

Walk this Way: a pilot study investigating the effect of a motivational pedometer based walking intervention to reduce sedentary behaviour and increase activity levels of people with serious mental illness

Submission date 04/08/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

People with serious mental illness have a shorter life expectancy than the general population for many reasons including the effects of antipsychotic medication and unhealthy lifestyle. Walking is a simple and gentle form of exercise which may help people with psychosis lose weight. Breaking up sessions of sedentary behaviour (i.e., sitting or lying) can help prevent heart disease. We wish to test the feasibility of a 16-week intervention to increase physical activity and break up sessions of sedentary behaviour with people using adult community mental health services in Lambeth.

Who can participate?

Adult patients with a serious mental illness who are overweight, diabetic, smoke tobacco, or have a sedentary lifestyle, and who use adult community mental health services in Lambeth.

What does the study involve?

We will recruit 40 people and randomise them to 50% intervention and 50% control. We will collect outcome data on the person's level of activity (which will involve asking participants to wear an accelerometer for four days pre and post intervention) and wear a pedometer during the intervention. We will also collect details of sociodemographics, physical health status, and mental well-being pre and post intervention. We will also undertake a process evaluation of the intervention to understand the experience of participants by interviewing participants after the intervention has finished. We will use the information from this study to plan for a larger Randomised Controlled Trial.

What are the possible benefits and risks of participating?

We hope that participants will benefit from improved physical health in terms of increased activity, possible weight loss and increased well-being. We do not foresee any risk for the

participants but there is potential for a bruise to occur following the blood test and wearing the accelerometer may be burdensome for participants.

Where is the study run from?

South London and Maudsley NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?

September 2015 to June 2016.

Who is funding the study?

National Institute for Health Research (UK).

Who is the main contact?

Julie Williams

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Contact information

Type(s)

Public

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Walk this Way: a pilot study investigating the effect of a motivational pedometer based walking intervention to reduce sedentary behaviour and increase activity levels of people with serious mental illness

Study objectives

Our study questions is: can we recruit people with serious mental illness, who also have physical risk factors, to a walking intervention and retain them in the intervention for 4 months?

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee - City Road and Hampsted, 21/08/2015, REC ref: 15/LO/1188

Study design

Single-centre small-scale randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Serious mental illness defined as schizophrenia, bipolar disorder or major depression

Interventions

Our intervention is a 4-month intervention to support people to be more active. This will include an initial group education session regarding the benefits of physical activity lasting approximately 2.5 hours, two weekly 'coaching' sessions with a mental health worker, and the provision of a pedometer to measure the number of steps taken. Participants will also be invited to a weekly walk.

The control group will receive brief information on the benefits of being more active in one individual session.

Intervention Type

Mixed

Primary outcome measure

Amount of sedentary behaviour and physical activity measured by an accelerometer which will be worn by participants for 4 days before and after the intervention

Secondary outcome measures

1. BMI and waist circumference
 2. Self report sedentary behaviour and physical activity measured using the International Physical Activity Questionnaire
 3. Motivation to engage in physical activity measured using the Behavioural Regulation in Exercise Questionnaire 2
 4. insulin resistance, long-term blood glucose control, fasting lipids and c reactive protein measured from blood samples collected from participants
 5. Mental well-being measured using the Warwick Edinburgh Mental Well-being Scale
 6. Functional mobility measured using the Timed Get up and Go (TUG) Test
- All outcomes, primary and secondary, will be measured at baseline and follow-up, which is at the end of the 16-week intervention.

Overall study start date

01/09/2015

Completion date

01/06/2016

Eligibility**Key inclusion criteria**

1. Has a serious mental illness
2. Is any of: overweight, diabetic, smokes tobacco, has a sedentary lifestyle
3. Uses secondary mental health services

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

40

Total final enrolment

40

Key exclusion criteria

1. Has no physical health issue as listed in inclusion criteria
3. Is unable to give informed consent

Date of first enrolment

01/09/2015

Date of final enrolment

31/10/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

South London and Maudsley NHS Foundation Trust

United Kingdom

SE9 8AA

Sponsor information

Organisation

King's College London

Sponsor details

Hodgkin Building

Guy's Campus

London

England

United Kingdom

SE1 4UL

Sponsor type

University/education

Website

<http://www.kcl.ac.uk/index.aspx>

ROR

<https://ror.org/0220mzb33>

Organisation

King's College Hospital NHS Foundation Trust

Sponsor details

161 Denmark Hill

London

England

United Kingdom
SE5 8EF

Sponsor type

Hospital/treatment centre

Website

<https://www.kch.nhs.uk/>

ROR

<https://ror.org/01n0k5m85>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

We plan to publish in peer-reviewed journals, at conferences and in written reports to participants and service managers.

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/09/2019	20/09/2019	Yes	No
HRA research summary			28/06/2023	No	No
Protocol article		12/12/2016	10/10/2023	Yes	No