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The FAB Study: Feedback, Awareness and Behaviour in the Fenland Study

Submission date	Recruitment status
29/08/2007	No longer recruiting
Registration date	**Overall study status**
11/09/2007	Completed
Last Edited	**Condition category**
27/09/2013	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

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

Acronym
FAB

Study objectives
Aim: To quantify the effect of measurement and feedback on physical activity behaviour

Measurement objectives:
1. Self awareness of physical activity levels
2. Effect of measurement on awareness
3. Effect of feedback on awareness and intentions
4. Effect of feedback on behaviour
5. Level of false reassurance

More details can be found at: http://www.mrc-epid.cam.ac.uk/Research/Studies/FAB/index.html

Ethics approval required
Old ethics approval format

Ethics approval(s)
Full ethical approval received from Cambridgshire 2 Research Ethics Committee on 03/05/2007 (ref: 07/Q0108/79)

Study design
Cohort study with randomisation to one of four different physical activity feedback groups (following participation in the Fenland Study)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Physical activity behaviour

Interventions
The FAB Study has been set up as a nested cohort study within the Fenland Study, but with a very different purpose, and with separate ethical approval.

Volunteers in the Fenland Study have agreed to undergo oral glucose tolerance test and precise measurement of body anthropometry, body composition and physical activity over a one-week period (using individually calibrated Actihearts which measure heart rate and movement). Those who volunteer for FAB are randomly allocated to one of four groups:

Group 1: Control group - no feedback
Group 2: Physical activity feedback type A - Physical Activity Level (PAL)
Group 3: Physical activity feedback type B - PAL + daily heart rate and movement printouts
Group 4: Physical activity feedback type C - PAL + daily heart rate and movement printouts + goal setting and modelling information

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Objectively measured physical activity over 1 week (one month post-feedback), using a combined heart rate and movement sensor.

Secondary outcome measures
1. Self-reported physical activity - RPAQ (baseline, and 1 month after feedback)
2. Self-rated physical activity (baseline, immediately after feedback, and 1 month after feedback)
3. Worry about own physical activity (baseline, immediately after feedback, and 1 month after feedback)
4. Physical activity outcome expectations (baseline, immediately after feedback, and 1 month after feedback)
5. Physical activity self-efficacy (baseline, immediately after feedback, and 1 month after feedback)
6. Intention to change physical activity (baseline, immediately after feedback, and 1 month after feedback)
7. Time orientation (baseline only)

Overall study start date
03/09/2007

Completion date
03/06/2008

Eligibility

Key inclusion criteria
1. Aged 30-55 years
2. Registered with participating general practices in the Cambridgeshire Primary Care Trust
3. Participating in the Fenland Study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400 (100 per group)

Key exclusion criteria
1. Have diagnosed diabetes
2. Have a terminal illness with a prognosis of less than 1 year
3. Suffer from psychotic illness
4. Are pregnant or lactating
5. Are unable to walk unaided

Date of first enrolment
03/09/2007

Date of final enrolment
03/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Epidemiology Unit
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details

Medical Research Council Head OFfice
20 Park Crescent
London
United Kingdom
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corporate@headoffice.mrc.ac.uk

Sponsor type
Government

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Government

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

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	18/03/2010		Yes	No
Results article	results	16/09/2013		Yes	No