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Person-centred care after acute coronary syndrome, from hospital to primary care — A randomised controlled trial☆,★

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ABSTRACT

Aim: To evaluate if person-centred care can improve self-efficacy and facilitate return to work or prior activity level in patients after an event of acute coronary syndrome.
Method: 199 patients with acute coronary syndrome <75 years were randomly assigned to person-centred care intervention or treatment as usual and followed for 6 months. In the intervention group a person-centred care process was added to treatment as usual, emphasising the patient as a partner in care. Care was co-created in collaboration between patients, physicians, registered nurses and other health care professionals and documented in a health plan. A team-based partnership across three health care levels included transparent knowledge about the disease and medical state to achieve agreed goals during recovery. Main outcome measure was a composite score of changes in general self-efficacy ≥5 units, return to work or prior activity level and re-hospitalisation or death.
Results: The composite score showed that more patients (22.3%, n = 21) improved in the intervention group at 6 months compared to the control group (9.5%, n = 10) (odds ratio, 2.7; 95% confidence interval: 1.2–6.2; P = 0.015). The effect was driven by improved self-efficacy ≥5 units in the intervention group. Overall general self-efficacy improved significantly more in the intervention group compared with the control group (P = 0.026). There was no difference between groups on re-hospitalisation or death, return to work or prior activity level.
Conclusion: A person-centred care approach emphasising the partnership between patients and health care professionals throughout the care chain improves general self-efficacy without causing worsening clinical events.

1. Introduction

Acute coronary syndrome (ACS) is one of the most common conditions in Western countries. Mortality rates after an ACS event have declined in recent decades owing largely to reductions in incidence and case-fatality rates [1] and radically improved and refined methods for the acute treatment of people with ACS. Still the recovery period among ACS survivors remains problematic. Patients report symptoms after discharge from hospital [2] and return to work and everyday life is hampered by several factors beyond the cardiovascular condition, such as social aspects and co-morbidity [3]. In Sweden, sick-leave and re-admission rates after a myocardial infarction have declined during recent years. Nevertheless, in 2013 approximately 30% of patients with an ACS were still on sick leave up to 10 weeks after the cardiac event and 15% were readmitted to hospital during the following year [4].

Treatment during the acute event and in the recovery phase after an ACS has a focus on the medical condition with assessment of the coronary disease and pharmacological therapy driven by health care professionals. There is growing evidence that patients, who are actively involved in their own care, receive effective treatments, self-management support and regular follow-up in coordinated systems, report better outcomes and satisfaction with their care [5,6].

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.
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Person-centred care (PCC) has been identified as a core component for sustainable, high quality health care [7,8]. Although there is currently no consensus definition of PCC it is generally recognised that the focus of care is on the patient as a person rather than on the disease alone. An approach to PCC has been operationalised and tested by the Gothenburg Centre for Person-Centred Care (GPCC) [9,10]. In this approach (henceforth gPCC) the patient narrative is the point of departure, which forms the basis for a partnership between the patient and health care professionals, which in turn is formalised, documented and implemented in a jointly developed gPCC plan [9]. Congruent with the principles of shared decision-making, a fundamental aim of the gPCC approach is to engage and empower patients as active partners in their care. Self-efficacy, defined as a person's belief that he/she is able to successfully execute behaviours necessary to achieve desired goals [11], has been proposed as a central concept in gPCC [12]. Increasing self-efficacy and active patient involvement are decisive factors to improve outcomes [12,13]. To date, we have evaluated gPCC in in-hospital setting, showing that the approach is effective in reducing length of hospital stay [10] and uncertainty in illness [14]. The purpose of this study was therefore to assess the potential added benefits of gPCC, over conventional care, applied at all links in the chain of health care – from hospital, to outpatient and primary care – in terms of improved self-efficacy and return to work or prior activity level 6 months after an acute coronary event.

