Walking for Wellbeing in the West: a pedometer-based walking programme in combination with a physical activity consultation with a 12-month follow-up

Submission date	Recruitment status No longer recruiting	Prospectively registered		
11/02/2008		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
31/03/2008	Completed	[X] Results		
Last Edited 01/10/2012	Condition category Other	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Study website

http://ewds.strath.ac.uk/sparcoll/ResearchFramework/Phase2/tabid/1672/Default.aspx

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The "Walking for Wellbeing in the West" randomised controlled trial of a pedometer-based walking programme in combination with a physical activity consultation with a 12-month follow-up

Acronym

WWW

Study objectives

Walking has been identified as an ideal mode of exercise to promote physical activity in the general population. Large knowledge gaps exist on the optimum methods to promote and sustain walking behaviour in a community setting. Following the RE-AIM principles, WWW is investigating whether a pedometer-based walking programme, in combination with a physical activity consultation will help community dwelling low active adults achieve and sustain the physical activity recommendation of 30 minutes of activity at least 5 days of the week. The study has six key research components (behavioural, psychological, environmental, physiological, qualitative and economic) allowing an insight into the complex relationships between behavioural change, health consequences and the role of the environment, along with participants' views and experiences and the cost effectiveness of this approach.

Research question:

Can a pedometer-based walking programme, in combination with a physical activity consultation increase and maintain walking behaviour over a 12 month period?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the University of Strathclyde Ethics Committee on the 19th July 2006 (ref: UEC0506/56).

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Promotion of physical activity in the general population

Interventions

Participants were randomised into one of two groups: immediate intervention (Group 1) or waiting list control (Group 2).

Participants randomised to Group 1 received a 30 minute physical activity consultation with a trained member of the research team. The participant was given an individualised 12-week walking programme and a pedometer. Following the 12-week walking programme, the participants received a second individual physical activity consultation focusing on relapse prevention. Participants received a written physical activity advice leaflet at 24 weeks and a telephone consultation at 36 weeks.

Participants randomised to Group 2 were allocated to a 12 week waiting list and were requested not to amend their current physical activity levels. After 12 weeks Group 2 received an individualised 12 week walking programme identical to Group 1, brief advice and a pedometer but did not receive a physical activity consultation (i.e., the waiting list control group then became a minimal intervention group).

At 24 weeks and 36 weeks participants received a short feedback session.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Walking behaviour: pedometer step counts (Omron HJ-109E Step-O-Meter).

Timepoints of measurement: Intervention group - at baseline, 3, 6 and 12 months Control group - at baseline, 3, 6, 9 and 15 months

Secondary outcome measures

- 1. Walking behaviour: seven-day recall of physical activity using the International Physical Activity Questionnaire (IPAQ) (long version, self-report). This will be assessed at baseline, 3, 6 and 12 months (intervention) and at baseline, 3, 6, 9 and 15 months (control).
- 2. Psychological: the four constructs of the Transtheoretical Model (stages of change, processes of change, self efficacy, and decisional balance questionnaires), along with mood (Positive and Negative Affect Schedule [PANAS] questionnaires) and quality of life (European Quality of Life [EQ-5D] questionnaires). This will be assessed at baseline, 12, 24 and 48 weeks (intervention) and at baseline, 12, 24, 36 and 60 weeks (control).
- 3. Physiological: Body composition, blood pressure, heart rate, total cholesterol, high density lipoprotein (HDL) cholesterol, insulin and glucose, and circulating levels of inflammatory

markers. For the intervention group, all physiological measures were taken at baseline and 12 weeks. At 24 weeks body mass, body mass index (BMI), waist-to-hip ratio, percentage body fat, blood pressure and heart rate were assessed. In the control group, all physiological measures were assessed at baseline, 12 week and 24 weeks. At 36 weeks body mass, BMI, waist-to-hip ratio, percentage body fat, blood pressure and heart rate were assessed.

- 4. Environmental: perceived (subjective) environmental barriers or facilitators to activity, and also any changes in physical activity levels and environmental perceptions over the course of the study using the Neighbourhood Quality of Life Study (1st Survey; NQLS). Questionnaires were completed at baseline, 12 weeks, 24 weeks and 48 weeks (interverntion) and at baseline, 12 weeks, 24 weeks, 36 weeks and 60 weeks (control). An environmental audit tool and geographic information system (GIS) data provides an objective assessment of the study area in relation to walking.
- 5. Qualitative: a qualitative evaluation is being undertaken alongside the main randomised controlled trial to understand the social context of the trial
- 6. Economic: A health economist is economically evaluating the trial to give cost-effectiveness in terms of cost/quality-adjusted life years (QALY) gained and the cost per individual achieving the target (30 minutes of exercise on 5 days/week)

Overall study start date

01/07/2007

Completion date

01/08/2008

Eligibility

Key inclusion criteria

- 1. Men and women, aged 18 65 years
- 2. Able to understand the rationale behind the trial
- 3. Able to walk independently for 5 10 minutes
- 4. Those who speak English
- 5. Those who are in the precontemplation, contemplation or preparation stages of the transtheoretical model of behaviour change (with respect to meeting the current physical activity recommendations) using an adapted stage of change algorithm

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

79

Key exclusion criteria

Involved in regular activity (i.e., not in stages 1 - 3 of the transtheoretical model of behavioural change).

Date of first enrolment

01/07/2007

Date of final enrolment

01/08/2008

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre Sport, Culture and Arts

Glasgow United Kingdom G13 1PP

Sponsor information

Organisation

University of Strathclyde (UK)

Sponsor details

Research and Innovation 50 George Street Glasgow Scotland United Kingdom G1 1WQ

Sponsor type

University/education

Website

http://www.strath.ac.uk/ri

ROR

https://ror.org/00n3w3b69

Funder(s)

Funder type

Government

Funder Name

Walking for Well-being in the West is part of work carried out by the Scottish Physical Activity Research Collaboration (SPARColl). SPARColl is managed by NHS Health Scotland, hosted by the University of Strathclyde, Glasgow and funded by the Scottish Government.

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?
Protocol article	protocol	26/07/2008		Yes	No
Results article	results	31/03/2011		Yes	No
Results article	results	19/03/2012		Yes	No