

Increasing physical activity in older adults

| | | |
|--|---|--|
| Submission date 16/01/2014 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 16/01/2014 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 15/05/2017 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Many older adults are both highly sedentary (i.e. spending considerable amounts of leisure time sitting) and physically inactive (i.e. performing little physical activity). This study will try an intervention that centres on a theory-based leaflet giving recommendations for simple activities that can be done to both increase physical activity and displace or prevent sedentary behaviour. The recommendations are designed to promote habit formation, which theory suggests should bring behavioural gains over the long term.

Who can participate?

Participants aged 60-75 who are sedentary (i.e. spend 6 or more hours sitting per day) and inactive (i.e. do less than 30 cumulative minutes of at-least-moderate physical activity per week), with no physical impairments preventing increases in physical activity.

What does the study involve?

Each participant participates for a 12-week period. Potentially eligible patients are telephoned and asked to confirm their eligibility. They then attend their general practice to provide consent. At this session, participants are fitted with an accelerometer and invited to an initial measurement session at University College London in central London, UK. At the initial session, participants complete measures of sedentary behaviour and physical activity, habit, health and wellbeing. Participants are then randomly allocated to one of two groups. The intervention group receive the intervention leaflet and the control group an existing NHS factsheet outlining government recommendations for physical activity and sedentary behaviour but no information on specific activities to achieve these guidelines. After four weeks, participants are telephoned to arrange an 8-week follow-up measurement session. For the intervention group, this phone call also serve as an opportunity to offer additional motivational support or clarification to participants. At the 8-weeks session, participants complete follow-up measures of physical activity and sedentary behaviour, habit, health, and wellbeing. After 12 weeks, participants complete the same measures as above and are also interviewed about their experiences of the intervention and study procedures. All participants also wear sealed accelerometers (for measurement purposes) for one-week periods before the initial assessment and at 8 and 12 weeks later.

What are the possible benefits and risks of participating?

Participants in the intervention group are expected to benefit from increasing and maintaining

their engagement in physical activity, and reducing time spent sitting, both of which are expected to lead to sustainable gains in health, wellbeing and functioning. There may also be gains for those in the control arm, given that they receive a leaflet advising on recommended levels of physical activity, and on reduction of sedentary behaviour. The financial and time burdens associated with attending measurement sessions, completing measures and participating in a study for 12 weeks are at least partly balanced by reimbursing participants' travel expenses (up to £20) incurred in attending each session, and giving them a £10 shopping voucher to thank them for helping us with assessment. Participants are also given a £30 shopping voucher, for the same reason, upon completion of the 12-week follow-up session, conditional upon their attending the 8- and 12-week follow-up sessions and returning the accelerometer. No adverse events are expected for participants. The intervention leaflet has been developed by experts, in collaboration with inactive older adults themselves, so that the activities it recommends are feasible and low risk, and may be performed at low levels of intensity, so as to reduce the potential for harm or injury. The control treatment is an existing NHS factsheet setting out physical activity and sedentary behaviour guidelines and poses minimal risk.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run?
April 2014 to February 2015

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Benjamin Gardner
b.gardner@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Benjamin Gardner

Contact details
Department of Epidemiology and Public Health
University College London
Gower Street
London
United Kingdom
WC1E 6BT
-
b.gardner@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

15919

Study information

Scientific Title

Increasing physical activity in older adults: a randomised controlled pilot trial of a brief, habit-based intervention

Study objectives

The primary aim of the study is to assess the feasibility of our intervention leaflet (designed to reduce sedentary behaviour and increase physical activity) and our study procedures, as a basis for informing sample size calculations and procedures for a future definitive randomised controlled trial.

The secondary aim is to assess changes in sedentary behaviour, physical activity, habits, and health.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC approval date 03/12/2013, 13/LO/1549

Study design

Randomised; Interventional; Design type: Prevention

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England, Generic Health Relevance and Cross Cutting Themes; Subtopic: Not Assigned, Generic Health Relevance (all Subtopics); Disease: All Diseases

Interventions

Control treatment: A control group will receive an NHS factsheet setting out government recommendations for physical activity, and (minimising) sedentary behaviour.

'On Your Feet' intervention: This intervention centres on a leaflet offering ten tips for simple behaviours that can be adopted to reduce sitting time and increase physical activity, and increase physical activity habit strength. It also includes 'ticksheets' to allow participants to track their adherence to the tips.

Follow Up Length: 3 month(s); Study Entry : Registration and One or More Randomisations

Intervention Type

Behavioural

Primary outcome measure

Recruitment and attrition rates; Timepoint(s): Study entry, baseline, 8 weeks, 12 weeks

Secondary outcome measures

1. Physical activity; Timepoint(s): Baseline, 8 weeks, 12 weeks
2. Physical activity habit strength; Timepoint(s): Baseline, 8 weeks, 12 weeks
3. Physical health; Timepoint(s): Baseline, 8 weeks, 12 weeks
4. Sedentary behaviour; Timepoint(s): Baseline, 8 weeks, 12 weeks
5. Sedentary behaviour habit strength; Timepoint(s): Baseline, 8 weeks, 12 weeks
6. Wellbeing; Timepoint(s): Baseline, 8 weeks, 12 weeks

Overall study start date

01/04/2014

Completion date

27/02/2015

Eligibility

Key inclusion criteria

1. Aged 60-75 years
2. Retired
3. Inactive (<30 consecutive minutes of leisure time physical activity of at least 3 METs per week)
4. Sedentary (>6 total leisure time hours sitting per day)
5. Able to speak and read English
6. Able to provide full informed consent for themselves

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Planned Sample Size: 120; UK Sample Size: 120; Description: 60 intervention patients, 60 controls

Key exclusion criteria

1. Reporting a disabling impairment which prevents them from engaging in regular light physical activity
2. Currently participating, or has participated in the previous 3 months, in a physical activity promotion or sedentary behaviour reduction study
3. Unable to provide informed consent due to mental incapacity or active psychotic illness
4. Terminally ill
5. Aged under 60 or over 75 years at time of first contact
6. Insufficient comprehension of English

Date of first enrolment

01/04/2014

Date of final enrolment

27/02/2015

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University College London

London

United Kingdom

WC1E 6BT

Sponsor information**Organisation**

University College London (UK)

Sponsor details

Gower Street

London

England

United Kingdom

WC1E 6BT

Sponsor type

University/education

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK) - National Prevention Research Initiative; Grant Codes: MR/J000396/1

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 | 20/09/2014 | | Yes | No |
| Protocol article | updated protocol | 05/08/2015 | | Yes | No |
| Results article | results | 08/05/2017 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |