

Bridging the intention-behaviour gap: promoting compliance with medication for coronary heart disease

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 19/10/2011	Condition category Circulatory System	<input type="checkbox"/> 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
RRCC218LG

Study information

Scientific Title

Study objectives

To test whether: implementation intention strategies increase three-month compliance to prescribed medicines among patients in primary care compared to those control group patients using their usual strategies.

Do implementation intentions increase adherence to medication prescribed for coronary heart disease? N.B. The pilot study revealed problems with recruiting non-adherent participants. Two alternative studies were, therefore, administered.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular diseases: Heart disease

Interventions

Both studies were randomly controlled trials:

Study 1:

120 cardiac patients were recruited and randomised into three groups (control, Theory of Planned Behaviour (TPB) questionnaire only, TPB questionnaire + formed implementation intention). They were telephoned at 7, 28 and 90 days post-recruitment. Fruit and vegetable consumption was recorded at recruitment and at each of the follow-up time points. 97 participants completed the study.

Study 2:

249 patients presenting with a prescription for antibiotics were recruited and randomised into four groups (control, TPB questionnaire only, TPB questionnaire + formed own implementation intention, TPB questionnaire + researcher provided implementation intention). They were telephoned on the day after their antibiotics were due to be completed to record their adherence to the medication. A fifth group of participants was recruited who only received the follow-up telephone call. 241 participants completed the study.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Study 1: Daily fruit and vegetable consumption (self-report and 24-hour recall)

Study 2: Adherence to antibiotics (self-report and pill count)

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2001

Completion date

31/10/2003

Eligibility

Key inclusion criteria

Study 1: Patients attending a secondary prevention CHD clinic in primary care

Study 2: Patients presenting to a pharmacy with a prescription for an antibiotic

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

370

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2001

Date of final enrolment

31/10/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Leeds

Leeds

United Kingdom

LS2 9TJ

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Study 1: results	01/05/2005		Yes	No
Results article	Study 2: results	01/05/2006		Yes	No