Enhanced psychological care in cardiac rehabilitation services for patients with new-onset depression: the CADENCE feasibility study and pilot RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

The CADENCE feasibility study and pilot RCT

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Scientific summary

Background

Depression is common in people with coronary heart disease (CHD), affecting up to 20% of such individuals, and is approximately four times more common than in the general population. Such depression is associated with a doubling of the risk of subsequent morbidity and mortality. The detection and appropriate management of depression among people with CHD is a policy priority.

Routine clinical care for people with CHD who have experienced acute coronary syndrome [(ACS) including myocardial infarction, non-ST elevation myocardial infarction (NSTEMI) and unstable angina] includes the provision of cardiac rehabilitation. Cardiac rehabilitation in the UK is conceptualised as a seven-stage model beginning from when the patient presents with ACS, and incorporates education, exercise, weight management, medical management and psychological support. Psychological support can include the assessment of symptoms of anxiety and depression, and the provision of relaxation or stress management. Only a minority of services have direct access to specialist psychological support. Thus, despite the availability of evidence-based interventions for depression in primary and secondary care, the majority of people attending cardiac rehabilitation do not receive adequate psychological care.

Our research aimed to address this gap in the provision of psychological support for people with depression by developing and evaluating enhanced psychological care (EPC), a complex intervention embedded within routine cardiac rehabilitation. In line with the funding brief, our research focused on people with new-onset depression.

Our research comprised:

- the development of clinical and training materials to support cardiac rehabilitation nurses in the delivery of EPC, involving a maximum of eight sessions of behavioural activation (BA) for depression and mental health-care co-ordination to ensure adequate monitoring of depression, and the assessment and management of any associated risk and onwards referral, where appropriate
- an uncontrolled pre–post feasibility study, which aimed to determine the feasibility and acceptability of implementing/experiencing EPC from the perspective of cardiac rehabilitation nurses and patients, modifying the intervention when indicated
- a pilot cluster randomised controlled trial (RCT), which aimed to identify the methods and procedures required to undertake a fully powered evaluation of the clinical effectiveness and cost-effectiveness of EPC for depression delivered within routine cardiac rehabilitation compared with usual care (UC).

Objectives

The objectives of the feasibility study were to:

- develop and refine the EPC intervention for implementation by cardiac rehabilitation nurses
- describe the psychological support routinely offered by cardiac rehabilitation services
- determine the feasibility and acceptability of implementing/experiencing EPC
- determine (1) the proportion of patients with new-onset depression attending cardiac rehabilitation assessment, (2) participant attendance at, and adherence with, the cardiac rehabilitation programme with EPC and (3) the psychological care co-ordination provided within usual cardiac rehabilitation care
- develop and undertake preliminary testing of the study methods required to implement a pilot trial.

The objectives of the pilot cluster RCT were to:

- quantify the flow of patients from the cardiac event to the 8-month follow-up, and to document the flow of those participants who agreed to take part in the pilot trial
- collect participant outcome data to estimate the standard deviation (SD) for outcomes
- establish the data collection methods required to support a definitive economic evaluation
- gather qualitative evidence from patients and nurses on the acceptability of receiving/implementing EPC, of study methods and procedures and on the content of usual psychological care.

Methods

Intervention development

Behavioural activation is an evidence-based treatment for depression that is suitable for the training of, and delivery by, non-psychologically trained clinical practitioners. Using mental health expertise within our team, we developed materials to support the delivery of BA, tailored to the needs of people with CHD and suitable for delivery within cardiac rehabilitation services. The mental health-care co-ordination components of the intervention were based on current National Institute for Health and Care Excellence guidance, targeting the recognition and management of depression in adults with chronic physical health problems.

Consistent with the Medical Research Council's guidance for the development and evaluation of complex interventions, we conducted a two-phase study.

Feasibility study

We conducted a multimethods study to determine the feasibility and acceptability of implementing/experiencing EPC from the perspective of cardiac rehabilitation nurses and patients.

Five nurses from participating cardiac rehabilitation services received 2 days of training in EPC. Of the five nurses trained, four engaged in the recruitment of participants; one nurse attended training but did not participate in patient recruitment or EPC delivery.

In the preliminary observational study, we aimed to recruit 20 patients with depression, referred by nurses from three operationally distinct cardiac rehabilitation teams in Devon, UK. Adult patients referred to cardiac rehabilitation services following an episode of ACS, and scoring in the depressed range [Patient Health Questionnaire-9 (PHQ-9) score of 10 or more], were eligible for inclusion. Patients were excluded if they had received treatment for depression in the previous 6 months, if they experienced alcohol or drug dependency, if they were actively suicidal or if they had uncontrolled bipolar disorder or schizophrenia.

Patient research assessments were conducted at baseline and at 5 months. Nurses recorded a screening log to record patient throughput, and maintained clinical notes to record patient engagement with EPC. We conducted qualitative interviews with nurses before the intervention development, again within 4 weeks of completing training and, finally, towards the end of the EPC delivery. We also gauged nurses' experiences through observations of nurse training and nurse/clinical supervisor meetings, clinical supervisors' supervision summaries and field notes. Patients were interviewed once they had completed EPC.

Pilot study

We conducted a pilot cluster RCT to test the methods, and procedures, needed to facilitate the planning and design of a subsequent fully powered evaluation of EPC for depression among individuals attending cardiac rehabilitation compared with UC. UC was standard NHS cardiac rehabilitation (including psychological care), as delivered in the locality of the teams randomised to that arm.

Quantitative assessments were conducted at baseline, 5 months and 8 months. At baseline, data were recorded on demographic characteristics, medical/cardiac status and psychiatric diagnostic status. At baseline and follow-up, assessments were made of depression severity [using the Beck Depression Inventory, version 2 (BDI-II)], anxiety [using the Beck Anxiety Inventory (BAI)], health-related quality of life [using the EuroQol-5 Dimensions (EQ-5D) and the Heart Quality Of Life scale (HeartQoL)], degree of BA [using the Behavioural Activation for Depression Scale – Short Form (BADS-SF)] and satisfaction with treatment [using the Client Satisfaction Questionnaire – 8 (CSQ-8)]. A preliminary economic evaluation was conducted to pilot methods to collect data on costs.

Qualitative data were collected during observations of staff training and during interviews with nurses who had delivered EPC, and with patients in both trial arms (after the 5-month assessment) and patients who had been offered, but had declined, trial participation.

Results

Feasibility study

At a pre-training meeting with cardiac rehabilitation nurses, it became apparent that there was considerable variation in the way in which different cardiac rehabilitation services were organised, which affected how nurses conducted their rehabilitation programmes.

At interviews following training, nurses reported that they liked the content and format of training and the supporting materials provided, and were positive about the prospect of using BA. Nurses commented that the training had given them the confidence to discuss and manage risk issues with patients, and that care co-ordination provided them with options over where to direct patients. Nurses raised concerns about how they would fit in the BA sessions around the rest of their workload.

Between September 2014 and March 2015, of the 203 patients screened for study eligibility, 30 met the inclusion criteria, of whom nine agreed to take part. The mean age of patients participating in the study was 60.4 years; 78% were male and all self-reported their ethnicity as white and their preferred language as English. Of those recruited, 22% met the diagnostic criteria for a ‘mild’ depressive episode and 22% for a ‘severe’ depressive episode.

Data collected from nurse notes indicated that the nine recruited patients attended between 1 and 18 sessions of cardiac rehabilitation. Nurses discussed a mental health referral for four individuals.

Of the nine patients interviewed after receiving EPC, most felt that EPC had helped their mood, and valued the opportunity to discuss their feelings, although participants remembered little about the contents of the intervention materials.

Feedback on study procedures indicated that most participants reported that assessments were of ‘the right length’ and had ‘the right number of questions’. Eight out of nine participants completed the participant-reported outcome data.

Transition between the feasibility study and the pilot study

We modified the research procedures for the pilot study based on findings from the feasibility study, including broadening the eligibility criteria to include all patients referred for cardiac rehabilitation, and reducing our recruitment target from 64 to 43 participants.

We modified the EPC intervention based on the feasibility study findings. We increased the emphasis on care co-ordination and, to reduce the burden on nurses, shifted from nurse-delivered to patient-led/nurse-supported BA. Treatment and training materials were modified to reflect these changes.

Pilot study

Between December 2014 and February 2015, 8 out of 20 teams approached agreed to participate, and were then randomised: five to the EPC arm and three to the UC arm. One team from the EPC arm dropped out post randomisation, but was replaced with a matched team. NHS governance (research and development) approvals in two areas took < 2 months from the initial contact; in five areas, it took between 2.5 and 3.5 months and, in the final area, it took > 5 months, which led to some delays in participant recruitment.

Fifty-five of the 614 patients screened were eligible for recruitment, and 29 patients took part (67% of the revised target sample size of 43). Trial arms were well matched for sex, ethnicity and preferred language. Patients in the EPC arm were younger than those in the UC arm (mean age 62.7 vs. 68.1 years), with higher depression scores at baseline (BDI-II scores: 18.4 vs. 12.5).

Summary of the quantitative results

At 5 months, the mean BDI-II score was reduced from baseline in the EPC and UC groups, and the mean between-group difference (adjusting for baseline score) was 1.7 [95% confidence interval (CI) –3.8 to 7.3]. Reductions in BDI-II scores at 5 months were observed in 5 out of 12 patients (42%) in the EPC arm and 7 out of 14 patients (50%) in the UC arm. Of the participants with a BDI-II score of > 14 (caseness) at baseline who attended the 5-month follow-up, 3 out of 7 patients (43%) in the EPC arm and 6 out of 7 patients (86%) in the UC arm were in remission (i.e. a BDI-II score of < 14).

At 5 months, the mean BAI score improved in the EPC and UC arms, and the between-group mean difference (adjusting for baseline score) was 4.6 (95% CI –0.8 to 10.0); heart-related quality of life (HeartQoL) improved in both treatment arms (adjusted between-group mean difference of –8.2, 95% CI –14.9 to –1.4), and generic health-related quality of life [EuroQol-5 Dimensions, five-level version (EQ-5D-5L)] remained largely unchanged in both treatment arms (adjusted between-group mean difference of 0.05, 95% CI –0.02 to 0.11).

All of the participants in the EPC arm, and most of the participants in the UC arm, were extremely satisfied with the amount of help they received (11/11 and 8/13 participants, respectively).

Economic evaluation

We successfully gathered information on the use of health services (clinical notes) across the period of involvement for 27 out of 29 participants. Apart from a difference at baseline between the two groups in EQ-5D-5L scores, there were no notable differences or changes over time. If a definitive trial were to be conducted, these health-related quality-of-life estimates could be used to determine a trial sample size based on the expected cost-effectiveness of the intervention.

The total estimated cost of providing EPC ($n = 15$) was £13,384 (i.e. an estimated cost per participant of £959). A substantial proportion (93%) of the overall cost was attributable to nurse training, with the estimated length of time nurses spent to deliver EPC contributing a relatively small amount (£63 of the estimated £959 per participant).

Case note review

The manual case note review of general practitioner (GP) records and cardiac nurse records proved to be satisfactory. Good or very good agreement between patient and either set of records was observed for information regarding accident and emergency attendance or hospital admission, but agreement was poor in respect to information on primary care resource use (when compared with GP records). The availability of physiological and biochemical information varied among participants, generally with greater availability of physiological data in GP or cardiac rehabilitation notes than that of biochemical data.

Summary of the qualitative results

Eighteen patient participants (twelve in the EPC arm and six in the UC arm) were interviewed, as well as three patients who declined trial entry. Trial participants described the major impact that their cardiac

event had had on both their mental and physical health. EPC participants described the one-to-one dedicated time they had received from nurses to focus on their mental health as vital to their recovery, and felt that embedding EPC in cardiac rehabilitation was timely and appropriate. UC participants felt that they had not discussed their mental well-being with their nurse in any depth or at all. Individuals who declined EPC reported that they did so because they did not feel low, were not keen to discuss mood and/or they felt overloaded with information following a cardiac event.

Seven cardiac nurses were interviewed from four intervention teams. The provision of psychological support was viewed as a key part of their role. Training in best-practice mental health-care co-ordination and managing risk was universally valued, and nurses felt that some patients had benefited from BA. Nurses commented that it was helpful that EPC had been integrated within cardiac rehabilitation, as many patients declined referrals to other services; they felt able to deliver the intervention, but had struggled to implement it within their existing workloads.

Conclusions

Implications for health care

- Patients and nurses acknowledged the importance, and recognised the value, of having psychological support embedded within routine cardiac rehabilitation, rather than having it provided elsewhere.
- The patient-focused format of EPC, as modified for our pilot trial, was acceptable to both patients and nurses.
- Cardiac rehabilitation nurses can be trained to deliver EPC. Although valued by both patients and nurses, organisational and workload constraints were significant barriers to implementation.
- Consideration should be given to delivering EPC by dedicated mental health workers, such as psychological well-being practitioners (PWPs), working closely with cardiac rehabilitation services.

Recommendations for research

- Enhanced psychological care, as delivered by dedicated PWPs working closely with cardiac rehabilitation services, should be considered for further evaluation in a large-scale clinical trial.
- The future definitive trial would require involvement of a substantial proportion of UK cardiac rehabilitation teams.
- A future study should review the need for cluster randomisation, and explore the potential for an individual randomised design.
- All depressed patients attending cardiac rehabilitation should be included, not just those with new-onset depression.
- The BDI-II was suitable as a primary outcome measure.
- Assessment of the primary outcome at 5 months is viable, although a longer follow-up period (12 months) is required to capture cardiac events, and to inform the health economic evaluation.

Trial registration

This trial is registered as ISRCTN34701576.

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