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# LAMP: The development and evaluation of a Lay-facilitated Angina Management Programme

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| **Submission date**<br>30/06/2005 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>23/08/2005 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>05/02/2016 | **Condition category**<br>Circulatory System | [_] Individual participant data |

## Plain English summary of protocol

Background and study aims
Coronary heart disease (CHD), also known as ischemic heart disease, is one of the leading causes of death worldwide. CHD develops because of the build-up of fatty deposits (plaque) on the walls of the coronary arteries (the arteries that supply the heart with oxygen-rich blood). When arteries are blocked or narrowed, the heart does not receive enough blood to function properly, which can cause pain and tightness in the chest (angina). Some forms of angina can be treated using medications, however many people need surgical treatment in order to show significant improvement. A recent study showed that educating angina patients about how to better manage their condition could help to improve symptoms and encourage changes to unhealthy lifestyle choices. This study will to look at a lay-led angina management (LAMP) programme, in which patients will be educated about their conditions and receive cognitive behavioural therapy (a type of talking therapy designed to help change ways of thinking and behaving). The aim of this study is to look at whether the LAMP programme can be used to help people to better manage their angina.

Who can participate?
Adults with angina who require surgical treatment.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group attend the clinic of an angina nurse specialist where they will receive a 15 minute appointment giving lifestyle advice, such as quitting smoking, and written information about their condition. Those in the second group take part in a 45 minute appointment with a trained lay (plain English) facilitator (people with experience of heart disease either personally or as a carer) where they are given in-depth advice and explanations about their condition. These patients are also given access to cognitive behavioural therapy (CBT) to help them change their habits, a workbook to record their progress which is discussed with the lay facilitator in follow up home visits or phone calls and a relaxation programme on CD. Participants are also referred to their local stop smoking service (if applicable). Participants in both groups are asked to keep a week-long diary recording their angina symptoms which is assessed at the start of the study and again after 6 months to see if their symptoms have improved.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Bury Primary Care NHS Trust and Fairfield Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2005 to September 2008

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Dr Gill Furze

# Contact information

### Type(s)
Scientific

### Contact name
Dr Gill Furze

### Contact details
University of York
Department of Health Science
Area 2
Seebohm Rowntree Building
York
United Kingdom
YO10 5DD

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
BHF No. PG/05/048

# Study information

### Scientific Title
LAMP: The development and evaluation of a Lay-facilitated Angina Management Programme

### Acronym
LAMP

## Study objectives
The primary objective is to assess whether a manualised self-help cognitive behavioural therapy (CBT) rehabilitation programme for patients with angina, facilitated by lay workers, will produce a greater reduction in angina frequency than a health education session delivered in a clinic by a specialist nurse.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
North Manchester LREC, Ref: 05/Q1406/66

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## Study type(s)
Treatment

## 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
Angina

## Interventions
Participants will be randomised to receive:
1. A 15 minute follow-up appointment with adjunctive written materials and routine medical care
2. Lay-led Angina Management Programme and routine medical care

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome measure
Frequency of angina as measured using a patient held angina diary (mean number of angina episodes per week).

## Secondary outcome measures

Secondary outcomes will include differences between baseline and six-month follow-up on: Euroaction SCORE of cardiovascular disease (CVD) risk, scales of the Seattle Angina Questionnaire, anxiety and depression scores on the HADS, increased activity levels as measured by a weeks ambulatory monitoring and self-rated activity level, economic cost utility including service use, cost of the intervention, and the EQ-5D.

### Overall study start date
01/10/2005

### Completion date
30/09/2008

## Eligibility

### Key inclusion criteria
All patients receiving a diagnosis of angina following symptom-limited exercise treadmill test, thallium scintigraphy or angiography and not, in the judgement of the cardiologist, requiring urgent coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA).

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
200

### Key exclusion criteria
1. Exercise induced arrhythmias or loss of systolic BP greater than 20 mmHg during exercise stress testing
2. Self-report of rapidly increasing number and duration of attacks of angina
3. A score of 4 on the Canadian Heart Association classification of angina or the New York Heart Association (NYHA) classification of heart failure
4. Myocardial infarction still awaiting cardiac rehabilitation
5. Life-threatening co-morbidities
6. Documented psychiatric problems (other than mild to moderate uni-polar depression or a simple anxiety state)
7. Dementia or confusion

### Date of first enrolment
01/10/2005

### Date of final enrolment
30/09/2008

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**University of York**
York
United Kingdom
YO10 5DD

# Sponsor information

**Organisation**
University of York (UK)

**Sponsor details**
Department of Health Science
Area 3
Seebohm Rowntree Building
York
England
United Kingdom
YO10 5DD

**Sponsor type**
University/education

**ROR**
https://ror.org/04m01e293

# Funder(s)

**Funder type**
Charity

**Funder Name**
British Heart Foundation (BHF) PG/05/048 (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

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/10/2012 | | Yes | No |