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Self-management education for rehabilitation inpatients: A cluster-randomized controlled trial

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ABSTRACT

Objective: To evaluate generic self-management modules (SelMa) as an adjunct to disease-specific educational programs during inpatient medical rehabilitation.
Methods: A bi-center cluster-randomized controlled trial with 698 patients with coronary artery disease, metabolic syndrome, or inflammatory bowel disease was conducted. We compared two versions of SelMa, a group with 3 h or a lecture with 1 h, respectively, in addition to disease-related patient education, to usual care (only disease-related education). SelMa aims at providing skills that may help implementing health behavior. The primary outcomes were goal setting and behavior planning at discharge and goal attainment and health behavior at 6- and 12-months follow-up. Secondary outcomes included motivation, knowledge and self-management competences.
Results: At discharge, SelMa group, but not SelMa lecture, proved superior to usual care regarding goal setting ($p = 0.007$, $d = 0.26$), but not behavior planning ($p = 0.37$, $d = 0.09$). Significant effects were also observed on several secondary outcomes. At later follow-up, however, no effects on primary outcomes emerged. Participants' satisfaction was higher in the group than the lecture format.
Conclusions: These short modules did not succeed in improving self-management skills in the long-term.
Practice implications: A self-management group may foster self-management skills in short term. Interventions should be developed to increase sustainability of effects.

1. Introduction

Patient education conveyed by disease-specific self-management programs are targeting disease-related knowledge, self-management skills and health behavior to reduce the impact of disease and foster health-related quality of life [1,2]. Self-management requires a dynamic and continuous process of self-regulation performed by the individual deemed responsible for his/her health management [1,3]. Self-management patient education comprises a number of behavior change approaches, such as providing information, encouragement, and skill training enabling patients to take an active role in their treatment [2]. Behavior change techniques with regard to changing health behavior have been systematized by Michie and Colleagues [4]. Systematic reviews and meta-analyses provide evidence for the effectiveness of self-management programs, but the effects vary depending on conditions and outcomes [5–9]. Due to the diversity of included interventions, information on the most effective means of delivery, educational approaches and techniques is incomplete.

In Germany, patient education is a mandatory part of (inpatient) medical rehabilitation for patients with chronic somatic diseases. Previous trials showed the superior efficacy of interactive patient-centered disease-specific group programs with regard to illness-knowledge and self-management outcomes [10–12]. Furthermore, theory-based interventions addressing self-regulatory variables, like planning, showed favorable effects on physical activity [13–15]. Additionally, plan enactment, a significant proximal outcome, was positively associated with later physical activity [16]. However, many programs are still predominantly providing knowledge or disease-related skills and lack a strong focus on behavior change techniques to foster health behavior change maintained after inpatient rehabilitation. Moreover, many

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programs are lecture based, provided in larger group settings and lack patient-oriented didactics [17]. Generic self-management modules promoting general self-management skills for taking action regardless of any specific disease and addressing self-tailored health behavior goals are not available so far. We therefore developed such generic self-management modules (SelMa) for use in inpatient rehabilitation. In the realm of health behavior change, we used evidence-based effective techniques [18,19], self-tailoring [3] and the Health Action Process Approach [20,21] as a theoretical framework. In consideration of applicability in routine care, we developed two SelMa interventions: a group program and a single lecture.

In this study, we evaluated the effects of both interventions employed in addition to disease-specific patient education as compared with usual care in inpatient rehabilitation. Usual care includes disease-specific patient education, among others. We hypothesized that the SelMa interventions are superior to usual care regarding goal setting and planning in short-term, as well as goal attainment and health behavior in medium-/long-term (primary outcomes). In addition, we expected superior effectiveness of the new interventions regarding motivation, knowledge and several self-management competences (secondary outcomes). We also explored differences in intervention satisfaction between the two self-management interventions.

2. Methods

2.1. Design and procedure

This study was a bi-center cluster-randomized controlled trial in inpatient rehabilitation centers in Germany. Clusters were patient education groups that comprise patients recruited within one week after commencement of inpatient rehabilitation. Clusters were randomly assigned to the three study groups using a computer-generated list of random numbers. Randomization was performed by a scientific assistant at the university research institute (central randomization per phone) guarantying allocation concealment until a cluster had been recruited. Data were assessed at admission (t1) and three follow-up occasions, including discharge (t2), and after 6 (t3) and 12 months (t4), using self-report questionnaires. Sample size was powered to detect small to medium effects in the primary outcomes ($d = 0.3$, 2-sided $\alpha = 0.05$, $1\text{-}\beta = .80$). Thus, 176 persons were required in each study group. Accounting for clustering, a design effect of 1.14 was assumed, resulting in a necessary overall sample size of 600 patients. The trial conformed to the Declaration of Helsinki and was approved by the Ethics Committee of the Faculty of Medicine, University of Würzburg.

2.2. Participants

Eligibility criteria for participants were a diagnosis of inflammatory bowel disease (ICD-10: K50, K51) in one center, and a diagnosis of coronary heart disease (ICD-10: I20-I25, Z95.1, Z95.5) or metabolic syndrome in the second cardiac rehabilitation center. Exclusion criteria comprised age <18 or >70 years, inadequate German language ability, severe co-morbid psychiatric disorder, and severe cognitive, visual or hearing impairment.

Patients were consecutively recruited between March 2014 and July 2015; one-year follow-up was completed in August 2016. Fig. 1 shows the study flow. A total of 1361 patients fulfilling the inclusion criteria were identified at the beginning of rehabilitation and asked to participate. Of those, 738 signed the informed consent form, were allocated to a cluster and randomly assigned to a study

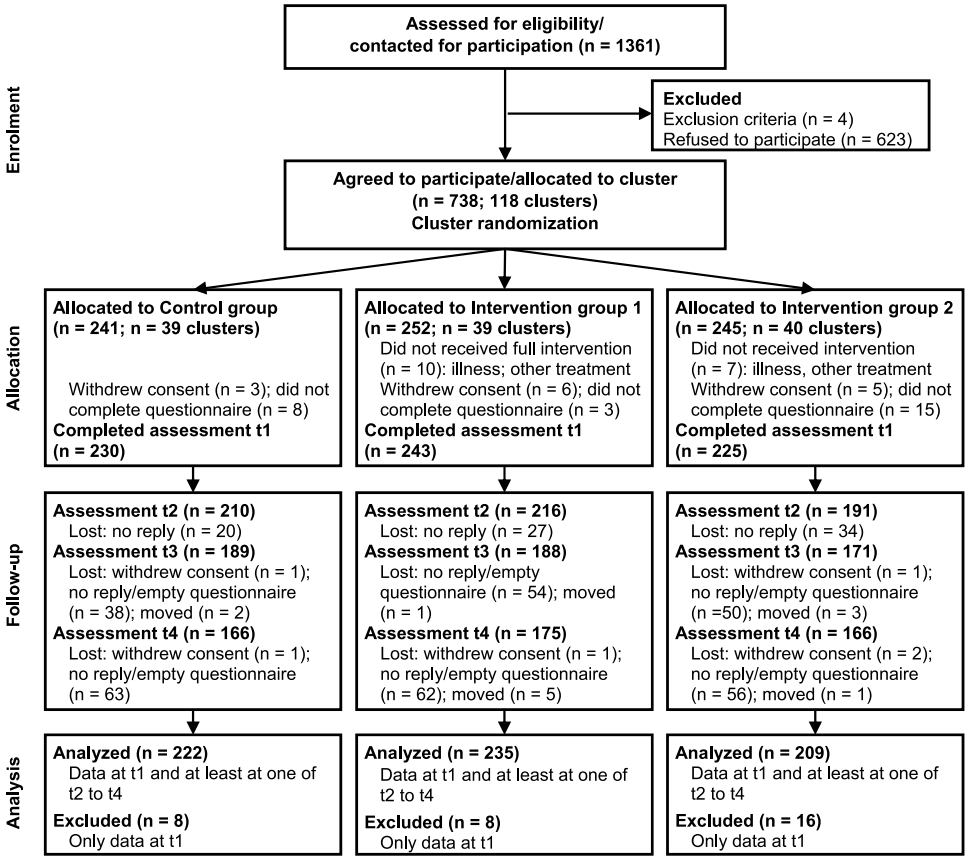

Fig. 1. Patient flow.

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