ISRCTN29760311 https://doi.org/10.1186/ISRCTN29760311

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

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 19/10/2011	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rebecca Lawton

Contact details
University of Leeds
School of Psychology
Leeds
United Kingdom
LS2 9TJ
+44 (0)113 343 5715
r.j.lawton@leeds.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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. 241participants completed the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Study 1: Daily fruit and vegetable consumption (self-report and 24-hour recall)
Study 2: Adherence to antibiotics (self-report and pill count)

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9TJ

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

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	Study 1: results	01/05/2005		Yes	No
Results article	Study 2: results	01/05/2006		Yes	No