Randomised controlled trial of buddy support in the reduction of cardiovascular risk related behaviour

Recruitment status	 Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Circulatory System	Record updated in last year
	No longer recruiting Overall study status Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Martin Edwards

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

REC00155

Study information

Scientific Title

Study objectives

The study will test the hypothesis that buddy support significantly enhances the effect of lifestyle advice from a practice nurse. 700 adults aged 35-65 will receive advice and instruction in lifestyle modification designed to minimise cardiovascular risk factors. Participants will be randomly allocated to one of two conditions: solo or buddy. Buddy subjects will be allocated a buddy, a same-sex individual also from the buddy condition. Buddy pairs will be encouraged to maintain contact for six months in order to encourage each other to maintain lifestyle modifications. Solo participants (controls) will receive lifestyle advice from the nurse, but without peer support. Evaluation after six months will compare successful lifestyle modification (smoking, exercise, alcohol consumption, diet, body mass index, blood pressure) between solo and buddy groups.

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)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Cardiovascular disease

Interventions

i. Buddy - allocated of a buddy, a same-sex individual also from the buddy condition. Buddy pairs will be encouraged to maintain contact for six months in order to encourage each other to maintain lifestyle modifications.

ii. Solo (controls) will receive lifestyle advice from the nurse, but with no peer support.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Change in Body Mass Index, serum cholesterol, diastolic and systolic blood pressure, smoking cessation, exercise and alcohol consumption.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/1998

Completion date

01/10/2000

Eligibility

Key inclusion criteria

Adults registered with participating practices, aged between 35 and 65.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Patients with a history of use of psychotropic medication including antidepressants and benzodiazepines within the previous six months; a current or past history of psychotic illness, alcohol or drug abuse, or personality disorder; or with insufficient command of English for buddying to be practical.

Date of first enrolment

01/04/1998

Date of final enrolment

01/10/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Jenner Health Centre London United Kingdom SE23 1HU

Sponsor information

Organisation

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

Sponsor details

The Department of Health Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Executive London, 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