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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

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 28/02/2018	**Condition category** Circulatory System	

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
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
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Sponsor information

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

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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