ISRCTN73125647 https://doi.org/10.1186/ISRCTN73125647

Simple versus informed choice invitations to screening

Submission date	Recruitment status
23/12/2005	No longer recruiting
Registration date	**Overall study status**
09/01/2006	Completed
Last Edited	**Condition category**
21/12/2012	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

Protocol serial number
076838

Study information

Scientific Title
Didactic versus informed choice invitations to screening: balancing public health benefits and individual choice

Acronym
DICISION

Study objectives
We propose to develop a feasible and effective informed choice strategy and to evaluate its impact on attendance at screening and motivation to follow subsequent advice, both overall and stratified by social deprivation. The work is set within the important public health context of screening for type two diabetes. We will test two hypotheses:
1. Uptake of screening for diabetes is higher following a traditional, didactic invitation compared with an informed choice invitation.
2. Amongst those who attend for screening, intentions to change behaviour to reduce risks are stronger following an informed choice invitation compared with a traditional invitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 1 Research Ethics Committee gave approval on the 5th May 2006 (ref: 06/Q0104 /17)

Study design
Multicentre single-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Informed choice for screening for type two diabetes

Interventions
1. Traditional invitation:
This will be a brief letter based on previous invitations for screening tests, including diabetes and coronary heart disease. It will include:
a. name of the condition i.e. type two diabetes
b. aims of screening i.e. to reduce risks of diabetes and associated cardiovascular disease
c. procedure i.e. review of risk including blood tests and clinical measures, advice and treatment as indicated

2. Informed choice invitation:
This will comprise the same brief letter but with additional detailed information based on General Medical Council (GMC) guidelines, and linked to a self-administered informed choice aid based on similar tools successfully used to facilitate personal decisions in other health care contexts.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Uptake of screening, which will be recorded by the practice nurses conducting the screening.

Key secondary outcome(s))
1. Intention to change behaviour to reduce risks of diabetes: behavioural intentions are good predictors of behaviour change. Three core behavioural intentions will be assessed in those attending:
a. increasing physical activity
b. restricting calories by eating low fat foods
c. taking preventive medication, if indicated
d. stopping smoking will also be assessed, when relevant
2. Self-reported behaviour assessed using standard questionnaires:
a. physical activity
b. diet
c. smoking and use of medication to reduce risk of diabetes
3. Attendance for post screening blood tests and subsequent practice nurse advice will be recorded
4. Social deprivation: area (post code) and individual level measures (education, home ownership and access to car) will be used. Age, gender, and ethnic group and risk factors known before screening will also be recorded.
5. Risk stratification: all those attending will be given a risk score to indicate their risks of developing diabetes and experiencing a cardiovascular event over the next ten years. Those with confirmed diabetes, expected to be about 30 individuals, will also receive their Coronary Heart Disease (CHD) risk scores
6. Informed choice: choices to participate in screening will be classified as informed to the extent that they are based on understanding diabetes screening and reflect the decision-makers values, using a standardised method we have developed and validated in other screening contexts

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. 1200 men and women aged 40 to 69 years
2. In the top 20% of risk of undiagnosed diabetes on practice registers, defined by a validated risk score applied to routine data on general practice population registers. The Cambridge Diabetes Risk Score includes the following risk variables:
a. age
b. gender
c. family history of diabetes
d. smoking status
e. prescription of steroid or anti-hypertensive medication
f. body mass index

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients considered by the practice nurse or General Practitioner to be unsuitable for the project, for example, people who are severely ill, will be excluded from the study.

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Psychology Dept. (at Guy's)
London
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Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (ref: 076838)

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?
Results article	results	13/05/2010		Yes	No
Results article	results	01/09/2011		Yes	No
Protocol article	protocol	20/02/2009		Yes	No