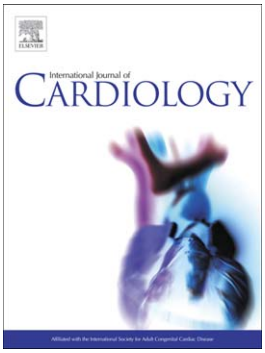
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Effects of person-centred care after an event of acute coronary syndrome: two-year follow-up of a randomised controlled trial

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Keywords: acute coronary syndrome; patient-centered care; person-centred care; randomised controlled trial; self-efficacy; cardiac rehabilitation

Conflicts of interest: none.

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Abstract

Aim: To assess the long-term effect of person-centred care (PCC) in patients with acute coronary syndrome (ACS).

Method: Patients with ACS were randomly assigned to treatment as usual (control group) or an added PCC intervention for six months. The primary endpoint was a composite score of changes in general self-efficacy ≥ five units, return to work or to a prior activity level and re-hospitalisation or death.

Results: The composite score improved in the PCC intervention group (n = 94) at a two-year follow-up compared with the control group (n = 105) (18.1%, n = 17 vs. 10.5%, n = 11; P = 0.127). In the per-protocol analysis (n = 183) the improvement was significant in favour of the PCC intervention (n = 78) compared with usual care (n = 105) (21.8%, n = 17 vs. 10.5%, n = 11; P = 0.039). This effect was driven by the finding that more patients in the PCC group improved their general self-efficacy score ≥ 5 units (32.2%, n = 19 vs. 17.3%, n = 14; P = 0.046). The composite score improvement was significantly higher in the PCC intervention group without post-secondary education (n = 33) in comparison with corresponding patients in the control group (n=50) (30.3%, n = 10 vs. 10.0%, n =5; P = 0.024).

Conclusion: Implementation of PCC results in sustained improvements in health outcome in patients with ACS. PCC can be incorporated into conventional cardiac prevention programmes to improve equity in uptake and patient health outcomes.

Trial registration: Swedish registry, Researchweb.org, ID NR 65 791

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1. Introduction

The mortality rate of coronary heart disease (CHD) has decreased over the past 20 years, where more than half of this positive trend is due to a reduction in cardiovascular risk factors [1]. Despite widespread recommendations about the value of secondary prevention, only a minority of the patients with CHD participate in cardiac rehabilitation programmes [2]. Non-attendance is particularly obvious in populations with low socioeconomic demographics who usually have higher risk levels at baseline and are less responsive to implement healthy lifestyle changes after a myocardial infarction [3]. As a result, the advantages of secondary prevention in terms of reduced mortality, morbidity and recurrence of cardiac events as well as increased quality of life (QoL) are absent for most of the patients [2, 4].

Secondary prevention programmes tailored to the individual have been shown to be effective in improving patients' modifiable risk factors (e.g., total cholesterol level, smoking, dietary habits and physical activity) [5, 6]. However, the effects are limited after completion of the interventions and long-term effects are rarely published. Redfern et al [7] reported from a randomised controlled study in which the intervention was based on a programme providing tailored management to reduce coronary risk factors. The four-year follow-up report showed improved changes in modifiable risk factors were maintained when compared with a control group [8]. The authors used an approach that builds on individual needs and preferences and collaborative goal setting has been considered as an attractive option [2].

Person-centred care (PCC) has been suggested as a core component for a sustainable care of high quality [9]. One definition of PCC has been tested and evaluated according to the Gothenburg PCC (gPCC) approach [10], which means to process and transfer a person-centred ethic into practice that highlights the importance of knowing the patient also as a person, a capable human being with resources and needs, in order to engage the person to be

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an active partner in his or her care and treatment. Interventions based on gPCC principles in patients with cardiovascular diseases have shown significant effects in patients with worsening chronic heart failure in terms of decreased length of hospital stay [11] and rehospitalisation [12] and in patients after hospitalisation for an acute coronary syndrome (ACS), a subsequent improved self-efficacy level [13]. A patient's self-efficacy, which is referred to in PCC, is vital during recovery for disease management [14] and impacts the capability to overcome setbacks and adversities. Owing to this, we performed a study that evaluated the effects of PCC after an event of ACS assessed by a composite score of changes comprising general self-efficacy, return to work or a previous activity level and re-hospitalisation or death. The six-month results showed that more patients in the PCC group had a significant clinical improvement in general self-efficacy combined with return to work or to a prior activity level without increasing the risk for clinical events compared with the control group [15]. The effects were most pronounced in patients with a lower education level [16]. Given these benefits after six-months, it is important to establish the long-term sustainability of the intervention. The aim of this study was therefore to determine the long-term effect of a PCC intervention and reassess the composite outcome after two years.

