whereby heart rate workload points are gathered and extrapolated to age predicted maximal heart rate (49). Mental health assessments, the cognitive test, anthropometric measures, lifestyle assessments and the bicycle YMCA submaximal fitness test will be repeated at week 6 and week 12 (post-intervention). Participants who are unable to complete the YMCA test will be excluded to avoid AEs of an incomplete capacity to engage in HIIT. Following successful completion of these assessments the participant will be assigned a unique code that will be sent to King's Clinical Trial Unit for randomisation. Participants will be randomised in a 1:1 ratio to HIIT or TAU conditions using block randomisation with varying block sizes. Participants and researchers will be notified of allocation after completion of all baseline assessments.

Those allocated to HIIT will receive two, one-to-one, sessions per week for 12 weeks, comprising 24 sessions in total in addition to TAU. HIIT sessions will take place in the hospital physiotherapy department and will be supervised by a member of the research team, additional support will be provided by a healthcare assistant, nurse or occupational therapist where Sect. 17 leave conditions stipulated accompany off ward by ward-based staff (Mental Health Act, 1983, (50)).

2.4.2 Naturalistic Design: Part B

Participants will complete a sociodemographic questionnaire. All participants recruited to the naturalistic study phase will be invited to take part in HIIT, no time limit for participation will be applied. Participants will be able to take part in two HIIT sessions per week for the full duration that the study is running and will not be excluded if they wish to take part at a reduced capacity. HIIT sessions will take place on the ward in which the patient resides. A member of the research team will deliver the session remotely via projector screen with a ward-based member of staff on hand to assist the patient where required, or face-to-face (dependent on Covid-19 restrictions).

Additionally, participants will be able to use the bike to conduct self-directed sessions of their own chosen length and intensity either in addition to the supervised HIIT sessions or instead, these sessions will be facilitated by ward staff.

2.5. Intervention

2.5.1 High Intensity Interval Training

Each session will take part on a stationary bike and will comprise a four-minute warm up, five one-minute intervals at 85–95% of maximum heart rate (HRmax) interspersed with 90 seconds of cycling at 60–70% of HRmax, followed by a four-minute cool down. The total session duration is 19 minutes. Heart rate will be recorded at the end of each high intensity interval using handlebar sensors or a chest strap to monitor compliance with target heart rates. Heart rate ranges will be achieved by adjusting ergometer resistance, and speed. Duration will be adapted for those unable to complete the standardised format (e.g., intensity and/or length of sessions reduced), and the intervention will be incrementally increased as fitness improves. For Part A only, failure to attend sessions for two weeks without reason will result in withdrawal from the study as it will be assumed that the participant no longer wants to take part in the trial. Music will be played for the duration of HIIT sessions to maximise motivation.

2.5.2 Treatment as Usual

Participants allocated to TAU will be instructed to maintain their usual dietary habits, no restrictions will be applied to their current level of physical activity.

2.5.3 First HIIT Session (Part A Only)

Participants will complete the Subjective Exercise Experiences Scale (SEES)(51) and self-report measures of appetite and cigarette cravings immediately before and immediately after their first exercise session to determine the acute effects of HIIT on psychological states and cravings. Participants allocated to TAU will complete these assessments before and after 19 minutes of sitting still in quiet, with no distractions such as music or reading material, during the first week of enrolment.

2.6. Outcomes

2.6.1 Primary Outcomes

Feasibility will be assessed using multiple primary endpoints: a) percentage of wards consulted that agree to hosting the project; b) recruitment numbers and reasons for disinterest; c) completion rates; d) attendance to HIIT sessions; e) adherence to HIIT protocol; and f) AEs (defined as any untoward medical occurrence in a subject to whom a therapy has been administered including occurrences which are not necessarily caused by or related to that therapy).

Acceptability will be assessed at the end of each HIIT session using a single item 10-point Likert scale from 1 (not satisfied) to 10 (most satisfied), and an end of study survey consisting of 12-items for the

HIIT group, and 5-items for the TAU group, rated on a 5-point Likert scale (strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree) will be employed. This survey was adapted from the acceptability questionnaire originally employed by Chapman et al. (2017)(39). Questionnaire items are shown in Supplementary Tables 1–2, Additional file 1.

Additionally, in Part B we will measure whether patients take part in HIIT sessions or conduct self-directed sessions on the bike. For self-directed sessions we will ask patients to note whether they follow the HIIT format or conduct a different form of exercise and we will measure satisfaction as above.

