ISRCTN31844443 https://doi.org/10.1186/ISRCTN31844443

Get Moving! Supporting active living: Evaluation of three minimal human contact interventions to promote fitness and physical activity

Submission date
02/06/2010

Recruitment status
No longer recruiting

Registration date
18/06/2010

Overall study status
Completed

Last Edited
22/12/2020

Condition category
Other

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
It is well known that being physically active provides a number of health benefits: evidence shows that regular exercise can increase the levels of HDL (good) cholesterol, lower high blood pressure, promote healthy blood sugar levels, and improve fitness and bone density. It can also help to boost the immune system, improve body shape, and improve mood. Yet despite this, most of us are not very active in our everyday lives. We wish to compare the effectiveness of three different approaches to promoting physical activity in staff working on the Cambridge Biomedical Campus at Addenbrookes Hospital. We are also interested in what people think of the different approaches. This will help us to develop interventions that are effective in increasing peoples fitness and physical activity, thereby reducing their risk of disease and helping them to feel better.

Who can participate?
Healthy individuals aged 18 - 65.

What does the study involve?
Participants have a comprehensive health and fitness check where their height, weight and blood pressure are measured and a blood sample (less than 2 tablespoons) is taken to measure cholesterol, glucose levels and nutritional status. Other measurements like body composition and an ECG (heart trace) reading are also taken and two questionnaires are completed, which should take around 20 minutes. In order to measure fitness and physical activity levels participants walk on a treadmill at different speeds and inclines for a maximum of 20 minutes, increasing to a jog for the last few minutes if that is comfortable. Participants only need remain on the treadmill for as long as they feel comfortable. Participants wear a small heart rate monitor on their chest for 6 days after their visit. When they have worn the heart rate monitor for 6 days, they return it. Participants are then randomly allocated into one of four study groups: three groups involve participants monitoring their physical activity daily using different methods, and one group receive no intervention and act as the comparison group.
1. Comparison group - no intervention
2. Self-monitoring using a paper diary

3. Activity band with web-based feedback graphs
4. Activity band with web-based feedback graphs and support programme
Information on the wearer's physical activity levels is uploaded via Bluetooth to the program website where the support and/or feedback programs can also be accessed. Participants in group 4 also receive a set of interactive Bluetooth-enabled weighing scales to enable them to monitor their weight. After 12 weeks all participants return to the MRC Epidemiology Unit testing facilities in the Addenbrookes Treatment Centre for a repeat visit, and to return all equipment and diaries. This visit is the same as the first visit, to see if anything has changed over the 12-week period. Participants are asked to wear the heart rate monitor again for 6 days before the visit. After the visit, they complete a final questionnaire and return this by post. Participants may also be invited to take part in a short, audio-recorded interview with a researcher who asks for their own ideas about behaviour related to physical activity, what they thought of the intervention they received, and their experience of taking part in the study, to understand the extent to which behaviour changes might become long-term habits.

What are the possible benefits and risks of participating
Participants are provided you with a comprehensive health report detailing the clinical results from both your assessments, and with their permission their GP is provided with the results of their health and fitness assessments. This will allow participants to discuss their results with their GP, should they wish to do so. The interventions being tested in this study may increase levels of physical activity. Evidence shows that regular exercise can increase the levels of HDL (good) cholesterol, lower high blood pressure, help improve body shape, promote healthy blood sugar levels, promote bone density, boost the immune system and improve mood. Should the interventions encourage participants to adopt a more physically active lifestyle while they are in the study, these benefits rely on them maintaining this lifestyle once the study finishes. The risks of taking part in the study are negligible. Participants will feel a small scratch at the site of blood sampling which will be no more than that usually experienced during the same procedure by a nurse or GP. Trained staff take blood samples and carry out all measurements. Thorough medical checks will be undertaken before participants are asked to go on the treadmill, and if there is any indication of a possible risk the test will be abandoned. The treadmill is fitted with safety handrails and volunteers will be supervised by a trained researcher at all times. The sticky pads that attach the heart rate monitor to the chest have been known to cause itching and a rash in about 10% of people. Participants are provided with information at your visit as to what to do if this happens whilst you are wearing the monitor. If participants increase the amount of physical activity they do, this may increase the risk of sports or exercise-related muscle strains and sprains.

Where is the study run from?
Institute of Public Health (UK)

When is the study starting and how long is it expected to run for?
July 2010 to December 2013

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. Imperative Health Ltd (UK)
3. National Institute for Health Research (UK)

Who is the main contact?
Prof. Simon Griffin
sjg49@medschl.cam.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Simon Griffin

Contact details
Institute of Public Health
University Forvie Site
Robinson Way
Cambridge
United Kingdom
CB2 0SR
+44 (0) 1223 763431
sjg49@medschl.cam.ac.uk

Additional identifiers

Study information

Scientific Title
A randomised controlled trial evaluation of the effectiveness of three minimal human contact interventions to promote fitness and physical activity in an occupational health setting

Study objectives
1. To test the effectiveness of three minimal human contact interventions to increase physical activity and fitness over 12 weeks
2. To investigate the feasibility and acceptability of each intervention
3. To investigate the psychological and cognitive mechanisms through which each intervention works

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 2 Research Ethics Committee (REC), 26/03/2010, ref: 09/H0308/187

Primary study design
Interventional

Study design
Open-label parallel-group randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied

Physical activity, fitness & related metabolic diseases & cardiovascular risk factors

Interventions
Following a baseline measurement visit, participants will be randomised into one of four groups:
1. Comparison group no intervention
2. Self-monitoring using a paper diary
3. Activity band with web-based feedback graphs
4. Activity band with web-based feedback graphs and support programme
The intervention will last for 12 weeks, after which time follow-up measurements are taken.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Physical activity energy expenditure (PAEE) kJ/kg/day
2. Fitness (predicted VO2max) ml O2/min/kg
All outcomes will be measured at baseline and post-intervention (12 weeks)

Key secondary outcome(s)
1. Anthropometric measures (BMI, body fat percentage, waist)
2. Blood pressure
3. Plasma vitamin C levels
4. Biochemical measures (HbA1c, cholesterol, triglycerides)
5. Self-reported quality of life, using SF-8
6. Theory of planned behaviour measures
7. Perceived stress, using 4-item Perceived Stress Scale
8. Self-monitoring behaviour
9. Self-reported physical activity (RPAQ)
All outcomes will be measured at baseline and post-intervention (12 weeks)

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Aged 18 - 65 at the start of the study
2. Has freely given informed consent
3. Has personal use of a Windows PC and the internet at home

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. A score of ≥ 30 on the Godin Leisure-Time Exercise Questionnaire (using moderate and vigorous activities only)
2. Participation in another human or clinical randomised trial
3. Instructed by their GP not to engage in regular physical activity
4. Taking ≥ 100 mg a day of a beta-blocker such as Atenolol or equivalent
5. Women who are pregnant
6. Planning to leave employment at Addenbrookes Hospital in the 4 months following recruitment
7. Unable to walk briskly on the flat for 15 minutes without help
8. Unable to operate a PC unaided or cannot use an English-language website
9. Body mass index (BMI) of ≤18 kg/m2
10. Mean blood pressure of ≥ 160/100 mmHg

Date of first enrolment
01/07/2010

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Public Health
Cambridge
United Kingdom
CB2 0SR

Sponsor information

Organisation
University of Cambridge (UK)

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Imperative Health Ltd (UK) - General Practice & Primary Care Research Unit

Funder Name
Added 27/06/2014:

Funder Name
National Institute for Health Research - Research for Patient Benefit (NIHR RfPB) (UK)

Results and Publications

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	27/03/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		20/02/2014	25/02/2019	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes