

# Home visit versus telephone follow up in Phase II Cardiac Rehabilitation following myocardial infarction: effects on anxiety, depression, attendance at Phase III program and visits to accident and emergency (A&E) or readmission

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/02/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mrs Janet McPaul

**Contact details**  
Epsom and St. Helier NHS Trust  
Wrythe Lane  
Carshalton  
United Kingdom  
SM5 1AA

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

N0112186411

# Study information

## Scientific Title

Home visit versus telephone follow up in Phase II Cardiac Rehabilitation following myocardial infarction: effects on anxiety, depression, attendance at Phase III program and visits to accident and emergency (A&E) or readmission

## Study objectives

Is visiting a patient at home after hospital admission following a heart attack (myocardial infarction) more effective than a telephone call in reducing anxiety and depression, encouraging attendance at Phase III and/or reducing readmission to hospital and visits to Accident and Emergency departments with cardiac symptoms? Phase III refers to exercise and education classes available for 7 weeks, usually starting 4 weeks after myocardial infarction (MI).

## Secondary Research Objectives:

If effective, which types of patients benefit most from home visits? Groups to be examined by age, sex, ethnic origin, attendees versus non attendees at Phase III classes, number of risk factors and levels of anxiety and depression during hospital admission.

## 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)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Cardiac rehabilitation

## Interventions

This is a prospective independent groups design using simple random allocation of patients admitted during the study period to usual care (telephone call) or study intervention (home visit). The same semi-structured interview format will be used during telephone calls and home visits. Telephone calls and home visits will take place within one week of discharge from hospital if possible. A validated questionnaire, the Hospital Anxiety and Depression Scale (HADS) will be used to assess anxiety and depression. It will be administered at baseline (Phase I), 4 weeks after the heart attack (at entry to Phase III) and approximately 11 weeks after the heart attack (at the end of Phase III).

The study will involve all patients admitted with a diagnosis of an MI except those who meet the exclusion criteria over a period of approximately 6 weeks until 46 patients have agreed to participate in the study (allowing for nearly 10% of patients in each group to drop out of the study before completion as 21 are required in each group). Eligible patients will be recruited by the cardiac rehabilitation nurse specialists when they are seen on the ward after a diagnosis of a heart attack has been made. The study will be explained and an information sheet will be given to each patient. Patients will be invited to participate in the study and if they give consent will be randomly allocated to usual care or home visit groups using sealed envelopes. They will be asked to complete a HADS questionnaire (as described in question A9) before being discharged from the hospital.

If they are going to be visited at home (the intervention) they will be telephoned first to arrange a convenient date and time. Before they are telephoned the nurse will check that they are not in another hospital (patients are frequently transferred directly from St Helier for Angora, usually at St Georges, Tooting) and have not died (normal practice) and inform the researcher. Home visits will be carried out by the researcher, an Occupational Therapist who works in Cardiac Rehabilitation. A semi-structured interview format will be used during the visit and notes will be recorded on the topics discussed. These notes will be filed in the patient's cardiac rehabilitation notes.

If they are not going to be visited at home a nurse will telephone them to discuss their progress (usual treatment) using the same semi-structured interview format.

All patients will be invited to attend exercise and education classes, usually starting 4 weeks after their heart attack. All patients are normally asked to complete a HADS form just before starting these classes. At the end of the classes (a 7-week course) patients will be asked to fill in a final HADS form. Normally all patients attending the classes are asked to fill one of these in when they finish but patients taking part in this study will also be asked to fill one in if they do not attend or finish the classes. Eleven weeks after their heart attack, or when the patient finishes Phase III classes, the nurse will look up on the hospital computer system whether they have visited Accident and Emergency or been readmitted to hospital with heart problems during this time. This will be recorded in the patient's cardiac rehabilitation notes.

Data to be collected:

1. Age
2. Sex
3. Ethnic origin
4. HADS scores (on three occasions)
5. Attendance at Phase III classes (those who attend at least one class will be considered attendees for the purpose of this study)
6. Number of visits to A&E with cardiac (heart-related) symptoms during Phases II and III
7. Number of days of rehospitalisation with cardiac symptoms during Phases II and III

**Timetable:**

Weeks 1 - 6: Recruitment of patients for study. Baseline measurements - record age, sex, ethnic origin and HADS scores for each group. Within 4 days of discharge from hospital the researcher will contact each patient who has been selected for a home visit and arrange to visit as soon as possible. Patients who have been selected to receive a telephone call (usual care) will be contacted by the Cardiac Rehabilitation Nurse Specialists. Visits should be completed within two weeks after the end of the third month unless there are patients whose discharge was delayed in which case some may be later than this.

Weeks 5 - 11: As patients become eligible for Phase III start to record attendance. Patients should start Phase III 4 weeks post-MI but sometimes this is delayed (e.g., because they have been awaiting additional treatment before being able to start) therefore an additional week has been included to allow for this.

Weeks 12 - 18: Seven weeks after attendance at Phase III was due to commence (non-attendees) or at the end of Phase III (attendees) ask each patient in the study to complete a final HADS form. Score HADS forms and file in patients' notes. At the same time the Cardiac Rehabilitation Nurse Specialists will access patients' records via the computer system and record the number of visits to A&E and any readmissions to hospital with cardiac symptoms in the patients' cardiac rehabilitation notes.

Week 18 and over: Analyse findings and start to prepare final report.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Levels of anxiety and depression 4 and 11 weeks after MI - expressed as HADS scores.

**Secondary outcome measures**

1. Attendance at Phase III - expressed as percentage attending at least one session
2. Attendance at A&E readmission to hospital with cardiac symptoms - expressed as number of visits to A&E and or days in hospital

**Overall study start date**

17/07/2006

**Completion date**

30/09/2007

**Eligibility****Key inclusion criteria**

Patients admitted to St Helier Hospital with a diagnosis of myocardial infarction (heart attack) during the study period.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

42

**Key exclusion criteria**

1. Patients who are mentally unable to complete a HAD questionnaire, e.g. due to dementia or mental handicap or are considered by the CRNs to be too severely ill to be asked to complete a questionnaire
2. Patients who live too far away to be visited at home
3. Patients with a known history of violence because they may be a threat to the researcher visiting them at home
4. Prisoners, due to their lack of freedom to decide for themselves whether or not to attend exercise and education classes
5. Patients who die, are discharged or are transferred to another hospital without being seen by the CRNs

**Date of first enrolment**

17/07/2006

**Date of final enrolment**

30/09/2007

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Epsom and St. Helier NHS Trust**

Carshalton

United Kingdom

SM5 1AA

## **Sponsor information**

**Organisation**

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

**Sponsor details**

The Department of Health  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Epsom and St Helier University Hospitals NHS Trust (UK) - NHS R&D Support Funding

## **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