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

Submission date	Recruitment status	[X] Prospectively registered
21/04/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/11/2019	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
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

450, distributed across five groups

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