2. Methods

2.1 Study design

The present study is a two-year follow-up of a previously reported study, which was a two-armed, multicentre randomised controlled trial (RCT) investigating the effects of PCC along the transition of health care in patients diagnosed and treated for ACS [15]. The study was approved by the Regional Ethical Review Board (DNr 275-11) and conforms to the Declaration of Helsinki provisions.

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2.2 Setting and patients

Two hospital sites within the Sahlgrenska University Hospital, Gothenburg Sweden, outpatient cardiac clinics and all public primary care centres participated in the study. Five of these centres were selected to provide geographical coverage within the city and had designated health care professionals (physicians and registered nurses [RNs]) who cooperated with patients in teams (PCC team) in the intervention group. Patients were eligible for the study if they were < 75 years of age and with a provisional diagnosis of ACS (ICD=I200, I209 or I21) within 72 hours after admission to hospital. Patients were excluded from the study if they were not willing to participate in the study, currently listed at a private primary care centre, planned coronary artery bypass grafting (CABG) or other heart surgery, other ACSs (type 2-5), cognitive dysfunction, alcohol or drug abuse or a severe disease with expected survival less than one year. The recruitment process ran between June 2011 and February 2014, and after written informed consent to participate, 252 patients were randomised 1:1 to either a control group receiving usual care or a group receiving the PCC intervention added to usual care. After randomisation, 53 patients were excluded because of meeting additional exclusion criteria (not having ACS as the main discharge diagnosis, hospital stay exceeded 14 days and planned heart surgery (e.g., CABG)) and eight patients withdrew. Thus, the final sample comprised 199 patients (105 control, 94 intervention).

2.3 Control group and PCC intervention group

Patients in the control group were managed by usual care, which means standard care procedures according to national guidelines [17] throughout the continuum of care in the tertiary, secondary and primary care levels. The intervention, which has been described in detail elsewhere [15], is summarised briefly below.

In addition to usual care, the intervention group received PCC according to the gPCC framework, containing three routines for guiding of a PCC process to initiate, integrate and

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safeguard person-centred care in daily clinical practice [10]. The PCC teams were specially trained through lectures, seminars and workshops on how to apply the intervention. Moreover, booster sessions were held with the PCC teams during the study period to share experiences and maintain a continuing application of PCC. The first routine was to listen thoroughly to the patient's narrative to include his or her experience, resources and needs in the treatment and care process. The second routine focused on co-creation of goals and milestones agreed upon by both the patient (together with relatives if needed) and the health care professionals. The third routine safeguarded the care process by documentation of the PCC health plan, a shared document that comprised the patient's beliefs, resources and needs together with medical expertise. In the present study these routines were implemented and systematically followed-up throughout predefined milestones:

- A personal narrative that guided a jointly developed PCC health plan at the hospital within 48 hours after randomisation
- Scheduled to a follow-up meeting at four weeks post-discharge to a specially trained cardiologist and an RN at the outpatient clinic
- Assigned to and scheduled for a follow-up meeting within eight weeks to one of five designated primary care centre teams with a specially trained PCC team (general practitioner and RN)

2.4 Measures

The primary endpoint was a composite score of changes [18] as assessed by the combination of general self-efficacy, return to work or previous activity level and re-hospitalisation or death. The general self-efficacy scale [19] (GSE scale) is a 10-item psychometric scale that refers to the global confidence in a person's belief in the ability to successfully respond to challenges across a wide range of stressful life events (e.g., dealing efficiently with

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unexpected events, handling unforeseen situations and finding solutions to problems). Respondents are asked to rate their self-confidence on a four-point scale (1 = not at all true, 2 = barely true, 3 = moderately true, 4 = exactly true). The total score can range from 10–40. An improvement of 4.6 in the GSE scale is considered as a limit for a minimal clinically important difference [20]. The Saltin-Grimby Physical Activity Level Scale [21] is a validated self-reported measure of leisure time physical activity that was used by patients not working to determine return to prior activity level. Ratings are made on a four-point scale (1 = sedentary, 2 = moderate, 3 = demanding, 4 = strenuous). At 24 months post-discharge, each patient was classified as improved, unchanged or deteriorated. Improved corresponds to an increase in the GSE scale with ≥ five units, return to work or previous activity level (improved from step 1 or at least unchanged from step 2) and no re-admission for unscheduled cardiovascular reasons or death. Baseline characteristics include patients' highest level of education (none = 1, compulsory school = 2, secondary school = 3, vocational college = 4, or university = 5), which was dichotomised into those without post-secondary education (1-3) and those with post-secondary education (4-5).

2.5 Statistical analysis

Descriptive statistics was applied to characterise the study groups. Fischer's exact test was used to determine between group differences in baseline characteristics. Logistic regression was performed to estimate odds ratios for an improved composite score with 95% confidence intervals (CIs). All statistical tests were two-sided, conducted at a nominal 5% level of significance using SPSS version 23.

3. Results

No significant differences in baseline characteristics were observed (Table 1). The study continued as planned, except that at one of the five designated centres the trained PCC

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professionals changed jobs during the initial stages of the study period and were replaced with professionals lacking PCC training. Therefore, this centre was considered as non-adherent to the study protocol, and the patients in the PCC group assigned to this centre (n=13) were censored in the per-protocol analysis (PP analysis). In addition, patients who missed the primary care visit (n=3) were excluded in the PP analysis according to the predefined criteria in the study protocol. Consequently, the PP analysis included 78 patients from the PCC group and all patients in the control group (Figure 1).

3.1 Effects

The intention to treat analysis (ITT analysis) (n = 199) showed that a higher proportion of patients in the PCC group (n = 94) improved in the composite score compared with the control group (n = 105) at the 24-month follow-up (18.1%, n = 17 vs. 10.5%, n = 11; OR = 1.9, 95% CI: 0.8-4.3; P = 0.127). There were 28 events (six deaths, 22 re-admitted) in the PCC group and 30 events (five deaths, 25 re-admitted) in the control group. At 24 months, 91.0% of the PCC group, in comparison with 92.5% in the control group, had returned to work or to their previous activity level. More patients in the PCC group improved by ≥ five units on the GSE scale compared with the control group (27.1%, n =19 vs. 17.3%, n = 14; P = 0.169). In the PP analysis (n = 183) the improvement in the composite score was significantly higher in the PCC group than in the control group (21.8%, n = 17 vs. 10.5%, n = 11; OR = 2.4, 95% CI: 1.0-5.4; P = 0.039). This effect was driven by more patients in the PCC group who improved in the GSES by ≥ five units (32.2%, n = 19 vs. 17.3%, n = 14; P = 0.046) (Table 2).

In the group of patients with lower education (n = 90) a non-significant difference in the ITT analysis in favour of the PCC group (n = 40) vs. the control group (n = 50) was observed in the composite score (25.0%, n = 10 vs. 10.0 %, n = 5; OR = 3.0, 95% CI: 0.9-9.7; P = 0.065). The PP analysis yielded a significantly higher improvement in the composite score in the PCC group (n = 33) compared with the control group (n=50) (30.3%, n = 10 vs. 10.0 %, n =5; OR =

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3.9, 95% CI: 1.2-12.8; P = 0.024) (Table 3). No significant between-group differences were seen in the group of patients with higher education, either in the ITT or PP analysis.

4. Discussion

At the two-year follow-up of this RCT targeting patients after an event of ACS, we found that adding PCC to usual care in comparison with usual care alone resulted in a non-significant improvement in the primary endpoint. This improvement was more pronounced in patients with lower education, where the difference between groups was even more explicit (although non-significant). When the PCC intervention was fully adhered to according to the predefined study protocol, the PP analysis yielded a significant effect in the primary endpoint composite score in favour of the PCC group, which was particularly prominent in patients with lower educational levels. There were no differences between the two groups in the two-year readmission and death rates, nor were there differences in return to work. Significantly more patients improved ≥ five units in the GSE scale, a minimal clinically important difference [20], which is in line with the previously reported results at six months [15]. These results showed that full implementation of the gPCC framework provides long-term benefits extending to at least two years after the randomisation.

Long-term changes are seldom reported and usually stay with reporting risk factor outcomes at one year [4]. Effects of gPCC have been tested and evaluated in patients at several health care levels and conditions. For instance, in patients with chronic heart failure the results show that a fully implemented gPCC shortens hospital stay and maintains functional performance [11], reduces uncertainty [22], improves the discharge process [23] and is less costly than conventional care [24]. Other RCTs of gPCC have shown decreased re-hospitalisation and increased QoL [12], increased use of target doses of life-prolonging medication [25] and a significant cost reduction in patients with severe chronic heart failure [26]. gPCC emphasizes

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the patient´s own resources which helps identifying reasonable goals during recovery [27], and facilitates both formal and informal partnership which patients perceive as a sense of ease and security [28]. From the perspective of health care professionals, gPCC introduces a new practice by facilitating active patient participation in decisions about their care, as well as creating a more person-centred approach toward improved inter-professional teamwork [29]. This study extends previous findings and is, as far as we know, the first study showing two-year long-term effects of PCC.

Studies have demonstrated that the probability to improve patients' health status through behaviour change is low if the patients' self-efficacy were low, i.e. without a belief in their own ability to accomplish their goals and manage different situations effectively [14]. Our findings at a two-year follow-up show improved and sustained general self-efficacy levels, which have previously been associated with improvement in participation in cardiac rehabilitation programmes [30], concordance to drug therapy and related to lower health care use [31]. Even though self-efficacy has been shown to predict healthier lifestyle habits (e.g., a better diet, improved physical activity and better management of stress) [31] , when effects in terms of improved risk factor profiles have been reported [5-8], these often do not include patients' self-efficacy levels, which is why a causative relationship between a person's self-efficacy level and clinical outcomes remains unclear. Cardiac rehabilitation programmes are complex. Hence, the mechanisms through which positive effects are gained are hard to determine if they are due to a single factor or a combination of several factors [2]. Self-efficacy appears to be a crucial component to improve patients' clinical outcomes; therefore, interventions that improve a patient's self-efficacy level in relation to risk factors are warranted [31].

gPCC can influence self-efficacy in the sense that it builds on a person's own capabilities rather than simply trying to convince patients to comply to prescribed regimens and certain

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activities. gPCC aims to empower the patient as an active partner in his or her care through an innovative and collaborative partnership between patients and health care professionals [10]. Patient engagement, in turn, is likely to increase self-efficacy levels [14]. We suggest that the partnership between the patient and health care professional has been the most active component in the improvement of self-efficacy in our results. This reasoning is strengthened by the more prominent effects of the gPCC intervention observed in patients with low education, who often are disadvantaged by a more directive and less participatory consultation approach [32, 33]. The gPCC intervention is based on ethical principles and implies a shift away from a model in which the patient is a passive recipient of intervention that often focuses exclusively on the disease and driven by health care professionals to an approach in which a contractual agreement is formed involving the patient as an active partner in the care and decision-making process. In this trial PCC was practically applied using the gPCC framework, which enabled patients in the intervention group to influence and participate in their care and rehabilitation, regardless of socioeconomic status.

The gPCC intervention was planned jointly by the patient and health care professionals across three health care levels. The problem with non-adherence to the protocol at one of the primary care centres, where the newly installed team lacked both theoretical and practical knowledge of the gPCC education, suggests that gPCC is beyond and above usual care and not a quick fix and thus points towards the challenges of wide-ranging changes and implementation effects. Cardiac rehabilitation programmes are recognised as focusing on patients changing their behaviour based on current recommendations for their health status from a health care professional perspective. In Europe less than half of eligible patients choose to participate in such programmes [2]; in populations with low socioeconomic status these figures are even lower [30, 34]. Vulnerable patient groups are traditionally difficult to reach, which is alarming because negative lifestyle behaviours, such as smoking, use of alcohol and less exercise, are

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more typical in socioeconomic disadvantaged populations [3]. We suggest that implementation of a person-centred approach can reduce inequalities regarding uptake and health outcomes.

5.1 Study limitations

There are several limitations to our findings. First, we intended to investigate whether a gPCC approach could influence patients' general self-efficacy during their rehabilitation after an ACS, mainly performed in a primary care setting, without the need for major additional hospital care. Accordingly, as specified in the protocol, we excluded those patients who, after randomisation, needed longer hospital stay (>14 days) or more complicated interventions (e.g., CABG). Any effects of the gPCC intervention on those situations need to be addressed in future studies. Second, we excluded also patients who were ≥ 75 years, had a life expectancy less than one year and were scheduled for heart surgery. Thus, our patient sample may be biased in favour of healthier patients with ACS.

Our PP analysis is an exploratory attempt to study the effect of PCC in those patients who were exposed to such a care approach. The excluded patients were pre-defined in the protocol. The PP analysis is used in sensitivity analyses of non-inferiority trials as well as in interventional trials to analyse the actual impact or adverse effects of interventions (e.g., pharmaceutical agents) [35]. It cannot replace the ITT analysis but can, as in our study, be used as explorative and supportive.

6. Conclusion

These results suggest that a fully implemented gPCC implies long-term effects, particularly in patients with low socioeconomic status, as reflected in improved general self-efficacy combined with return to work or a previous activity level without jeopardising clinical outcomes.

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Contributors: All authors designed the study, formulated the research questions and developed the person-centred intervention. AF drafted the manuscript and performed the analysis. IE, KU, AW and KS critically revised and edited the manuscript. All authors approved the final manuscript.

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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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Table 1: Baseline characteristics

	Control (n=105)	Intervention (n=94)	Intervention (per-protocol) (n=78)
Age, years (mean(SD))	61.3(8.9)	60.5(9.3)	60.3(9.3)
Female(%)	32(30.5)	23(24.5)	17(21.8)
BMI (mean(SD))	28.6(5.0)	28.5(4.6)	28.7(4.6)
General self-efficacy score (mean(SD))	30.3(5.6)	29.5(6.2)	28.9(6.5)
Length of hospital stay (mean(SD))	4.34(2.7)	4.36(2.3)	4.38(2.3)
Activity(%)			
Work	60(57.1)	54(57.4)	47(60.3)
Retired	45(42.9)	40(42.6)	31(39.7)
Indexed events(%)			
STEMI	24(22.9)	24(25.5)	20(25.6)
NSTEMI	51(48.6)	38(40.4)	33(42.3)
Unstable angina	30(28.5)	32(34.0)	25(32.1)
PCI	83(79.0)	67(71.2)	57(73.1)
Medical history(%)			
Heredity	34(32.4)	26(27.7)	22(28.2)

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Previous MI	25(23.8)	23(24.5)	20(25.6)
Previous angina	34(32.4)	28(29.8)	22(28.2)
Previous PCI	29(27.6)	26(27.7)	21(26.9)
Hypertension	58(55.8)	50(53.2)	37(47.4)
CABG	14(13.3)	13(13.8)	10(12.8)
Stroke	4(3.8)	5(5.3)	4(5.1)
Diabetes	27(25.7)	23(24.5)	19(24.4)
ICD	2(1.9)	0(0)	0(0)
Pacemaker	2(1.9)	1(1.1)	1(1.3)
Current or previous smoker (%)	61(58.1)	57(60.6)	48(61.5)

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

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Table 2: Endpoint

	Interventio n	**Control**			
Intervention vs. control group (ITT analysis)	n=94	n=105			
Composite score			P-value	OR	CI
			0.127	1.887	.834-4.267
Improved n(%)	17(18.1)	11(10.5)			
Unchanged n(%)	39(41.5)	50(47.6)			
Deteriorated n(%)	38(40.4)	44(41.9)			
Intervention vs. control group (PP analysis)	n=78	n=105			
Composite score			P-value	OR	CI
			0.039*	2.382	1.045-5.429
Improved n(%)	17(21.8)	11(10.5)			
Unchanged n(%)	31(39.7)	50(47.6)			
Deteriorated n(%)	30(38.5)	44(41.9)			

*Composite score at 24 months dichotomised into improved vs. deteriorated/unchanged.

OR=odds ratio; CI=confidence interval

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Table 3: Endpoint – patients with a low educational level

	Intervention	**Control**			
Intervention vs. control group (ITT analysis)	n=40	n=50			
Composite score			P-value	OR	CI
			0.065	3.000	.932-9.653
Improved n(%)	10(25.0)	5(10.0)			
Unchanged n(%)	17(42.5)	23(46.0)			
Deteriorated n(%)	13(32.5)	22(44.0)			
Intervention vs. control group (PP analysis)	n=33	n=50			
Composite score			P-value	OR	CI
			0.024*	3.913	1.196-12.802
Improved n(%)	10(30.3)	5(10.0)			
Unchanged n(%)	14(42.4)	23(46.0)			
Deteriorated n(%)	9(27.3)	22(44.0)			

*Composite score at 24 months dichotomised into improved vs. deteriorated/unchanged. OR=odds ratio; CI=confidence interval

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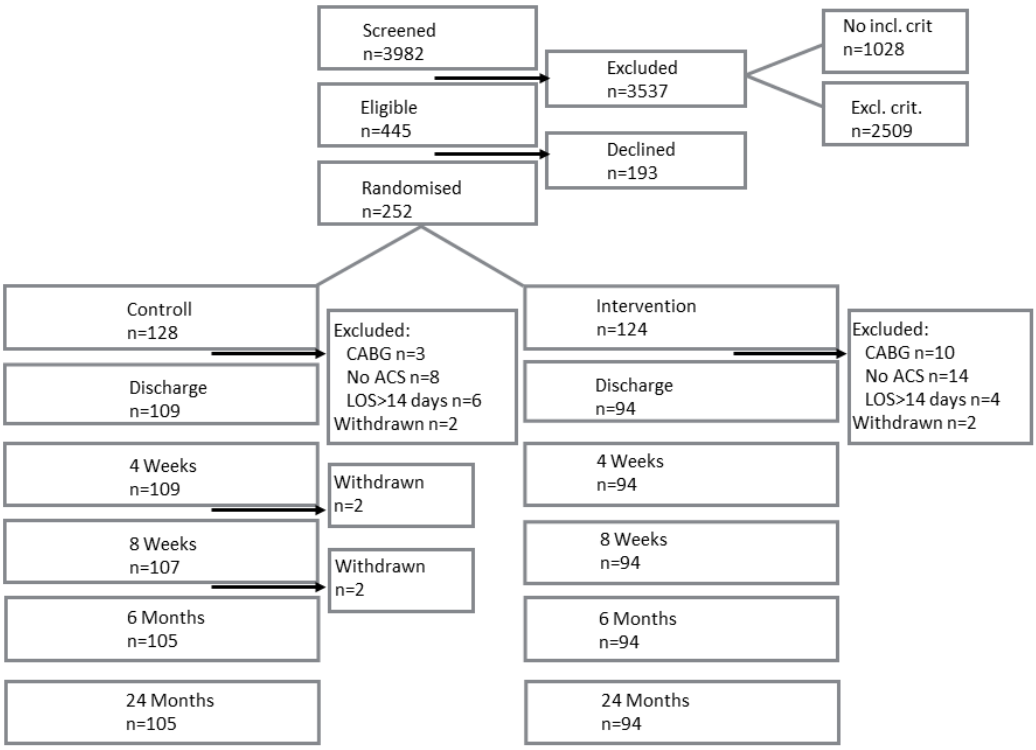
Figure legends

Figure 1. Trial profile

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Figure. Trial profile.



CABG=coronary artery bypass grafting; ACS=acute coronary syndrome; LOS=length of hospital stay

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Highlights

The first study presenting results for up to two years after a person-centred intervention

Person-centred care results in sustained health outcome improvements after ACS

Populations with lower socioeconomic status benefits the most of person-centred care

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