A study of the effects of different types information about physical activity after diabetes screening

	[X] Prospectively registered
No longer recruiting	Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Nutritional, Metabolic, Endocrine	Record updated in last year
	Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 pragmatic randomised trial of the impact of brief, written anticipated regret manipulations on intentions for, and subsequent self-reported, physical activity in adults receiving normal results of diabetes screening

Study objectives

Brief written anticipated regret manipulations can promote intentions for, and self-reported, physical activity in people receiving normal results of screening for type two diabetes.

As of 17/06/2009 this record was updated to include a new anticipated end date; the initial end date at the time of registration was 31/12/2006.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leicestershire, Northamptonshire and Rutland Research Ethics Committee, November 2005, ref: 7254

Study design

Pragmatic randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Prevention of type two diabetes or promotion of physical activity in healthy individuals

Interventions

The interventions consist of written information which is sent in conjunction with the letter confirming the results of a participants diabetes test. Participants are randomly allocated to one of five groups:

- 1. Anticipated regret group, no consequences made salient
- 2. Anticipated regret group, short term consequences made salient
- 3. Anticipated regret group, long term consequences made salient
- 4. Control group one: test result and physical activity message but no written anticipated regret manipulation; anticipated regret assessed on questionnaire
- 5. Control group two: test result and physical activity message but no anticipated regret manipulation; anticipated regret not assessed on questionnaire

As of 17/06/2009 the end of recruitment date for this trial was 08/12/2006.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. Self reported physical activity
- 2. Intentions for self-reported physical activity

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/05/2006

Completion date

30/01/2007

Eligibility

Key inclusion criteria

Individuals will be eligible to participate in the current study if they receive a normal result of an oral glucose tolerance test for diabetes performed as part of the Leicester part of the ADDITION study (ISRCTN99175498).

Added 17/06/2009:

- 1. White European participants aged between 40 and 75 years, either sex
- 2. Asian, Black or Chinese participants aged between 25 and 75 years, either sex

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Key exclusion criteria

Potential participants will be excluded from the ADDITION study and thus ineligible for this study if they:

- 1. Are housebound
- 2. Have a terminal illness
- 3. Have diabetes mellitus
- 4. Have an active psychotic illness resulting in the individual being unable to provide informed consent
- 5. Are pregnant or lactating
- 6. Are simultaneously participating in any other clinical trials

Date of first enrolment

01/05/2006

Date of final enrolment

30/01/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre King's College London

London United Kingdom SE1 9RT

Sponsor information

Organisation

King's College London (UK)

Sponsor details

Institute of Psychiatry De Crespigny Park London England United Kingdom SE5 8AF

Sponsor type

University/education

Website

http://www.kcl.ac.uk/

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 071202)

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