Exploring the ability of lay workers to support heart-health related behaviour change in deprived areas through Heart of Mersey

Submission date	Recruitment status	Prospectively registered
29/01/2007	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
11/05/2007	Completed	Results
Last Edited	Condition category	Individual participant data
28/02/2018	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G0501280

Study information

Scientific Title

Exploring the ability of lay workers to support heart-health related behaviour change in deprived areas through Heart of Mersey

Acronym

LhtIST (Lay health trainer Intervention STudy)

Study objectives

To examine the feasibility of a Randomised Controlled Trial (RCT) to assess lay health worker intervention to reduce Coronary Heart Disease (CHD) risk using lifestyle/behaviour change.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval MREC ref: 07/H1002/65

Study design

Feasibility study for a two-group 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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cardiovascular disease

Interventions

Lay worker support delivered in the home and links to existing community initiatives to promote heart-health diet, physical activity, sensible drinking and smoking cessation.

Intervention Type

Behavioural

Primary outcome measure

A feasibility study for a RCT, to examine recruitment strategies, outcome measures, and delivery methods of the intervention. Aim of the main trial will be to reduce CHD risk factors.

Secondary outcome measures

Not provided at time of registration

Overall study start date

18/09/2006

Completion date

17/09/2008

Eligibility

Key inclusion criteria

18+ years old with one or more diagnoses of:

- 1. Hypertension
- 2. Raised total cholesterol
- 3. Diabetes
- 4. Obesity
- 5. Smoker

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100 for this feasibility study

Key exclusion criteria

- 1. Established CHD
- 2. Non consenting
- 3. On current diet conflicting with heart-health dietary guidelines
- 4. Homeless/hostel/residential/nursing home residents
- 5. Life-expectancy <2 years
- 6. Physical/mental health reasons

Date of first enrolment

18/09/2006

Date of final enrolment

17/09/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Manchester

Manchester United Kingdom M13 9PT

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

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Sponsor type

University/education

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type

Government

Funder Name

The Medical Research Council (MRC): The National Prevention Research Initiative (NPRI) (UK)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration