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

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

**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**
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
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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