2.6.2 Secondary Outcomes (Part A Only)

Secondary outcomes include a range of mental, cognitive and lifestyle outcomes, and will be measured at 6 weeks and 12 weeks post randomisation:

Mental health status

Symptoms of poor mental health will be assessed using the Depression Anxiety Stress Scale (DASS21) (52), the Short Warwick Edinburgh Mental Well-being Scale (SWEMWBS)(53), the Brief Psychiatric Rating Scale (BPRS)(54), and the brief insomnia severity index (ISI)(55). The DASS21 is a 21-item questionnaire containing 3 subscales (depression, anxiety, stress) of 7 items, with possible scores ranging from 0 to 21. The subscales have high internal reliability in adults across a range of mental illnesses (Cronbach's a ¼ 0.94, 0.87 and 0.91 for depression, anxiety, and stress respectively) (56). The SWEMWBS is a brief 7-item scale that measures key aspects of psychological functioning, scores range from 7–35, validated in people with SMI (53, 57). The BPRS measures psychiatric symptoms including hallucinations, unusual thought content, emotional withdrawal, depression, anxiety and self-neglect (54) over 18-items, with total scores ranging from 18–126, with high inter-rater reliability and validity (58, 59). The brief ISI is a 7-item questionnaire, with scores ranging from 0–28 whereby a score of 15 or above indicates clinical insomnia (55), validated for sleep disorders (55) and used previously in people with SMI (60–62).

Cognitive function

Cognitive function will be assessed using the Montreal Cognitive Assessment (MoCA) (63). This brief screening tool has high sensitivity and specificity for detecting mild cognitive impairments on a 0-30-point scale whereby a score below 26 indicates cognitive impairment (63).

Self-esteem

The Rosenberg Self-Esteem Scale (RSES)(64) measures self-esteem and global self-worth over 10-items, scores range from 0–30 (64). The RSES has adequate internal consistency, test-retest reliability and construct validity in people with SMI (65, 66).

Lifestyle measures

The Short-Form International Physical Activity Questionnaire (IPAQ-SF)(67) captures self-reported physical activity and sedentary behaviour over 7-items, has been validated in people with SMI (68, 69) with comparable reliability and criterion validity to that reported in the general population (68, 69). Motivation to engage in physical activity will be measured via The Behavioural Regulation in Exercise Questionnaire-3 (BREQ-3), it consists of 24 items related to six motivation types (amotivation, external regulation, introjected regulation, identified regulation, integrated regulation and intrinsic regulation), and has been validated in people with schizophrenia (70).

Cardiorespiratory fitness

The bicycle YMCA submaximal fitness test measures estimated VO2max (49). This test provides an inexpensive, quick (15 minutes to administer) and safe measure of VO2max in comparison with maximal fitness tests which may provide more accurate findings but require the use of expensive or off-putting equipment (such as oxygen masks or mouth pieces) and highly skilled personnel (49). Moreover, direct measurement requires participations to exercise until exhaustion, which may be challenging for those with lower baseline fitness and those with chronic psychiatric symptoms. The YMCA test has been validated for the prediction of VO2max (49), and has been used to predict VO2max in people with SMI (71, 72). Additionally, gait speed will be measured as time taken to walk 6 metres. Gait speed has been measured using similar estimates in previous studies with people with SMI (73, 74).

Anthropometric measures and cigarette intake

BMI, waist circumference (WC), blood pressure and cigarette intake will be collected as they provide an indication of cardiometabolic and cardiovascular disease risk (75, 76). WC will be taken from the umbilicus with the participant standing. BMI will be calculated based on height and weight. Systolic and diastolic blood pressure will be assessed via a blood pressure monitor using standardized techniques, two readings will be taken at 5-minute intervals and the second will be used. Participants will be asked their daily cigarette intake.

2.6.3 Tertiary Outcomes (Part A Only)

The SEES will assess psychological states, it has been validated to assess the effects of exercise on psychological states (51). This self-report questionnaire contains 12-items, rated on a 7-point Likert scale, subdivided into three subscales to assess immediate feelings of positive well-being, psychological distress and fatigue.

Smokers will be asked to rate cigarette craving on a 10-point Likert scale, with higher scores indicating higher levels of cravings. All participants will be asked to rated appetite craving on a 10-point Likert scale, and will be additionally asked “If you do feel like eating what would it be?”.

2.7. Data Management

Each participant will be allocated an anonymised patient identification number (PIN). All information collected will be kept confidential; all identifiable data will be stored in locked filing cabinets. The

outcome data will be collected on paper forms and will be transferred to an IBM Statistical Package for the Social Sciences (SPSS) database (SPSS version 27, Chicago, IL, USA). The research ethics committee will be consulted prior to any changes in protocol. The protocol used will be made available on request.

2.8. Safety

During Part A, all AEs and adverse reactions (ARs) (any untoward and unintended response in a subject to a therapy which is related to any duration of therapy administered to that subject), whether serious or not, will be reported to the ward-based clinical team within 24 hours. Serious AEs (SAE), serious ARs (SAR) and unexpected serious ARs (USAR) will be reported to the participant's GP. Appropriate action will be taken which may include: 1) withdrawing the participant from the trial, 2) adapting the exercise regime for the participant (and potentially for other participants), 3) terminating the trial if necessary.

SAEs, SARs and USARs are defined as any AE, AE or unexpected AR, respectively, that are life-threatening; require hospitalisation or prolongation of existing hospitalisation; or result in significant disability.

During Part B, if an AE or AR occurs during exercise the session will be stopped and a physical health check will be carried out if required. The clinical team will be consulted. Depending on the severity of the event the exercise regime may be adapted for that patient or it may be decided that they are not able to exercise at their current physical health status.

2.9. Data Analysis

Acceptability and feasibility outcomes will be reported post-randomisation and summarised by treatment arm (HIIT and TAU) and study phase (RCT and naturalistic phase).

For the secondary aim, to evaluate effectiveness of the intervention, changes pre- and post-intervention in mental and physical health parameters will be assessed and summarised by treatment arm. We will compare mean changes in secondary outcome measures in the HIIT group versus the TAU group using data from those recruited to the RCT study phase. This secondary analysis will be based on the intention-to-treat sample, the significance level will be set at 5% (2-sided).

For the tertiary outcomes, changes pre- and post-intervention in psychological wellbeing, psychological distress, fatigue, and appetite and cigarette cravings following a single bout of HIIT will be assessed and summarised by treatment arm. We will compare mean changes in tertiary outcome measures in the HIIT group versus the TAU group using data from those recruited to the RCT study phase. As above, this analysis will be based on the intention-to-treat sample, the significance level will be set at 5% (2-sided). An additional analysis will be conducted with those participants who adhered to the HIIT protocol (completed the full 19-minute HIIT session and who reached the target heart rate).

Data analysis will be conducted using Statistical Package for the Social Sciences (SPSS) version 27 (Chicago, IL, USA).

2.10. Reimbursements

Participants will not receive payment, although complementary reusable water bottles and gym tops will be provided.

In Part A of the study, participants who are discharged from the inpatient setting over the course of the trial will be invited to return to the hospital to resume HIIT sessions, subject to Covid-19 social restrictions, and associated travel costs will be reimbursed. In Part B of the study, participants who are discharged from the inpatient setting will not be invited to the hospital to resume HIIT sessions due to insurance limitations, Covid-19 social restrictions and simplistic nature of the study.

2.11. Follow-up

Participants who take part in part A of the pilot study will be invited to take part in individual semi-structured follow-up qualitative interviews. We hope to conduct each qualitative interview within 3 weeks of each participant finishing the HIIT pilot study/ within 3 weeks of drop-out if time commitments permit. We aim to find out 1) how participants experienced the intervention, 2) if there are any parts of the intervention that could be improved, and 3) what factors influenced people in completing/not completing the intervention.

Qualitative interviews will take place via telephone or video call. Each qualitative interview will begin with the issuing of consent forms. Then, a series of simple questions about the positive aspects and weaknesses of the intervention will then be asked, and participants will answer verbally. Overall, each individual interview will take 30–60 minutes.

Material gained from the follow-up will be analysed using thematic analysis (77). The themes generated will address the barriers and facilitators, and perceived enjoyment of the HIIT intervention and areas for improvement for future work. As such data generated will seek to complement the acceptability and feasibility data gathered from the primary trial endpoints. We will offer an interview to all patients recruited to Part A of the study.

2.12. Patient and Public Involvement

The research design and participant facing documents were reviewed by a team with experience of mental health problems and their carers who have been specially trained to advise on research proposals and documentation through the Young Person’s Mental Health Advisory Group (YPMHAG) and the Feasibility and Acceptability Support Team for Researchers (FAST-R): two separate free, confidential services in England provided by the National Institute for Health Research Maudsley Biomedical Research Centre via King’s College London and South London and Maudsley NHS Foundation Trust. Moreover, an ex-service user was consulted in the design process and with knowledge in mental health disorders and exercise, both from personal experience and undergraduate study, was consulted in the design process.

Focus groups were conducted with inpatients with SMI, carers and clinical staff to investigate perspectives on implementing HIIT interventions for service users in inpatient settings, including perceived barriers and enablers (discussed in background section above) (44). Practical and safety considerations were noted and methods to increase patient motivation were sought and incorporated into the research design.

3. Discussion

This pilot study aims to evaluate the feasibility and acceptability of an exercise intervention for inpatients with SMI. To the best of our knowledge, no HIIT interventions have been developed and tested in the NHS. This study will allow us to understand the feasibility of deploying the HIIT intervention itself and the use of the primary, secondary and tertiary outcome measures. Upon completion of the study, we will have a detailed overview of whether the delivery and planned evaluation approach are feasible and acceptable to deliver as part of a multi-centre large-scale definitive trial; namely whether participants agree to take part, continue to attend HIIT sessions and assessments, and adhere to the HIIT protocol. The design of the study, using both RCT and naturalistic study design elements will allow us to adapt to the Covid-19 pandemic and related social restrictions.

The physical health of people with SMI remains a high priority, and exercise has been identified as a modifiable lifestyle barrier that has the potential to reverse cardiovascular and cardiometabolic disease risk and reduce associated premature mortality. The National Institute for Health and Care Excellence (NICE) guidelines recommend that interventions be offered to support people with SMI to be more active (78). HIIT is a time-efficient intervention that has yielded benefits for physical and mental health in other settings and populations (27). If HIIT is found to be feasible and acceptable in inpatients with SMI there would be scope for large scale work and the potential implementation of this intervention in inpatient mental health facilities.

4. Trial Status

The trial is ongoing and recruitment is open.

Abbreviations

AE: adverse events

AR: adverse reaction

BPRS: the Brief Psychiatric Rating Scale

BREQ-3: the Behavioural Regulation in Exercise Questionnaire-3

DASS21: Depression Anxiety Stress Scale

EPA: European Psychiatric Association

FAST-R: the Feasibility and Acceptability Support Team for Researchers

HIIT: high-intensity interval training

HRmax: maximum heart rate

IPAQ-SF: the Short-Form International Physical Activity Questionnaire

ISI: the brief insomnia severity index

MDD: major depressive disorder

MICT: moderate intensity continuous training

MoCA: Montreal Cognitive Assessment

NICE: the National Institute for Health and Care Excellence

NHS: National Health Service

PAR-Q: Physical Activity Readiness Questionnaire

PIN: patient identification number

RCT: randomized controlled trial

RSES: the Rosenberg Self-Esteem Scale

SAE: Serious adverse events

SAR: serious adverse reaction

SEES: Subjective Exercise Experiences Scale

SLaM: South London & Maudsley NHS Foundation Trust

SMI: Severe mental illnesses

SPSS: Statistical Package for the Social Sciences

SWEMWBS: Short Warwick Edinburgh Mental Well-being Scale

TAU: treatment as usual

USAR: unexpected serious ARs

WC: waist circumference

YPMHAG: the Young Person's Mental Health Advisory Group

Declarations

Ethics approval and consent to participate – Ethical approval was granted from London - Bloomsbury Research Ethics Committee (REC ref. 19/LO/0901). All participants will be asked to provide written informed consent.

Consent for publication – non-applicable

Availability of data and material – The datasets used during the current study may be available from the corresponding author on reasonable request.

Competing interests – none

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Authors' contributions – The study was conceived by FG and BS. The study was designed by RM, FG, BS and JO. RM drafted the manuscript with input from all other authors. All authors approved the submitted version of the manuscript.

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Figures

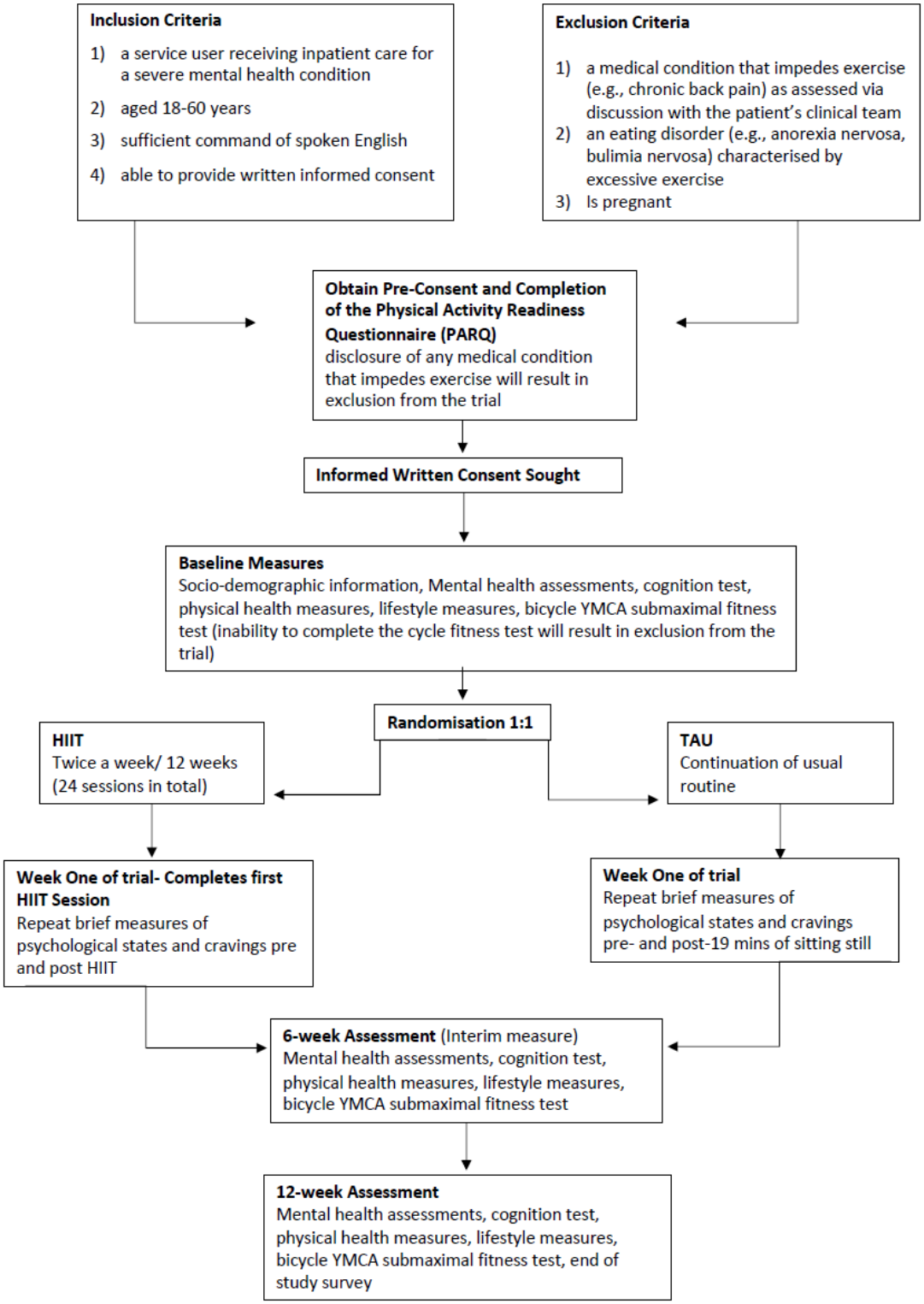

Figure 1

Study Flow Diagram Part A

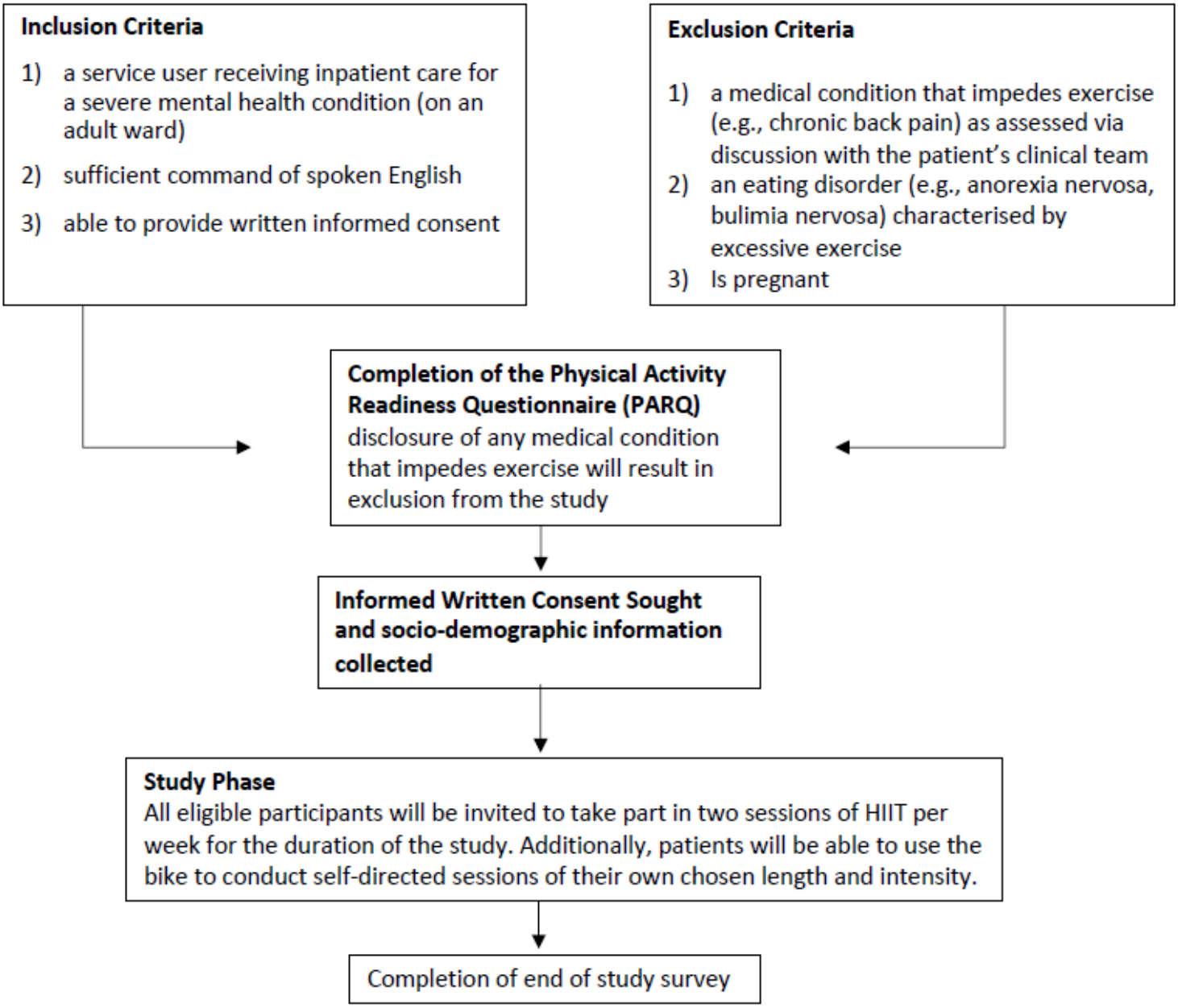

Figure 2

Study Flow Diagram Part B

Study Period					
		Post-allocation			
	Pre-allocation	Baseline	First HIIT session/ first week of TAU	6 weeks	12 weeks
Eligibility Screen	X				
PAR-Q	X				
Informed consent	X				
Randomisation*		X			
Interventions					
HIIT Group**		•----------•----------•			
TAU Group*		•----------•----------•			
Assessments					
Sociodemographics	X			X	X
Depression, anxiety, stress (DASS21)*	X			X	X
Psychiatric symptoms (BPRS)*	X			X	X
Mental wellbeing (SWEMWBS)*	X			X	X
Insomnia/ sleep quality (ISI)*	X			X	X
Cognitive function (MoCA)*	X			X	X
Self-esteem (RSES)*	X			X	X
Self-report sedentary behaviour and physical activity (IPAQ-SF)*	X			X	X
Motivation to exercise (BREQ-3)*	X			X	X
Cigarette Intake*	X			X	X
BMI*	X			X	X
Blood Pressure*	X			X	X
Waist Circumferences*	X			X	X
Gait Speed*	X			X	X
Acute Measures					
Psychological States (SEES)*			X		
Appetite Craving*			X		
Cigarette Craving*			X		

*= stages only applicable to Part A study design; **=participants recruited to Part B of study design had no fixed participation start and end date.

Figure 3

Schedule of enrolment, interventions and assessments in RCT

Supplementary Files

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- SupplementaryMaterials.docx