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The Fenland Measurement Reactivity (FMR) study

Submission date
16/04/2013

Recruitment status
No longer recruiting

Registration date
20/08/2013

Overall study status
Completed

Last Edited
21/05/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
There is some scientific evidence that suggests that when you measure something in a person, they sometimes respond by changing their behaviour related to what is being measured. It is human nature and is often done without thinking.
This theory applies to some of the measurements we commonly do here as part of our studies, including measurement of physical activity levels. We are interested in how people might alter their behaviour in response to having their physical activity measured. In particular, if people are asked to wear a monitor like the ActiHeart, do they tend to be more active than usual while they are wearing it? This is obviously a difficult area of science to research, as it is usually impossible to measure somebody without them knowing. We have been looking at another way of doing this, which is by varying the content of the information people are given about what is being measured, and why.

Who can participate?
This study was part of the Fenland study, a population-based study into lifestyle and health in 10,000 volunteers recruited through GP surgeries in the East of England. Volunteers are invited to attend a comprehensive assessment of metabolic health, diet and other lifestyle patterns, body composition and fitness and physical activity. The Fenland study is aimed at investigating the interaction between genetic and lifestyle factors in determining obesity, diabetes and related metabolic disorders which present a considerable public health concern.

What does the study involve?
When some participants were invited to take part in the Fenland study they were randomly assigned to one of two study groups, each of which received slightly different information about the ActiHeart they were asked to wear before their visit. One group was told that it measured heart rate, and the other group was told that it measured heart rate from which we could estimate their level of physical activity. We wanted to see whether this subtle difference in the information provided might affect physical activity behaviour whilst the ActiHeart monitor was being worn. For example, people who were told that it measured physical activity as well as heart rate may have been more physically active whilst wearing it than those that were told that

it measured heart rate. All participants were fully debriefed at their study visit. We will pool the ActiHeart data from participants in each group, compare the groups and see whether overall there was any difference in how active the two groups were.

What are the possible benefits and risks of participating?
Participants have a very thorough health check including a test for diabetes and measurement of blood cholesterol. Participants will receive detailed individual feedback on the results from the tests and the results will be passed to their GP. This will include information on how participants body composition and fitness compares to the rest of the population. The information participants receive will be straightforward to understand and we will tell them how their measurements impact on their health.
In some instances, individuals may experience minor skin irritation or develop a slight rash from wearing the electrodes used to attach the combined heart rate and movement monitor. From previous research this was reported for less than 10% of volunteers wearing electrodes. The irritation is localised and goes away on its own.

Where is the study run from?
The Medical Research Council Epidemiology Unit & Primary Care Unit, University of Cambridge, UK.

When is the study starting and how long is it expected to run for?
The study started in July 2012 and ran until February 2013.

Who is funding the study?
Medical Research Council (UK) and NIHR School for Primary Care Research (UK)

Who is the main contact?
Chief Investigator Professor Simon Griffin

Contact information

Type(s)
Scientific

Contact name
Prof Simon Griffin

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised test of reactivity to objective measurement of physical activity embedded in the Fenland study: the Fenland Measurement Reactivity (FMR) study

Study objectives
Because of the well-known limitations of self-report measures of physical activity, objective measurement is being increasingly recommended and used in epidemiological studies and trials of physical activity interventions to replace or complement self-report measures. The participant is asked to wear a device such as an accelerometer or heart rate monitor for a period of time (e. g. 7 days), and the data are used by the researchers to estimate the individuals level of physical activity or energy expenditure over that period. However, even if the device does not have a visual display that provides feedback to participants, it is possible that it may be reactive i.e. participants may increase their physical activity levels while wearing the device. The device may act as a salient prompt or reminder to engage in physical activity and participants know that the research team will be able to tell how active they have been and they cannot easily influence the data without making real changes in their physical activity.

Depending on the size of the reactivity effect, it could affect the validity of conclusions drawn from studies of physical activity. In descriptive epidemiological studies, the mean physical activity level would be over-estimated. If there are systematic individual differences in reactivity (i.e. if some kinds of people react more to measurement than others), this could affect the observed associations between the measure of physical activity and measures of determinants or consequences. It is therefore important to try to estimate the size of the reactivity effect to enhance interpretation of study findings. Finally, a reactivity effect might inform the development of interventions to promote physical activity.

The Fenland study (an ongoing population-based cohort study of participants aged 30-55 years to investigate the influence of lifestyle, diet, and genetic factors on the development of diabetes, obesity and other metabolic disorders) provided an opportunity to embed a randomised test of reactivity to the Actiheart, a combined heart rate and movement sensor, by giving participants subtly different information about the purpose of the device and how the data will be used.

The hypothesis is that participants who are told that the device measures heart rate from which their physical activity level can be estimated will have a higher level of physical activity on average during the 6-day period of use compared with participants who are told simply that the device measures heart rate. The size of the reactivity effect (difference in means between groups) will be estimated with a given degree of precision.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NRES Committee East of England - Cambridge Central, approved 02/07/2012, ref: 04/Q0108/19 amendment 14 (REC#15)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

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
Physical activity levels

Interventions
Participants were randomised into two arms, each receiving different information about the ActiHeart monitor: one group was told that it measured heart rate, the other group was told that it measured heart rate from which we could estimate their level of physical activity.

The duration of the intervention is roughly 2 weeks the time between the participant receiving the PIS and invitation documentation (the intervention) and attending the study visit. There is no follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Daily accelerometer activity counts as measured by the Actiheart, averaged over six days of Actiheart use.

Secondary outcome measures
Physical activity energy expenditure (PAEE, measured in kJ/kg/day), using heart rate monitoring with individual calibration for the heart-rate energy expenditure relationship averaged over six days of Actiheart use.

Overall study start date
30/07/2012

Completion date
28/02/2013

Eligibility

Key inclusion criteria
Participants being invited to participate in the main Fenland study. The Fenland study is an ongoing population-based cohort study of participants born between 1950 to 1975 in the Cambridgeshire area to investigate the influence of lifestyle, diet, and genetic factors on the development of diabetes, obesity and other metabolic disorders. Eligible participants are recruited via their GP surgery.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
30/07/2012

Date of final enrolment
28/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care Unit
Cambridge
United Kingdom
CB2 0SR

Sponsor information

Organisation
MRC Epidemiology Unit (UK)

Sponsor details
Institute of Metabolic Science
Box 285
Addenbrooke's Hospital
Hills Road
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Sponsor type
Research council

Website
http://www.mrc-epid.cam.ac.uk/

ROR
https://ror.org/052578691

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NIHR School for Primary Care Research (UK)

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