2. Methods

2.1. Study design

We conducted a multicentre randomised parallel-group, controlled intervention study which assessed six-month outcomes of treatment as usual versus gPCC added to treatment as usual performed at three health care levels (hospital, outpatient and primary care). Randomisation was based on a computer-generated list, stratified for hospital site and employment status, and performed via opaque, sealed and numbered envelopes. The Regional Ethical Review Board approved the study (DNr 275-11) and the investigation conforms to the principles outlined in the Declaration of Helsinki.

2.2. Setting

Patients were enrolled at two hospital sites within the Sahlgrenska University Hospital, Gothenburg, Sweden between June 2011 and February 2014. After hospital discharge follow-up was performed first at an outpatient cardiac clinic and subsequently at public primary care centres in the greater metropolitan area of Gothenburg (n = 43). Five of these centres had designated gPCC professionals who worked exclusively with patients as a team in the gPCC intervention group. These centres were selected to provide good geographical coverage within the area.

2.3. Patients

Patients admitted to the designated wards were screened consecutively. Patients were considered eligible if they were provisionally diagnosed with ACS (ICD = I200, I209 or I21) within a 72-hour period after hospital admission. The time interval was imposed to ensure that the intervention could be initiated as early as possible during hospital stay. Exclusion criteria were: ≥75 years, currently listed at a private primary care centre or at a primary care centre in another region, no permanent address, planned heart surgery such as coronary artery bypass grafting (CABG), cognitive impairment, alcohol and/or drug abuse, survival expectancy less than one year or participating in a conflicting study. All eligible patients willing to participate were included in the study. After randomisation, additional exclusion criteria were misdiagnosed as ACS and anticipated extended hospital stay >14 days (e.g. CABG). All patients received oral and written information about the study and gave written consent to participate.

2.4. Control group

Patients enrolled to the control group were managed according to treatment as usual which followed guideline-directed care [15]. After hospital discharge patients underwent two standard individual cardiac check-ups at an out-patient cardiac clinic, one led by a registered nurse (RN) after two-three weeks and one by a physician after four-six weeks, where they were given advice and informed about the condition. When the patients were assessed as medically stable, they were referred to their regular primary care centre where medication and rehabilitation was planned by the primary care physician and, where appropriate, with other health care professionals (e.g. RN, physiotherapist). Medical referrals and discharge notes were shared by health care professionals at the units but not necessarily with patients.

2.5. Intervention group

The intervention group was also medically managed according to guideline-directed care [15], however, care planning and decision-making were performed collaboratively by patients and health care professionals according to the gPCC approach [9]. Follow-up at an outpatient cardiac clinic was conducted after three to five weeks by specially trained gPCC professionals consisting of a physician and RN. When the patient and the gPCC professionals agreed as a team (gPCC team) that the patient's clinical situation was stable, the patient was assigned to the gPCC professionals at the designated primary care centre located closest to their homes about four weeks thereafter.

All gPCC professionals had received training in the theory and practice of gPCC [9,10] through lectures, seminars and workshops and were given practice in how to formulate and execute gPCC plans. Training emphasised the importance of seeing the patient as a person with needs as well as resources and of a person-centred dialogue as a basis for engaging patients as actively involved partners in their own care. Four three-hour booster sessions with tutoring and case examples were provided during the study period to ensure adherence to the gPCC approach. In the gPCC-intervention group the partnership (initiating, working, safeguarding and maintaining the partnership) between the patient and health care professionals [9] was emphasised at all three health care levels (i.e. hospital, outpatient and primary care) which is described in detail below and in Fig. 1.

2.5.1. Hospital stay

2.5.1.1. Initiating the partnership. The point of departure in the gPCC approach was a structured patient narrative. The narrative was derived in a meeting with an RN held within 24 h after randomisation in which patients were asked to recount their expectations, preferences and goals for treatment along with their own capabilities for and limitations to achieving those goals. The narrative was discussed in a meeting between the patient, RN and physician with the aim to co-create a preliminary gPCC plan integrating the patient's values, expectations and goals with medical expertise and to identify possibilities and barriers to recovery after ACS.

2.5.1.2. Working the partnership. Within 48 h after randomisation, the patient, physician and RN met again to review and to come to a joint agreement on the content of the gPCC plan. The plan was signed by the patient and health care professionals. In addition to patients' medical status, the gPCC plan included information on personal capacities (e.g. motivation), description of the goals and measures

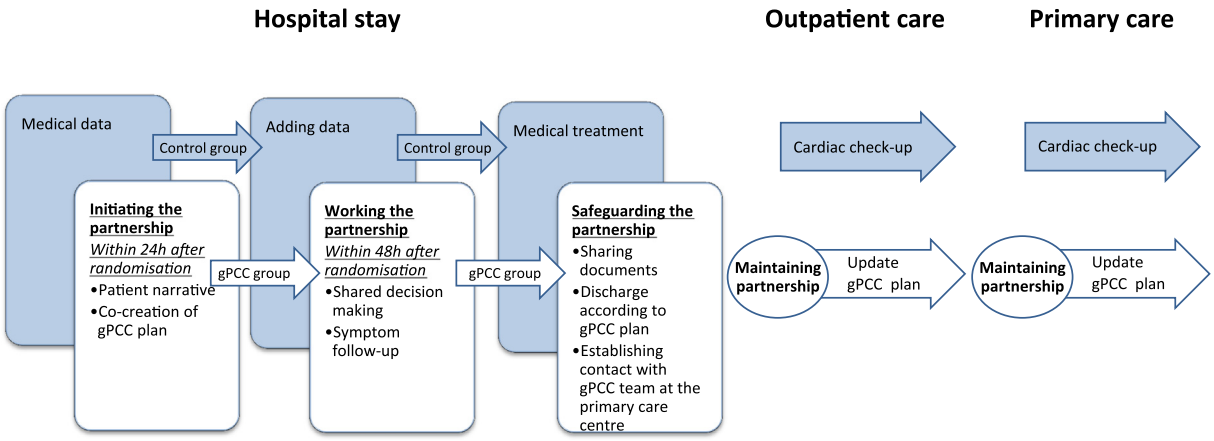

Fig. 1. The care chain for control and intervention. Both groups received the content in the blue area (treatment as usual). The Gothenburg University Person Centred Care (gPCC) components (white area) were added to treatment as usual in the intervention group. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

needed to accomplish them, categories of health care professionals required, projected day of discharge, site, schedule and objectives for outpatient and primary care follow-up visits. Patients' self-reports of symptoms were collected every 48 h during the hospital stay and symptom trends were incorporated into the ongoing dialogue within the gPCC team.

2.5.1.3. Safeguarding the partnership. Both patient and the health care professionals had access to the gPCC plan, which they could discuss and revise together if necessary. To assure transparency, standard medical and nursing discharge notes were shared with the patient. At discharge from hospital a condensed version of the gPCC plan was enclosed in the referral and sent along with all patient documents to the gPCC professionals at the outpatient clinic and subsequently to the primary care centre.

2.5.2. Outpatient care

2.5.2.1. Maintaining the partnership. About four weeks after discharge from hospital the patient met a physician and a RN in a team visit at the out-patient clinic. At the visit, the gPCC plan was reviewed, discussed and revised if necessary and served as a platform for discussing the patient's general condition. If the gPCC team decided that the patient's medical condition was stable, the patient was referred to one of the five designated gPCC primary care centres.

2.5.3. Primary care

2.5.3.1. Maintaining the partnership. A gPCC professional at the primary care centre contacted the patients directly after hospital discharge to confirm their assignment to the team, to set a date for the first visit, and to inform them that they could contact the team if needed before the visit. About eight weeks after the indexed discharge from hospital, the patient met the specialised gPCC professionals (physician and RN) at the dedicated primary care centre. The goals outlined in the patient's gPCC plan were assessed and, when required, were modified, e.g. goals were divided into several sub-goals to be achieved stepwise, or new goals were set. Personal resources, support from family and friends, and additional profession expertise, e.g. physiotherapy, that could potentially contribute to the realisation of goals were identified. Symptoms were also followed up. For example, if sleep disorders and/or anxiety were reported previously, strategies for managing these were discussed during the gPCC visit. The patient had access to the gPCC plan throughout the study period and could discuss it with the team. Additional gPCC team meetings were scheduled (but not necessarily) if suggested by either the patient or the health care professional.

2.6. Outcome variables

2.6.1. Instruments and follow-up periods

General Self-Efficacy Scale (GSE scale) is a 10-item self-assessment questionnaire designed to measure a broad and stable sense of personal competence to deal effectively with a variety of stressful situations [16], e.g. dealing efficiently with unexpected events, handling unforeseen situations, and finding solutions to problems. Ratings are made on a 4-point scale (1 = not at all true, 2 = hardly true, 3 = moderately true, 4 = exactly true) and are summed to a total score ranging from 10 to 40, where higher scores indicate greater self-efficacy [16]. The scale has been validated in several languages and is widely used internationally [17]. An increase of 4.6 units in the GSE scale has been applied in a previous study as a threshold for minimal important difference [18]. For the present study 5 units was considered a clinically important difference.

Saltin Grimby Physical Activity Level Scale (SGPALS) is a validated measure of self-reported physical activity. It comprises a single question which is rated against a 4-point scale (1 = sedentary, 2 = moderate, 3 = demanding 4 = strenuous) [19]. The SGPALS has been related to CVD risk factors [20].

Questionnaires were completed by patients at baseline in hospital and at four, eight and 24 weeks per post.

2.7. Primary endpoint

The primary efficacy endpoint was a composite of changes in general self-efficacy, return to work or prior activity level and re-hospitalisation or death as proposed by Packer [21]. Each patient was classified as improved, deteriorated or unchanged. A patient was classified as deteriorated if any of the following occurred:

- at 6 months, general self-efficacy had decreased by ≥5 units or,
- re-admission for unscheduled cardiovascular reasons or death.

A patient was classified as improved if:

- at 6 months, general self-efficacy increased by ≥5 units and
- no re-admission for unscheduled cardiovascular reasons and,
- had returned to work (yes or no) or improved in physical activity by the SGPALS, (improve from step 1 to 2 or unchanged/improved from step 2–4)

Those who had neither deteriorated nor improved were considered unchanged. Patients were dichotomised into improved versus deteriorated/unchanged.

2.8. Sample size

It was estimated that 91 patients per treatment arm would be needed to achieve a power of 80% at a 5% significance level for detecting an improvement in the composite score from 20% in the control group to 40% in the intervention group. We aimed to include 110 patients in each group to allow for withdrawals.

2.9. Statistical analysis

Descriptive statistics were used to characterise the study groups. Between group differences were tested using Fisher's exact test for dichotomous variables and the Mann–Whitney U test was used for continuous variables. Logistic regression was used to calculate odds ratio with 95% confidence interval. All statistical tests were two-sided with a significance level of $P \leq 0.05$. The data were analysed using SPSS version 22 [22].

3. Results

The trial profile is shown in Fig. 2. In total, 3982 patients were screened for study enrolment. Of the 445 who met eligibility criteria, 193 declined to participate. Hence, 252 were randomly assigned to the two treatment arms. According to protocol 45 patients were later excluded and 8 patients withdrew. Mean age was 60.9 years and most were men (72.4%). There was no significant difference concerning any baseline characteristics (Table 1). The study progressed according to plan except that one of the five gPCC professional groups changed jobs and had to be replaced; otherwise these were stable.

Table 1
Baseline characteristics.

	Control (n = 105)	Intervention (n = 94)
Age, years (mean(SD))	61.3(8.9)	60.5(9.3)
Female (%)	32(30.5)	23(24.5)
BMI (mean(SD))	28.6(5.0)	28.5(4.6)
General self-efficacy score (mean(SD))	30.3(5.6)	29.5(6.2)
Length of hospital stay (mean(SD))	4.34(2.7)	4.36(2.3)
Activity (%)		
Work	60(57.1)	54(57.4)
Retired	45(42.9)	40(42.6)
Indexed events (%)		
STEMI	24(22.9)	24(25.5)
NSTEMI	51(48.6)	38(40.4)
Unstable angina	30(28.5)	32(34.0)
PCI	83(79.0)	67(71.2)
Medical history (%)		
Previous MI	25(23.8)	23(24.5)
Previous angina	34(32.4)	28(29.8)
Previous PCI	29(27.6)	26(27.7)
Hypertension	58(55.8)	50(53.2)
CABG	14(13.3)	13(13.8)
Stroke	4(3.8)	5(5.3)
Diabetes	27(25.7)	23(24.5)
ICD	2(1.9)	0(0)
Pacemaker	2(1.9)	1(1.1)
Current or previous smoker (%)	61(58.1)	57(60.6)

BMI = body mass index; STEMI = ST elevation myocardial infarction; NSTEMI = non-ST elevation myocardial infarction; MI = myocardial infarction; PCI = percutaneous coronary intervention; CABG = coronary artery bypass grafting; ICD = implantable cardioverter defibrillator.

3.1. Effects

The composite score showed that more patients improved in the gPCC intervention group compared to the control group at six months (22.3%, n = 21 versus 9.5%, n = 10; odds ratio = 2.7, 95% confidence interval: 1.2–6.2; P = 0.015). This effect was driven by the fact that more individuals had an improvement in general self-efficacy ≥5 units in the gPCC group (Table 2). The mean improvement in general self-efficacy was significantly higher in the intervention group compared with the control group (P = 0.026). Moreover, 48.3% (n = 42) of the gPCC group compared with 31.6% (n = 31) of the control group improved more than 1.5 units (mean difference between groups) on the GSE scale (P = 0.024) (Fig. 3). There were 18 events (4 deaths, 14 re-admitted) in the intervention group and 16 events in the control group (2 deaths, 14 re-admitted). At 6 months 88.5% of the intervention group compared

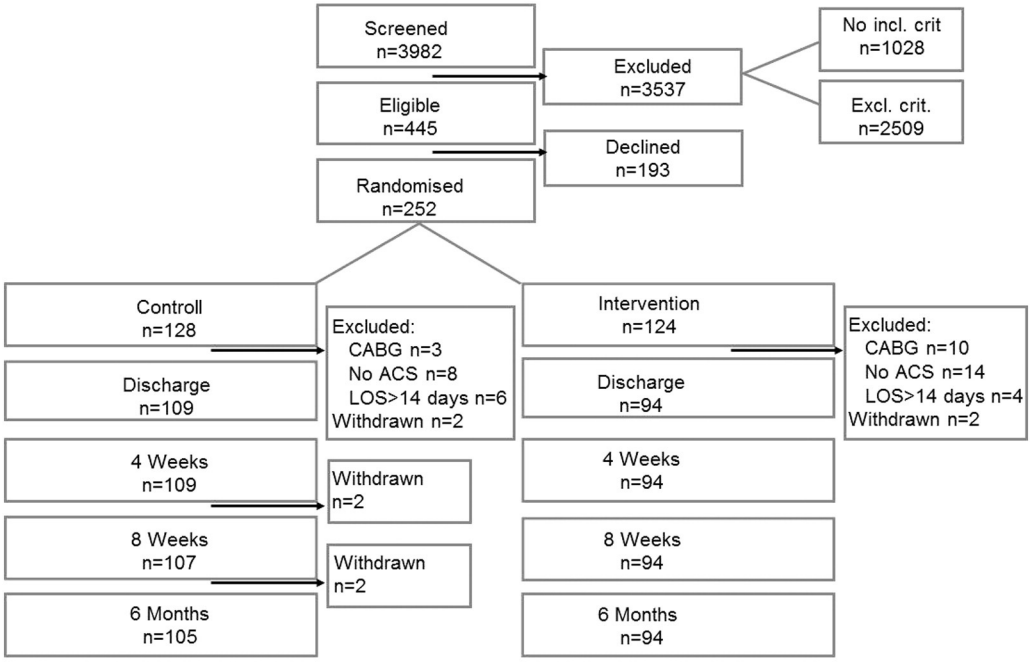

Fig. 2. Trial profile.

with 90.8% of the control group had returned to work or prior activity level. Of those working prior to the indexed event, 91.5% (n = 43) in the intervention group versus 81.1% (n = 43) in the control group had returned to work at 4 weeks (P = 0.16). After 8 weeks the corresponding proportions were 91.8% (n = 45) and 83% (n = 39), respectively (P = 0.23).

4. Discussion

This multicentre randomised controlled trial in patients with ACS showed that at six-month follow-up significantly more patients had improved after an intervention adding gPCC care to guideline-directed care than after guideline-directed care alone. Our study, performed mainly in primary care after discharge from hospital, thus adds to and extends existing evidence affirming the benefits of gPCC in reducing length of hospital stay in patients with hip-fractures [23], hip-replacement [24] and chronic heart failure [10], as well as in decreasing patients' uncertainty about chronic heart failure and its treatment [14] and in improving their quality of life [25].

Improvement was conservatively defined as a composite of clinically significant improvement in self-efficacy combined with any important worsening which could have resulted in re-admission and impaired return to work or prior physical activity level. The rationale for such an endpoint is the value of combining patient experience and clinical outcomes [21]. In our study, treatment outcome was primarily driven by clinically important improvements in self-efficacy, which were significantly more pronounced in the gPCC group. Self-efficacy is defined as a person's confidence in his/her ability to execute behaviours necessary to produce desired outcomes [11]. It has been shown to be significantly associated with lower health care utilisation and health care costs [26]; better attendance in cardiac rehabilitation [27] and exercise training programmes [28]; increased concordance to medication, diet and physical activity regimens as well as better stress management [29]; and is a predictor of future health status [13].

Self-efficacy is also considered a key concept in effective illness self-management in primary care [13,30]. Although the value of secondary prevention programmes during ACS recovery is well documented [31], adherence to medical regimens [32] and lifestyle recommendations remains poor [33,34]; attendance in cardiac rehabilitation is low [35]; and systematic follow-up is fragmented [36]. A vital aspect of secondary prevention is to give patients support in their efforts to self-manage their condition. The Institute of Medicine defines self-management support as “the systematic provision of education and supportive interventions by health care staff to increase patients' skills and confidence in managing their health problems” [37]. Critical to successful self-management is thus that patients not only understand why and how to perform self-management behaviours [38], but that they also feel confident in their ability to carry them out, i.e. self-efficacy [30]. The gPCC approach extends the concept of self-management to one where patients work together as partners with health care professionals — through supportive partnerships patients gain confidence in their own ability to manage their condition. The overriding aim of gPCC is to empower patients in matters related to their health and to engage them as active partners in their care. Hence, a primary goal is to improve patients' self-efficacy in order to reinforce their role and involvement in care partnerships with health care professionals. This in turn we believe ultimately leads to better disease control, better patient outcomes and reduced health care utilisation, particularly avertible emergency room visits and hospitalisations. Our results showed that the gPCC approach was effective in improving self-efficacy; nonetheless, we did not find corresponding improvements in more distal outcomes comprising the composite, i.e. reduced sick leave or readmission rates. Longer term studies are needed to reliably assess the effects of gPCC in relation to such outcomes. Nonetheless, a considerably larger proportion of employed gPCC patients than controls had returned to work by four weeks (91.5% vs 81.1%) and by eight weeks the figures were 91.8% of the gPCC patients and 83% of the controls, indicating a tendency for gPCC to hasten return to work. By comparison, according to 2013 statistics from the Swedish national heart register, SWEDEHEART, 70% of patients return to work by 6-10 weeks after an event of myocardial infarction [4]. That hospital readmission rates did not differ which may owe to the fact that we did not distinguish preventable from non-preventable admission. Previous open randomised controlled studies assessing complex interventions suggest that adherence to guideline-directed care increases, which may explain why the usual care group also returned to work earlier than could be expected from national statistics [39].

Rehabilitation after a cardiac event is complex and multifaceted and it is thus difficult to ascertain if observed intervention effects owe to a single component or a group of components [35]. Likewise, it is difficult to differentiate which components of gPCC contributed most to improved self-efficacy. Nevertheless, we believe that the core and most active component of gPCC is the patient–health care professional partnership, which is initiated through the patient narrative where the patient becomes a person with capabilities, goals and preferences. The partnership is strengthened through collaborative decision-making and maintained and guided by a co-created gPCC plan [9].

Table 2
Primary endpoint.

	Control n = 105	Intervention n = 94	
	6 months	6 months	
Composite score			P-value 0.018[a]
Improved n(%)	10(9.5)	21(22.3)	
Unchanged n(%)	65(61.9)	47(50.0)	
Deteriorated n(%)	30(28.6)	26(27.7)	

[a] Composite score dichotomised into improved versus deteriorated/unchanged.

5. Study limitations

There are several limitations to our study. Our designation of five GSE units as a clinical important difference derives from previous research in HIV and may not be valid in ACS. Our study was powered to detect differences in relation to our composite outcome variable, not in relation to its constituent variables. Larger sample sizes are needed to perform reliable sub-analyses of clinical events [40] and return to work was analysed in only a subset of patients, which may explain why no significant differences were found on either of these variables. We excluded patients who were 75 years or older, had a life expectancy less than one year, were scheduled for heart surgery (e.g. CABG) or longer hospital stays (>14 days), hence our patient sample may be biassed in favour of healthier patients with ACS.

6. Conclusions

In conclusion, we found that the gPCC approach improved patients' self-efficacy without causing worsening clinical events. Our findings emphasise the importance of establishing a partnership where patients, physicians, RNs and other health care professionals collaborate as a team through a co-created gPCC plan that is initiated in-hospital and formalised and maintained in primary care.

Contributors

All authors designed the study, formulated the research questions and developed the person-centred intervention. AF and IE drafted the manuscript. CT, AW and KS critically revised and edited the manuscript. All authors had input in revising and approved the final manuscript.

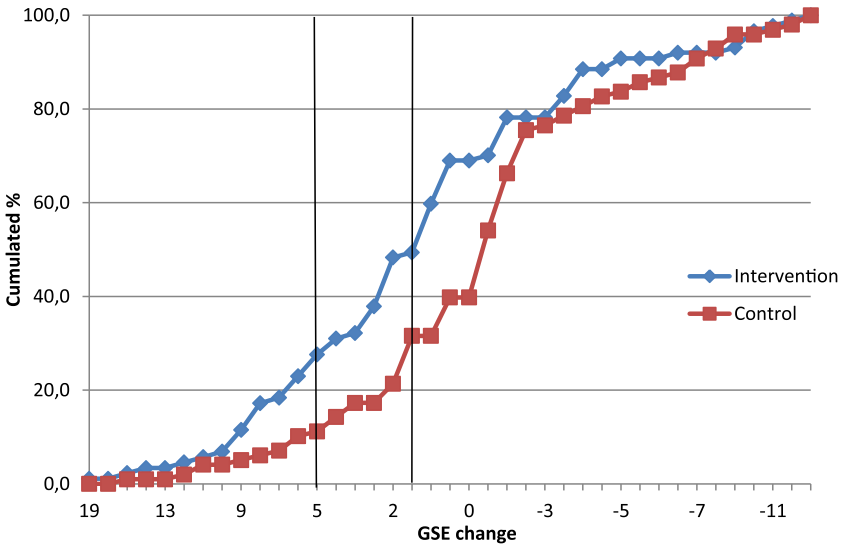

Fig. 3. Cumulative response curves showing individual change in general self-efficacy (GSE) from baseline to 6 months for the two treatment groups. The thresholds for clinical important difference (5 points) and the mean difference in the GSE score between groups (1.5 points) are illustrated by vertical lines.

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Ethical approval

This study was approved by the Regional Ethical Review Board at the University of Gothenburg, Sweden (DNr 275-11).

Conflict of interest

None.

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