The impact of a walking intervention on the physical activity levels and health of adults with intellectual disabilities

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
15/03/2012		[X] Protocol		
Registration date 03/04/2012	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		Individual participant data		
11/07/2016	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

The physical activity levels of adults with intellectual disabilities reported in previous research studies were below the recommended level to keep healthy. Not much is known about how best to support adults with intellectual disabilities to be more active. Walking is a sustainable form of physical activity that can be incorporated into everyday life. Interventions that support people to walk more have been shown to lead to improved health and wellbeing. This study will examine whether a walking intervention helps adults with intellectual disabilities increase how much walking they do and improves their health.

Who can participate?

Adults with intellectual disabilities between 18 and 65 years of age, living in the catchment area of NHS Greater Glasgow and Clyde can take part in this study. Potential participants should be able to walk for 10 minutes.

What does the study involve?

Before the walking program (intervention) starts, participants will be invited to meet with a researcher. The researcher will ask participants questions about current levels of physical activity and health. We would also like to ask carers some questions. We would also like to measure physical activity by asking participants to wear a belt round the waist. The belt has a small box attached called an accelerometer that measures physical activity and how many steps the wearer takes. Participants will also be invited to have their height, weight and waist circumference measured. These measurements will be repeated after the individual takes part in the walking intervention. The walking intervention lasts 12 weeks. Participants will meet with a walking coordinator three times. The walking coordinator will talk to participants and carers about physical activity and walking. With the help of the walking coordinator, participants will choose an individualised walking program to follow. The aim of the walking program is to help participants increase the time they spend walking gradually over the 12 week intervention period. At the end of the walking intervention we will ask participants and carers to tell us what they think about the intervention.

What are the possible benefits and risks of participating? Participants may experience health benefits by taking part in the intervention. They may also become more confident about taking part in physical activity. We do not anticipate any significant risks for participants.

Where is the study run from? University of Glasgow (UK)

When is the study starting and how long is it expected to run for? May 2012 to April 2014

Who is funding the study? This study is funded by the Chief Scientist Office, Scottish Government Health Directorates

Who is the main contact?
Craig Melville
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1.1

Study information

Scientific Title

The impact of a walking intervention on the physical activity levels and health of adults with intellectual disabilities: a randomised controlled trial

Study objectives

- 1. Does a 12-week walking intervention for adults with intellectual disabilities increase the average number of steps walked per day?
- 2. Does a walking intervention for adults with intellectual disabilities increase the average time spent per day in moderate-vigorous intensity?
- 3. Does a walking intervention for adults with intellectual disabilities reduce time spent on sedentary behaviour?
- 4. Are changes in walking behaviours, physical activity and sedentary behaviour maintained at follow-up, three months after the end of the walking intervention?
- 5. Does a walking intervention for adults with intellectual disabilities lead to improved wellbeing and self efficacy for physical activity?
- 6. How do individuals with learning disabilities who have participated in a walking intervention view the experience?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Scotland A Research Ethics Committee, 13/02/2012, ref: 12/SS/0003

Study design

Single-centre single-blind randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Intellectual disabilities

Interventions

- 1. Multi-component walking intervention accessible resources on the benefits of physical activity; physical activity consultation & individualised, structured walking program.
- 2. Waiting list control

Intervention Type

Behavioural

Primary outcome measure

Average number of steps walked per day

Secondary outcome measures

- 1. Average number of minutes spent in moderate vigorous physical activity per day
- 2. Average number of minutes spent in physical activity of any intensity per day
- 3. Average time spent on sedentary behaviour per day
- 4. Quality of life, self efficacy and vitality
- 5. Weight, body mass index (BMI) and waist circumference

Overall study start date

01/05/2012

Completion date

30/04/2014

Eligibility

Key inclusion criteria

- 1. 18-65 years old
- 2. Ambulatory and able to walk unaided for 10 minutes at a time, based on self/carer report
- 3. Any level of intellectual disabilities
- 4. Not currently taking part in any other research study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

- 1. Wheelchair user or significant mobility problems
- 2. Severe challenging behaviour, or other needs requiring constant one-to-one support from staff
- 3. Involved in regular physical activity meeting current public health recommendations for physical activity, for six months or more

Date of first enrolment

01/05/2012

Date of final enrolment

30/04/2014

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre Gartnavel Royal Hospital

Glasgow United Kingdom G120XH

Sponsor information

Organisation

NHS Greater Glasgow & Clyde (UK)

Sponsor details

NHS Greater Glasgow & Clyde Research & Development office Tennent Institute 38 Church Street

Western Infirmary

Western Infirmar Glasgow

Scotland

United Kingdom

G11 6NT

Sponsor type

Hospital/treatment centre

Website

http://www.nhsggc.org.uk

ROR

https://ror.org/05kdz4d87

Funder(s)

Funder type

Government

Funder Name

Chief Scientist Office (CSO) (UK) (ref:CZH/4/644)

Alternative Name(s)

CSO

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	01/07/2013		Yes	No
Results article	results	29/09/2015		Yes	No
Other publications	process evaluation	07/07/2016		Yes	No