ISRCTN34701576 https://doi.org/10.1186/ISRCTN34701576

A feasibility study and pilot study to establish methods for assessing the acceptability, and clinical and cost-effectiveness of enhanced psychological CAre in carDiac rEhabilitatioN serviCEs for patients with new onset depression compared with usual care

Submission date
22/05/2014

Recruitment status
No longer recruiting

Registration date
29/05/2014

Overall study status
Completed

Last Edited
04/06/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims

The UK NHS routinely offers cardiac rehabilitation to patients who experience an acute cardiac event (e.g. after a heart attack or heart surgery). Cardiac rehabilitation provides patients with the physical, mental and social support necessary to attain and/or regain good health and slow or reverse the progression of heart disease. This includes education and advice on the causes of heart disease and the management of risk factors (e.g. diet, smoking cessation); supported exercise; medical management (e.g. surgery, drugs); and psychosocial support. Support is offered in stages (numbered 0 to 6) by clinicians (e.g. doctors, nurses, physiotherapists) working in a range of settings (e.g. hospital wards, outpatient and community clinics). Stages 0-1 generally take place in hospital wards, while stages 2-5 are delivered as a structured course (e.g. 1-2 sessions per week for 8 weeks) by dedicated comprehensive cardiac rehabilitation teams, and stage 6 is located in primary care. On referral to a cardiac rehabilitation team, patients are routinely assessed by a nurse and around 17% show signs of depression. Although teams should provide psychological support, this is usually fairly limited; only 10% of teams offer expert psychological care. Effectively tackling depression in people with established heart disease is important as such symptoms predict worse patient outcomes (poorer health-related quality of life, greater morbidity and mortality) as well as a greater use of healthcare and greater healthcare costs. Normally most people with depression are advised to seek help from their family doctor. NHS guidelines suggest that initial treatment should consist of low-intensity community-based psychological therapy. Patients should only receive more intensive management (e.g. drug therapy) when their symptoms fail to respond to initial therapy or if symptoms are so serious they need more immediate high intensity treatment. There is an urgent need to train cardiac rehabilitation staff on how to improve patient referrals to existing community psychological services through implementing NHS good practice guidance. However,

we believe that putting a low-intensity behavioural activation therapy into the care already provided by nurses within rehabilitation teams may directly support patients, potentially removing the need for onward referral. This study will establish whether a treatment called enhanced psychological care intervention (EPC) delivered by cardiac rehabilitation nurses works better than standard care. Patients who are referred to a team, and who are found to have developed depressive symptoms since their cardiac event, will be offered study participation. EPC has two components: collaborative mental health care-coordination and referral, and a behavioural activation therapy offered within the cardiac rehabilitation programme. Standard care is usual cardiac rehabilitation care, which includes psychological support, supported exercise, and education.

Who can participate?
Patients that have been referred to cardiac rehabilitation and found to be depressed after a completion of a patient health questionnaire.

What does the study involve?
This study will be done is two phases. Phase 1 is an initial feasibility study, which will assess how practical it is to do the project. Phase 2 is a study where groups of people will be randomly split into different groups and will be interviewed.
Phase 1: Feasibility study.
This will develop and test the EPC, gather evidence from patients and staff on how best to implement it, test methods for identifying and recruiting eligible patients, describe the usual psychological support before EPC is implemented, and develop the methods needed in the next phase. The EPC will be developed by refining existing training materials. Three cardiac rehabilitation teams will be recruited and the nurses trained to implement the EPC. Patients will be invited to attend an initial rehabilitation appointment by one of these nurses. Those who show signs of depression during this consultation will be asked to take part in the study. Those that agree are then given EPC and interviewed 5 months after the treatment. We will measure how many patients agree to take part and assess the following before and after EPC: depressive symptoms, cardiac risk factors (blood pressure, smoking), quality of life, use of antidepressants and health care services, and overall satisfaction in care received. The EPC will be assessed though focus groups with health professionals from the cardiac rehabilitation teams, and in-depth interviews with the nurses and patients taking part. The EPC, and study materials and methods will be changed and improved according to the results of this initial study.
Phase 2: External pilot trial and nested qualitative study.
This will involve setting up eight cardiac rehabilitation teams which will be randomly allocated to a intervention or usual care (control) patient group. All patients managed by the teams will be offered the appropriate care. We will recruit 64 patients in total and follow them up twice (5 months, 8 months) using measures described in the feasibility study, plus data on how there disease progresses. We will also estimate how many people take part and the proportion of patients that drop out of the study. We will review whether estimates from the feasibility study (e.g. patient recruitment and drop-out rates) still apply, further describe the content of usual psychological support, and use pilot data to estimate the sample size needed (number of teams and patients) for a larger scale trial. In-depth interviews will also take place with staff and patients. These will explore their views and experiences of the study design and the intervention. Interviews will also be held with patients who decline to take part in the pilot trial. About 40 interviews will be held in total (10 staff, 30 patients); the final number will depend on when no new themes are reported.

What are the possible benefits and risks of participating?
No treatment is being withheld from patients in the control group, with cardiac rehabilitation services continuing to make any outward referrals for specialist mental health services for

patients who agree for this to happen. There are no known risks associated with the components of our EPC intervention; both behavioural activation and mental health care co-ordination are established methods of managing patients with newly identified depressive symptoms, and both interventions are currently recommended for use by the UK health service. In our study we are testing whether these established treatments can be successfully implemented within cardiac rehabilitation services.

Where is the study run from?
The University of Exeter Medical School (UK)

When is the study starting and how long is it expected to run for?
March 2014 to July 2016

Who is funding the study?
UK National Institute of Health Research: Health Technology Assessment Programme (HTA) (UK)

Who is the main contact?
Dr Suzanne Richards

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/189/06

Study information

Scientific Title

A feasibility study and pilot randomised controlled trial to establish methods for assessing the acceptability, and clinical and cost-effectiveness of enhanced psychological care in cardiac rehabilitation services for patients with new onset depression compared with treatment as usual

Acronym
CADENCE

Study objectives
The over-arching research aim is to establish methods for assessing the acceptability and effectiveness of enhanced psychological care (EPC) delivered by cardiac rehabilitation nurses compared with usual NHS cardiac rehabilitation care. To achieve this two phases of research, each with different aims and objectives, are planned.

Phase 1: Feasibility study
Aim: To develop, design and assess an EPC intervention, composed of care coordination and behavioural activation, and to test its implementation. We will also specify the psychological components within the control condition for patients with new onset depressive symptoms undergoing comprehensive cardiac rehabilitation following an acute cardiac event.
There are five objectives:
1. To develop, assess, and refine the underlying intervention theory of a standardised EPC intervention (including a supporting intervention manual and training package) for implementation by cardiac rehabilitation nurses.
2. To describe the content of psychological support routinely offered via rehabilitation teams; this may include active treatments embedded within the programme, or established referral practices to existing NHS mental health services.
3. To determine the feasibility and acceptability of implementing/experiencing EPC for rehabilitation staff and patients.
4. To describe cardiac rehabilitation process measures including: (i) the proportion of patients with new onset depressive symptoms identified on initial assessment by a nurse; (ii) patient attendance at, and adherence with, the rehabilitation programme with an embedded psychological therapy aimed at treating depressive symptoms and the time elapsed to start of treatment; and (iii) documenting psychological care coordination activities provided to patients on exit from the rehabilitation pathway either due to attrition before the rehabilitation programme, or for patients exiting it for any reason.
5. To develop and undertake preliminary testing of study methods (team and patient recruitment, data collection procedures) required to implement a pilot trial.

Phase 2: External pilot trial and nested qualitative study
Aim: To test the methods and procedures required to undertake a fully powered evaluation of the clinical and cost-effectiveness of cardiac rehabilitation teams implementing EPC for patients with new onset depressive symptoms using cardiac rehabilitation services compared with a control group of usual cardiac rehabilitation care.
There are four objectives:
1. To further describe the flow of patients (i.e. eligibility, recruitment and drop-out rates) from the cardiac event to the 8 month follow-up for patients entering into the cardiac rehabilitation care pathway, and in particular, to document the flow of those patients who agree to take part in the pilot trial.
2. To collect patient outcome data in order to (i) identify the most appropriate primary outcome measure and (ii) estimate the standard deviation for the various outcomes to inform sample size calculations (number of teams and patients) for a definitive trial.
3. To establish the data collection methods required to support a definitive economic evaluation.

4. To gather qualitative evidence from patients (including patients who did or did not adhere to the EPC, and those who declined to take part in the trial) and nurses on the acceptability of receiving/implementing EPC, and on the appropriateness of study methods and procedures. Further information will also be sought on the content of usual psychological care within cardiac rehabilitation teams.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1218906
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/118340/PRO-12-189-06.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southwest NHS Research Ethics Committee - Exeter, ref 11/SW/0139

Study design
Phase 1: Before-and-after observational feasibility study with qualitative interviews and observations
Phase 2: External pilot cluster randomised controlled trial and nested qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Patients referred to cardiac rehabilitations services identified with depressive symptoms

Interventions
Phase 1: Feasibility Study
The enhanced psychological care (EPC) intervention will be developed by refining existing training materials describing collaborative care co-ordination and behavioural activation therapy. Draft materials will be reviewed by clinicians and service users before being tested. A 'before and after' observational study will be conducted. Three cardiac rehabilitation teams will be recruited and the nurses trained to implement the enhanced psychological care intervention. Patients attending the initial rehabilitation appointment are screened by a nurse for depressive symptoms ('low mood'). Eligible patients will be offered study entry and given detailed information about the study. Patients who wish to take part will be put in contact with a researcher (independent of the clinical team), who will arrange a visit to obtain written consent

and baseline assessments before the patient begins the cardiac rehabilitation programme. Study participation will not affect patient access to cardiac rehabilitation care in any way. Patients will be interviewed again at 5 months (post-intervention). We will recruit up to 20 patients. The primary outcomes relate to patient uptake/adherence to the cardiac rehabilitation programme and enhanced psychological care intervention, and study implementation (e.g. patient recruitment rates, quality of data collection). We will also collect patient outcomes regarding: depressive symptoms; cardiac risk factors (e.g. blood pressure, smoking status); patient health related quality of life; use of antidepressant medication and health care services; and satisfaction with care. Focus groups with health professionals from the participating teams, and in-depth interviews with staff and patients will be held. The enhanced psychological care intervention, and study materials and methods will be modified in light of these findings prior to beginning the pilot trial.

Phase 2: External pilot trial and nested qualitative study

1. Enhanced Psychological Care (EPC) intervention (treatment arm)

We will seek to embed EPC within existing cardiac rehabilitation care pathways, with referrals to existing community mental health services as appropriate. Cardiac rehabilitation nurses will be trained to deliver EPC based on a training manual developed and theoretically refined during the feasibility study. There are two components: mental health care coordination, and the psychological intervention of behavioural activation (BA) delivered by the nurses. To deliver mental health care coordination, nurses will be trained to apply algorithms based on current best practice (e.g. stepped care, collaborative working), matching the intensity of treatment with patient preferences for mental health care. As patient attrition from the cardiac rehabilitation care pathway is high, care coordination will be available to all patients referred to a locality-based CCRP team and who agree to undertake an initial assessment, where their depressive symptoms will be ascertained using the Patient Health Questionnaire (PHQ-9). This tool assesses the 9 DSM-IV depression criteria, as experienced over the last two weeks from '0' (not at all) to '3' (nearly every day). The scores are summated, with higher scores representing greater depression severity (range 0-27), with symptom ranges of none (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27) symptom specified. Patients identified with new onset depressive symptoms (PHQ-9 = 10 or more), and who have not been receiving active treatment for their depression in the six months prior to the cardiac episode, will be eligible for EPC. Patients who explicitly opt-out of the subsequent intensive rehabilitation, for whatever reason, will receive care coordination only. Patients who actively engage in cardiac rehabilitation programme (including BA) will also receive care coordination on completion of (or early exit from) the programme. Care coordination is composed of several processes. At the point at which a patient exits the CCRP care pathway, structured details of the psychological care already received (if appropriate) will be routinely sent to the patients general practitioner (GP). The patients PHQ-9 score(s) will also be routinely fed back to their GP at a point when the GP is expected to become actively involved in their care. On completion of a PHQ-9, the cardiac rehabilitation nurse will discuss the results with patients and explore the appropriate evidence-based management options available. For patients declining further participation in cardiac rehabilitation, the appropriate mental health referrals will be put in place. This might include direct referral to specialist community mental health services, or a request that their GP takes the lead in their subsequent mental health care. For patients with PHQ-9 scores indicative of depression who are willing to undertake a structured cardiac rehabilitation programme, the psychological management option of BA will be offered. Participants will receive BA integrated within each rehabilitation appointment for a maximum of 30 minutes per appointment (see usual care description below) and it will be delivered using a modular treatment manual. BA will consist of a structured programme of increasing contact with potentially antidepressant environmental reinforcers through scheduling and reducing the frequency of negatively reinforced avoidant behaviours. Individual treatment programmes will

be developed collaboratively with the patient throughout their sessions. Specific BA techniques will include: the use of a functional analytical approach to develop a shared understanding with patients of behaviours that interfere with meaningful, goal-oriented behaviours; self-monitoring; identifying depressed behaviours; developing alternative goal orientated behaviours for routine, pleasurable and necessary activities, and activity scheduling of these identified behaviours. The overall goal of BA will be to re-engage participants with stable and diverse sources of positive reinforcement from their environment and to develop depression management strategies for future use. If the patient declines BA, or at any point opts out of rehabilitation, care coordination will be implemented. For those patients who complete cardiac rehabilitation, structured details of the care received will be sent to their GP. Patients whose depressive symptoms fail to respond to BA will be given an opportunity to review their management options with the nurse. The appropriate referrals for follow-on care will then be made based on UK NHS good practice guidance. Here, treatment response is defined as a minimally important clinical difference (MICD) for the PHQ-9 equivalent to a five point reduction in score. It is important to note, however, that some people who make a MICD may remain above the PHQ-9 diagnostic threshold (>10); the latter will be referred for extra mental health care as well.
2. Usual care intervention (control arm)
Usual care is defined here as the standard cardiac rehabilitation commencing at the point of assessment with a cardiac rehabilitation specialist nurse from a locality-based team. Around 17% of patients eligible for rehabilitation are identified with depressive symptoms during this assessment. Of patients invited to attend a structured rehabilitation programme, around 41% attend structured sessions within 2-10 weeks. Rehabilitation teams typically offer intensive rehabilitation for 1-2 sessions per week for approximately 8 weeks. Sessions generally last around 2 hours and include structured exercise, education (e.g. managing lifestyle and cardiac risk) and some psychological input (e.g. relaxation, stress management). On exiting a rehabilitation programme, a final assessment and discharge arrangements are made to community services. There is considerable uncertainty as to what constitutes standard psychological care for people undergoing cardiac rehabilitation, and a core objective of this study is to clarify this definition. National audit data found that psychological expertise within locality-based CCRP teams is uncommon (<10%). In Devon, patients with depressive symptoms may be referred to a clinical psychologist either by the tertiary centre or by locality-based rehabilitation teams. No systematic method is applied to identify patients suitable for referral; rather the decision is based on a combination of depression scores obtained in standard mood assessments, discussions with patients, and clinical judgment regarding who might benefit from referral. Informal discussions with mental health specialists and cardiac rehabilitation staff suggest that there is considerable variation in local protocols applied by rehabilitation teams across the UK.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Phase 1: Feasibility study
Descriptive Process Measures
1. Patient study eligibility and recruitment: number of patients attending an initial comprehensive cardiac rehabilitation programme nurse assessment, the proportion identified with depressive symptoms during this assessment, the prevalence of new onset (as opposed to

existing) depression symptoms and the number of patients eligible for study participation. Of eligible patients: the number offered study entry; and the number agreeing to be contacted by a researcher; and the number consented to take part and undergoing a baseline interview with a researcher.
2. Intervention fidelity: numbers of patients who do not attend intensive cardiac rehabilitation and the proportion of patients with documentary evidence of care coordination in their notes. For patients who commence intensive rehabilitation with behavioural activation: number of behavioural activation sessions offered and the number of sessions attended, and the number of patients with documentary evidence of care coordination on exiting the rehabilitation programme, and the type of referrals made (if appropriate).
3. Study compliance: number of patients completing the follow-up interview, the completeness of data recorded in patient schedules.

Phase 2: External pilot trial and nested qualitative study
Descriptive process measures (see feasibility study): The study is powered to detect the proportion of patients recruited who are successfully followed-up.
1. Patient reported outcome measure: depressive symptoms assessed using the Beck Depression Inventory (BDI-II). This 21-item self-report instrument measures severity of depressive symptoms with an emphasis on affective and cognitive symptoms. Higher scores represent greater depression severity (range 0-63), and minimal (0-13), mild (14-19), moderate (20-28) and severe (29-63) symptom severity ranges have been specified. Measured at baseline, 5 and 8 month assessments.

Secondary outcome measures

Phase 1: Feasibility study
Not applicable

Phase 2: External pilot trial and nested qualitative study
1. Routine Records: Cardiac and non-cardiac related deaths between baseline and 8 months. Incidence of any new cardiac events between baseline and 8 months i.e. hospital admissions for acute coronary syndrome or revascularisation procedures (CABG or PCI), or mental health events (e.g. self-harm, suicidality) arising since study enrolment extracted from acute hospital and primary care records.
2. Patient reported outcome data
Domain: Measure (assessment schedule)
(i). Anxiety: Beck Anxiety Inventory. 21 items asking patients to report anxiety symptoms over the last week from 0 (none: it did not bother me at all), 1 (mildly: it did not bother me much), 2 (moderately: it was very unpleasant, but I could stand it), and 3 (severely: I could barely stand it). Item scores are summated with scores of 8-15, 26-25, and 26-63 taken as cut-off points for mild, moderate, or severe anxiety respectively. (baseline, 5 months, 8 months)
(ii). Generic health related quality of life: EuroQOL EQ-5D. 5 items with 3 response categories representing no impairment, moderate impairment or severe impairment. (baseline, 5 months, 8 months)
(iii). Disease specific health related quality of life: HeartQoL. 14-items with 10-item physical and 4-item emotional subscales which are scored from 0 (poor health related quality of life) to 3 (better). (baseline, 5 months, 8 months)
(iv). Patient experiences of care: Client Satisfaction Questionnaire. 8 items completed using four-point Likert scales (1 to 4), with scores ranging from a possible 8 to 32 and higher values indicating higher satisfaction. (5 months only)
(v) Patient Treatment Preferences Questionnaire. To be developed by research team. (Baseline only)
3. Economic data collection: Resource and service use data extracted from routine

/administrative sources, and via patient self- report using the Service and Resource Use Questionnaire. (5 months, 8 months)

Overall study start date
01/04/2014

Completion date
31/07/2016

Eligibility

Key inclusion criteria
A pragmatic approach will be adopted, whereby adult patients (18 years or over) referred for cardiac rehabilitation based on local clinical referral protocols of participating rehabilitation teams will be screened for eligibility by a specialist nurse. This includes patients admitted with an Acute Coronary Syndrome, i.e. ST elevation myocardial infarction or non-ST elevation myocardial infarction and unstable angina, and/or following a coronary revascularization procedure, i.e. coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI). These currently constitute the majority of patients referred for rehabilitation. Within this group, eligible patients are those identified as experiencing a new episode of depression symptoms identified through nurse screening at the start of the comprehensive cardiac rehabilitation programme using the Patient Health Questionnaire-9 (PHQ-9 score of 10 or more).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Phase 1: 20 patients in observational study; 20 qualitative interviews (15 patients/5 staff).Phase 2: 64 patients (8 rehabilitation teams) in RCT, 40 qualitative interviews (30 patients/10 staff)

Key exclusion criteria
Current exclusion criteria as of 12/11/2014:
The following patient exclusion criteria will be applied during routine cardiac rehabilitation screening by a nurse specialist. Patients who report having been actively treated for depression (psychological or drug therapy) within 6 months before the acute cardiac event will be excluded. The nurse will also exclude patients where there is evidence of alcohol or drug dependency, being acutely suicidal, or having poorly controlled bipolar disorder or psychosis/psychotic symptoms based on a clinical review (and seeking external confirmation from the general practitioner or other clinicians as required).

Previous exclusion criteria:
The following patient exclusion criteria will be applied during routine cardiac rehabilitation screening by a nurse specialist. Patients who report having been actively treated for depression (psychological or drug therapy) within 6 months before the acute cardiac event will be excluded. The nurse will also exclude patients where there is evidence of alcohol or drug dependency, being acutely suicidal or cognitively impaired (e.g. diagnosed dementia), or having a bipolar disorder or psychosis/psychotic symptoms based on a clinical review (and seeking external confirmation from the general practitioner or other clinicians as required).

Date of first enrolment
01/04/2014

Date of final enrolment
31/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter Medical School
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/02/2017

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	02/02/2016		Yes	No
Results article	results	01/05/2018		Yes	No