# 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	Recruitment status No longer recruiting	Prospectively registered		
04/08/2015		[X] Protocol		
Registration date 25/09/2015	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		Individual participant data		
10/10/2023	Mental and Behavioural Disorders			

#### 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 pedomoter 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 julie.williams@kcl.ac.uk

# Contact information

#### Type(s)

**Public** 

#### Contact name

Ms Julie Williams

#### Contact details

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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

#### Key secondary outcome(s))

- 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.

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

United Kingdom

England

# Study participating centre South London and Maudsley NHS Foundation Trust United Kingdom SE9 8AA

# Sponsor information

#### Organisation

King's College London

#### **ROR**

https://ror.org/0220mzb33

#### Organisation

King's College Hospital NHS Foundation Trust

#### **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**

# 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
Protocol article		12/12/2016	10/10/2023	Yes	No
HRA research summary			28/06/2023	No	No