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

Submission date	Recruitment status	Prospectively registered
23/01/2004	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
23/01/2004	Completed	Results
Last Edited	Condition category	Individual participant data
16/12/2013	Circulatory System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

Completion date

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

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

United Kingdom

England

Study participating centre Jenner Health Centre London

United Kingdom SE23 1HU

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive London, UK

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration