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The patient education — Learning and Coping Strategies — improves adherence in cardiac rehabilitation (LC-REHAB): A randomised controlled trial

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ABSTRACT

Background: Despite proven benefits of cardiac rehabilitation (CR), adherence to CR remains suboptimal. This trial aimed to assess the impact of the patient education 'Learning and Coping Strategies' (LC) on patient adherence to an eight-week CR program.
Methods: 825 patients with ischaemic heart disease or heart failure were open label randomised to either the LC arm (LC plus CR) or the control arm (CR alone) across three hospital units in Denmark. Both arms received same amount of training and education hours. LC consisted of individual clarifying interviews, participation of experienced patients as co-educators, situational, reflective and inductive teaching. The control arm received structured deductive teaching. The primary outcomes were patient adherence to at least 75% of the exercise training or education sessions. We tested for subgroup effects on the primary outcomes using interaction terms. The primary outcomes were compared across arms using logistic regression.
Results: More patients in the LC arm adhered to at least 75% of the exercise training sessions than control (80% versus 73%, adjusted odds ratio (OR):1.48; 95% CI:1.07 to 2.05, $P = 0.018$) and 75% of education sessions (79% versus 70%, adjusted OR:1.61, 1.17 to 2.22, $P = 0.003$). Some evidence of larger effects of LC on adherence was seen for patients with heart failure, low education and household income.
Conclusions: Addition of LC strategies improved adherence in rehabilitation both in terms of exercise training and education. Patients with heart failure, low levels of education and household income appear to benefit most from this adherence promoting intervention.
Trial registration: www.clinicaltrials.gov identifier NCT01668394

1. Introduction

1.1. Background

Cardiovascular disease (CVD) is the most common cause of death in Europe accounting for more than 4 million deaths each year [1]. Nearly half of the deaths from CVD in both men and women are due to ischaemic heart disease (IHD) or heart failure (HF) [1]. Whilst incidence and deaths rates for IHD have decreased, the incidence of HF has stabilised worldwide over the last decades [2,3]. The prevalence of patients living with IHD and HF has increased in the same time period and accounts for approximately 300.000 hospital contacts per year in Denmark [4]. Hence, the burden of IHD and HF remains substantial with a need to prevent recurrence of IHD events and readmissions due to worsening of HF and improve the health-related quality of life (HRQL) of patients.

Cardiac rehabilitation (CR) is known to reduce CVD mortality, morbidity and improve HRQL by promoting a healthy lifestyle and decreasing cardiac risk factors [5–7]. Thus, CR is recommended in national and international clinical guidelines as an integral part of the management of secondary prevention in IHD and HF patients [8,9].

However, adherence to CR remains suboptimal [10]. Studies consistently report a 20% drop-out during CR [11] and that <50% of the patients maintain an exercise regimen six month after completion of CR [12]. Risk factors for poor adherence include: low illness

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perception, HF (due to poor functional capacity), distance from home to the CR unit, financial and work constraints, female gender, older age, low socioeconomic status, and depression [11–16]. By promoting adherence to CR the effectiveness of CR is likely to be increased [17].

Only a few interventions have been demonstrated to improve adherence in CR: self-monitoring of physical activity, action planning, goal setting, peer modelling, and tailored counselling [17]. Consequently, there is still a need to develop strategies to promote adherence in CR and to assess these new interventions using a robust experimental design [17].

Learning and coping strategies (LC) is a new patient education method that potentially could improve adherence in CR utilising some of the interventions mentioned above as well as addressing the patients' illness perception [18]. LC strategies build on situational, reflective and inductive teaching with a high involvement of the participants and include individual clarifying interviews and health professionals plan, teach and evaluate the CR program in cooperation with experienced patients [18]. The LC-REHAB trial was designed to assess the effectiveness of the addition of LC in CR on adherence, morbidity and mortality, HRQL and lifestyle- and risk factors [18]. The adherence results are reported in this paper.

1.2. Objectives

The aim of this randomised trial was to assess the effect of the addition of LC strategies on adherence in CR compared to standard CR alone. Primary outcomes were adherence to at least 75% of the training or education sessions. Secondary outcome was adherence defined as having completed the finishing bicycle exercise test performed after the eight-week CR program. The trial hypothesis was that adherence to CR would be higher with the addition of LC strategies to CR than CR alone.

2. Methods

The trial was reported and conducted according to the Consolidated Standards of Reporting Trials (CONSORT) extension for randomised trials of non-pharmacologic treatment [19].

2.1. Design

The trial was designed as an open randomised parallel group controlled trial in which patients were allocated to either the intervention (LC strategies in addition to standard CR) or to the control arm (standard CR). The patients were allocated in a 1:1 ratio stratified for hospital unit, patient gender and diagnosis (IHD or HF) in blocks of two to four using a web-based system that was implemented independently of the research team. The investigation was carried out in the three hospital units (Herning, Holstebro and Ringkøbing) at the Regional Hospital West Jutland in the Central Denmark Region. Full details of the trial design and interventions are described in the published study protocol [18].

2.2. Participants and implementation

Patients were recruited between 30th November 2010 and 20th December 2012. Patients were included if they were: aged above 18 years and referred for and motivated to participate in CR after hospitalisation with either a diagnosis of IHD (ICD-10 codes: I20 and I21) or HF (ICD-10-codes: I11.0, I13.0, I13.2, I42.0, I42.6-9, I50.0-3, and I50.8-9). Exclusion criteria included: acute coronary syndrome within five days, planned revascularisation, active peri-, myo-, or endocarditis, symptomatic and untreated valve disease, severe hypertension with blood pressure above 200/110 mm Hg, other severe cardiac or extra cardiac disease, dementia, participated within this trial previously, or assessed as having low compliance for undertaking full participation in either trial arms or for completing the trials outcomes. There were no changes to eligibility criteria after trial commencement.

The trial was carried out in agreement with the Declaration of Helsinki, version II and was approved by the Ethical Committee of Central Denmark Region (journal number 20100230). Trial information was sent by postal mail to eligible patients referred to CR. Written informed consent, randomisation and enrolment in the trial were performed by nurses or physiotherapists working in each CR unit within two weeks of discharge from hospital. Patients were allocated consecutively into the trial with a maximum of twelve patients included in each CR class. CR programs started the first workday after inclusion in the trial.

2.3. Interventions

Patients in both trial arms received a group-based CR program lasting eight weeks, with exercise training sessions three times a week and education once a week. Thus, a total of 24 exercise training and eight education sessions were planned for each patient [18]. The education topics as well as the training exercises in both arms were based on the Danish national guidelines for CR [9]. The education topics were the same in each arm but, the pedagogical approach differed between arms [18]. A finishing exercise bicycle test was performed following the eight-week CR program in both arms. Each CR class in both arms had a assigned team of nurse and physiotherapist throughout the eight-week program [18]. The CR program in each arm was performed at different times of the day in order to avoid patients in each arm seeing each other and the health professionals were designated to either the intervention or the control group throughout the trial.

2.3.1. Intervention arm

In addition to the above described program patients allocated to the LC arm received individual clarifying interviews before and after the eight-week group-based exercise training and education period [18]. The purpose of the initial interview was to help the patients to start a process clarifying their needs before CR to prepare them to learn how to cope with living with a chronic heart disease [18]. This interview also gave the health professionals awareness and insight into the individual patient's experiences that was addressed later in the group based sessions [18]. In the finishing interview, the patient and the health professional in partnership clarified what benefits the patient had got from CR and future strategies for coping with their chronic heart disease were discussed [18]. Experienced former CR patients participated as co-educators and narrators in all of the education sessions and in one exercise training session per week [18]. Each week, a one-hour evaluation meeting was held by the nurse, physiotherapist and experienced patient assigned to each specific LC class. This team discussed and reflected on the overall sessions and needs of the individual patients and they evaluated what went well and what went less successful [18]. Narratives told by the experienced patients that worked as good learning examples were identified and discussed so the health professionals could elaborate the narratives and make them generally applicable. Additionally, the team made plans for the following week's education and training sessions [18].

Before trial start, the health professionals and the experienced patients had completed a competence-education course in the LC strategies to be able to perform the intervention. LC strategies took a situational, reflective and inductive approach to education, by focusing on the individual patient's needs and concerns in relation to the relevant topic of the week rather than following a structured, pre-written slide show [18].

2.3.2. Control arm

Standard CR alone was the CR program that was formerly used in the hospital units. These education sessions were characterised by a structured deductive teaching approach using identical pre-written slide-shows in all three hospital units [18].

2.4. Outcomes

The primary outcomes were adherence to at least 75% of both the training or education sessions. This limit of 75% was set in accordance with recommendations for reducing mortality [5,17,20–22]. A secondary outcome of adherence to the CR program was defined as having performed the finishing bicycle exercise test after the CR program. Attendance to the specific sessions and completion of the finishing exercise test were registered by the health professionals at the CR settings and entered into dedicated trial databases.

Patient characteristics including age, gender, height and weight, diagnosis (IHD or HF), presence of diabetes, smoking and marital status, former participation in CR, depression, education level, and household income were collected at baseline. Presence of depression was assessed from the Major Depression Inventory (MDI) [23]. Patients' education level was coded into eight education levels via the Danish Education Nomenclature (DUN); a Danish version of UNESCO'S ISCED classification and merged into three levels, i.e. 0–3: 'low', 4–5: 'medium' or 6–8: 'high' [24,25]. Household income was classified as 'low': <250.000 Danish kroner (DKK)/year, 'medium': 250.000 to 699.999 DKK/year or 'high': >700.000 DKK/year. The mean value of one Danish person's gross income in 2012 was 292.200 DKK [26]. All trial outcomes were assessed by CR health professionals, except depression, level of education and household income which were self-completed by questionnaires at the baseline visit.

Missing data for any of these variables were identified and data were entered, when possible after manually reviewing the patients' medical records. A flow diagram was constructed containing: known number of people over 18 years living in the uptake area of Regional Hospital West Jutland assessed from Statistics Denmark in the median quarter of the recruitment period [27] and the target group of IHD and HF patients assessed to require CR in the three hospital units estimated in the Disease Management Program for Cardiovascular Diseases, Central Denmark Region [20].

2.5. Sample size

Assuming 80% of patients in the control arm adhered to 75% CR training and education sessions, 825 patients allowed us to detect an absolute difference in adherence between the intervention and the control arms of 10% at 90% power and an alpha of 5%.

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