ISRCTN41781196 https://doi.org/10.1186/ISRCTN41781196

# A study to find out the best way to help people to change their lifestyle after a hospital admission

**Submission date**
06/12/2012

**Recruitment status**
No longer recruiting

**Registration date**
16/01/2013

**Overall study status**
Completed

**Last Edited**
01/10/2015

**Condition category**
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Cardiovascular (heart) disease is a major health problem in the UK and a leading cause of death. However, cardiac or vascular events can be prevented by appropriate medication and lifestyle modification to reduce risk factors like high blood pressure (hypertension), high cholesterol and low levels of physical activity. There is no standardised approach to giving lifestyle advice. We think that the way that it is tackled with people can affect the uptake of referrals and subsequent behaviour change. The aim of this study is to test whether a lifestyle assessment tailored to the individual increases uptake of lifestyle interventions when compared to usual practice.

Who can participate?
People who are between the ages of 40 and 74, and admitted to a cardiology ward with a heart attack or symptoms of a suspected cardiac event, and who have risk factors for cardiovascular disease that can be modified, can take part in the study.

What does the study involve?
Participants will be asked to complete several questionnaires relating to health and behaviour. They will be randomly allocated to one of two groups to decide which lifestyle assessment will be conducted. One group will receive the usual lifestyle assessment and the other group will receive a new lifestyle assessment. Both groups will receive the same medical care and advice normally given to patients who are admitted on to a cardiology ward. Participants will be followed up twice at three and six months after the first (baseline) interview.

What are the possible benefits and risks of participating?
Some participants may find it beneficial to talk about their experiences of lifestyle change such as smoking cessation, weight loss and increased physical activity. This research will help the Leeds Teaching Hospitals Trust to improve their services which could be of benefit for patients in the future.
There are no adverse effects from participating in this type of study.

Where is the study run from?
University of Leeds (UK).

When is the study starting and how long is it expected to run for?
May 2012 to September 2013.

Who is funding the study?
The research is being funded by the National Institute of Health Research (NIHR) as part of the Leeds, York, Bradford CLAHRC (Collaboration for Leadership in Applied Health Research and Care).

Who is the main contact?
Dr Kate Hill
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# Contact information

### Type(s)
Scientific

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
12/YH/0086/Version3

# Study information

### Scientific Title
A randomised feasibility trial of systematic lifestyle referral assessment compared to standard assessment in an acute cardiology service

## Acronym
HHT

## Study objectives
Current local practice for patients admitted to hospital with a possible cardiac event is to ask routine questions about lifestyle and behaviours like smoking, alcohol consumption and diet. However, coverage using these questions is patchy, and there is no consistent approach to onward referrals in response to the needs identified. Our hypothesis is that using a systematic assessment that identifies individual barriers and tailors advice and referrals will improve uptake of lifestyle interventions and subsequent behaviour change.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
NRES Committee - Yorkshire and Humber - Leeds East Research Ethics Committee, 12/03/2012, ref: 12/YH/0086

## Study design
Randomised open feasibility trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Quality of life

## 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
Participants will be asked to complete several questionnaires relating to health and behaviour. They will be randomly allocated to one of two groups to decide which lifestyle assessment will be conducted.

One group will receive the usual lifestyle assessment and the other group will receive a new lifestyle assessment.

Both groups will receive the same medical care and advice normally given to patients who are admitted on to a cardiology ward.

Participants will be followed up twice at three and six months after the first (baseline) interview.

### Intervention Type
Behavioural

### Primary outcome measure
1. Modification of lifestyle behaviour or quality of life
2. Successful uptake, with two distinct components:
2.1. Accept referral or self referral to a formal lifestyle programme (yes/no)
2.2. Participate in a lifestyle change intervention or a self-directed programme of lifestyle modification (no participation; participation initiated; participation initiated/persisted; participation initiated/persisted/ maintained)
3. Participation will be evaluated by self-reported attendance or, for those who undertake self-directed lifestyle change, from self reported activities using structured qualitative methods. While the categories will be the same for acceptance and participation across arms and options, the criteria/derivation differs. Where data is taken from a qualitative interview, rather than a structured proforma, two raters will independently classify participants. Where there are discrepancies, these will be discussed and a consensus reached.

### Secondary outcome measures
1. Safety (i.e. death)
2. Acceptability of assessment tool (qualitative only)
3. Patient's experiences of making lifestyle changes (qualitative only)
4. Eligibility, refusal, recruitment and follow-up rates
5. Preferred/actual method of follow-up
6. Proportion of missing items, scales and visits
7. Change in lifestyle (i.e. change in smoking, alcohol consumption, diet and physical activity)
8. Social Satisfaction (SSQ)
9. Clinical Outcomes in Routine Evaluation (CORE-10)
10. European Quality of Life - 5 Dimensions (EQ-5D)

### Overall study start date
01/05/2012

### Completion date
30/09/2013

## Eligibility

### Key inclusion criteria
1. Admitted to hospital with a diagnosis of acute coronary event or myocardial infarction or symptoms of a cardiac nature
2. Male and females aged between 40 and 74 years of age
3. Willing to give written informed consent

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
120

### Key exclusion criteria
1. Aged less than 40 or over 74 years of age at the time of screening
2. Currently receiving specialist treatment with a primary focus on alcohol, smoking, diet or exercise
3. No risk factors for vascular events
4. No-fixed abode (i.e. not available for follow-up)
5. Currently serving a sentence in prison or outstanding legal issues likely to lead to imprisonment (i.e. not available for follow-up)
6. Unwilling to give written informed consent
7. Unable to give written informed consent
8. Unable to take part in either intervention using spoken English
9. Unable to self-complete the English language outcome measure tools

### Date of first enrolment
01/05/2012

### Date of final enrolment
30/09/2013

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### University of Leeds
Leeds
United Kingdom
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## Sponsor information

### Organisation
University of Leeds (UK)

### Sponsor details

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### Sponsor type
University/education

### Website
http://www.leeds.ac.uk/

### ROR
https://ror.org/024mrxd33

## Funder(s)

### Funder type
Government

### Funder Name
National Institute of Health Research (NIHR) as part of the Leeds, York, Bradford Collaboration for Leadership in Applied Health Research and Care (CLAHRC) (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? |
|---|---|---|---|---|---|
| Protocol article | protocol<br>results | 11/07/2013 | | Yes | No |

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|---|---|---|---|
| Results article | 01/11/2015 | Yes | No |