Effectiveness of the PREDOCS-programme: a pre-post test study

Effect of a nursing intervention 'PREvention Decline in Older Cardiac Surgery patients' (PREDOCS) programme for preventing postoperative complications in a hospital specialized in cardiac surgery

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ABSTRACT

Background: Postoperative complications such as infections, pressure ulcer, delirium and depression occur frequently in frail older patients after cardiac surgery. The intervention 'PREvention Decline in Older Cardiac Surgery patients' (PREDOCS-programme) is a complex nursing-intervention, to optimize patients aged ≥65 years indicated for cardiac surgery in the pre-admission period. Besides information about the operation, pain-management and good nutrition, patients at risk are detected using screening-scorecards. Also, tailored advices are provided, so that patients can work within their home-situation, reducing there increased risk for postoperative complications.

Aim: To evaluate the effect of the PREDOCS-programme by comparing the incidence of the combined incidence of the four postoperative complications in an intervention and control-group.

Method: A pre-post test design was carried out, as part of a still-running larger multicentre stepped wedge trial. The control-group exists out of patients who received usual care, the intervention-group received in addition the PREDOCS-programme.

Results: Besides collected data of 50 patients, data was supplemented with 200 patients using multiple imputation. 64/125 in the intervention-group and 61/125 patients from the control-group developed a postoperative complication, mostly a risk for developing a depression. After correction in a multivariate analysis only a slight non-significant difference was found between the groups (OR 0.954, 95%-confidence interval 0.556-1.634). In the intervention-group less pressure ulcer, infections or risk for depression was found, but significantly more patients developed a (risk for) delirium. Furthermore, significantly more patients in the control-group died (p=0.02).

Conclusion: These data showed no reduction of postoperative complications in older patients undergoing cardiac surgery when included in the PREDOCS-group.

Recommendations: To measure the effect of a pre-admission intervention, preoperatively re-screening patient's risk for postoperative complications could be beneficial when the patient is admitted to the hospital. Furthermore, to draw conclusions from the effectiveness of the pre-admission intervention PREDOCS-programme, results from the multicentre trial are needed.

Key words: postoperative complications – nursing care – older patients – cardiac surgery – pre-admission intervention

INTRODUCTION

As the aging population expands,[1-3] almost 60% of the cardiac surgery patients are aged ≥65 years.[4,5] Nowadays, due to surgery improvements and anaesthetic advances, more older cardiac surgery patients can pass a surgery-procedure safely.[6-9] These older patients usually have various comorbidities, which also differ in severity.[10] This vulnerable condition however, referred to as the geriatric syndrome of frailty, can lead to a higher operative risk.[3,11-16] Frailty develops as a consequence of age-related decline in many physiological systems, but exposure to a stressor like cardiac surgery could work as a precipitating factor.[17,18] Moreover, coronary heart disease commonly coexists with frailty.[19]

Frailty makes older patients highly vulnerable to adverse health outcomes like postoperative complications.[2,20-24] Common postoperative complications after cardiac surgery are nosocomial infections (8.3-54.5%),[25-27] pressure ulcers (14.0-18.0%),[28,29] delirium (14.7-54,9%),[30,31] and depression (10.0-37.7%).[32,33] These complications are associated with loss of independence, functional and cognitive decline and a diminished of quality of life.[11] Furthermore, postoperative complications can result in a prolonged length of stay, which induces additional health care costs.[2,34,35]

When patients at-risk for the aforementioned complications are recognized in the pre-admission period, interventions could be performed for prevention in an early stadium.[18,24] In developing an appropriate intervention for preventing postoperative complications in this population, the heterogeneous characteristics with respect to frailty should be taken into account. Consequently, this needs a targeted approach.[11,24,36,37] To give the patient tools to optimize their health condition preoperatively, Ettema et al.[38] developed an evidence-based multicomponent intervention using the Medical Research Council framework.[39,40] This intervention includes a nursing screening programme for older patients undergoing cardiac surgery and is called 'PREvention Decline in Older Cardiac Surgery patients' (PREDOCS-programme). A multicentre feasibility-study showed the PREDOCS-programme could be incorporated in clinical practice. It was found that the programme is cost-effective when in 6-16 out of 1,000 cardiac surgery patients postoperative complications would be prevented.[41]

The current study, which is part of a larger multicentre stepped-wedge trial in the next step of the MRC-framework, evaluated the PREDOCS-programme in one general hospital specialised in cardiac surgery. The research question of this pre-post test study was: What is the effect of the PREDOCS-programme in preventing postoperative occurring infection, pressure ulcer, delirium and/or depression in patients aged ≥65 years undergoing cardiac surgery in a general hospital?

METHODS

Design

The current study is part of a multicentre-cluster randomised controlled trial using a stepped-wedge design[39,42] which tested the effectiveness of the PREDOCS-programme in three centres (Figure 1). This design is applicable to examine the measurement of complex health interventions.[39,43,44] Built into the phasing of implementation, the intervention has been sequentially rolled out over a number of time-periods until all patients have received the intervention. With benefits for this design, four moments of data collection are needed for modelling the effect of time by the control/intervention group from the other hospitals. Therefore there was chosen to randomize on cluster level.

The data from which this single-centre study is drawn, is the second randomly-allocated centre for implementing the programme. The current study has a prospective pre-post test quasi-experimental design. The design allowed to determine the effects of the intervention by examining differences between different groups of patients.[45] The control-group included patients who were admitted before implementation. The intervention-group included those who received the PREDOCS-programme after implementation. Patients were not told to which group they were allocated. Besides, nurses from the postoperative ward, those who measured the patients, were blinded while in this hospital the preoperative and postoperative ward are separated.

<<Figure 1>>

Study population

The PREDOCS-programme was developed for patients aged ≥65 years and planned for cardiac surgery (all operations in which the pericard has to be passed to allow heart-surgery). From this target group, all patients of a general hospital specialized in cardiac surgery between February and May 2015 were eligible when planned electively at least 2-5 weeks before operation; admitted from their home-situation; and had signed informed consent. Patients were excluded when they were unable to speak or read Dutch; participating already in another conflicting study; diagnosed with any mental illness; had a history of a heart or lung transplantation or a present infection.

Sample size calculation was based on the combined incidence of the postoperative occurrence of delirium, depression, pressure ulcer and/or infection in a sample of 1,761 patients.[10] In this sample, complications occurred in 36.0% (51.3% with overlap of patients who had ≥1 complication). Given a power of 0.8 and alpha 0.05, a number of 229 patients per group were needed and six extra patients for taking into account lost-to-follow-up.

However, due to the design-effect of the stepped-wedge trial, only 2x74 patients were needed to include in this hospital. Missing data were imputed by multiple imputation[46] also using data from the other two hospitals.

Data-collection

The main outcome was the combined incidence of the occurrence of infections, pressure ulcer, (an increased risk for) delirium and/or an increased risk for depression in patients from the intervention and control-group:

- The possible presence of nosocomial infections in general was measured when the physician reported this in the electronic health record. According to the hospital protocol, lab testing is done standardly on the second and fifth day postoperatively at the nursing ward. Also, when there was a suspicion for an infection, cultures from blood, wound, sputum or urine were conducted.
- The occurrence of pressure ulcer was recorded when nurses reported the presence and degree (degree I or severe) of pressure ulcer in the nursing record, according to the International NPUAP-EPUAP Pressure Ulcer Classification.[47] According to the hospital protocol, nurses had to screen patients during their whole hospital-stay for the presence of pressure ulcer by observing patient's bony prominences.
- The complication delirium was accumulated by an increased risk for delirium and/or when the patient received antipsychotics for a suspected delirium from a physician. Nurses had to fill out the validated Delirium Observation Scale[48] questionnaire (sensitivity 0.25, specificity 0.96)[49] on the first and third postoperative day. This indicated a delirium, if the patient scored on average ≥3 points in one day (three shifts).
- The complication depression was recorded if the patient had an increased risk for a depression, i.e. ≥4 points on the GDS2-15[50] (sensitivity 0.96, specificity 0.57).[51] All patients, possibly together with the researcher, had to fill ou this questionnaire the first and third day postoperatively.

Secondary outcomes through file research were length of stay (LOS) in days at the postoperative nursing ward and mortality-rate. Measured baseline-characteristics were: socio-demographic characteristics, patient's vulnerability (EuroSCORE II[52], disabilities and resources), type of operation, discharge direction, pressure ulcer at admission, and patient's risk-assessment (second step of the intervention to detect patients-at risk for complications).

Study-procedure

All elective patients who visited the preoperative clinic two to five weeks before heart surgery were asked for informed consent by the researcher after receiving an information letter. During the current study-period, implementation only took place in another hospital, the first allocated centre. After sufficient patients were measured for the control-group, training-sessions of three hours were given to nurses by the developer of the PREDOCS-programme in order to perform the programme correctly. The implementation-method was beyond the scope of this study. After implementation, all eligible patients received besides usual care the PREDOCS-programme. Postoperative care was the same for both groups.

Intervention-group

Patients from the intervention-group received the PREDOCS-programme (see also supplementary data).[38] The patient, patient most preferably together with a close family member, met the nurse for a 20-30 minutes consult. This consults consisted out of:

1. The nurse gives information about the procedure, the patient's expectations, and information to enhance self-management. Also information is given about good nutrition, enabling a social environment and optimizing pain-management.
2. The nurse screens the patient for an increased risk of infection, pressure ulcer, delirium, or depression preoperatively using screening-scorecards.
3. In case of an increased risk for any of the complications, tailored written advices is given about preventive measures.

After the consult, the nurse reported in the electronic health record any increased risk. During the period between the consult and hospital-admission, the patient was able to work at home on declining the risk of the arising of complications. When the patient was admitted to the hospital for his operation, the execution of the advices was evaluated.

Control-group

Patients who were admitted to the hospital before implementation of the PREDOCS-programme received usual care prior to surgery. The day before surgery a nurse provided general information to the patient and possibly in the presence of a close family-member about the surgery procedure itself and optimal pain-management (ask for extra analgesics when the pain is untenable, i.e. a score of ≥4 on the Visual Analog Scale[53]). Furthermore, the patient received a leaflet with information both about the possibility of getting a delirium and advices to prevent the occurrence of pressure ulcers (the importance of good nutrition). No special actions were undertaken for preventing the risk of a depression and infection.

Data-analysis

Socio-demographic categorical data were presented by counts and percentages. Medians and interquartile ranges were calculated for presenting the distribution of the continuous data. Mann-Whitney U tests were done for the non-parametric continuous data. To show the crude effect of the PREDOCS-programme, the combined outcome of postoperative complications (occurrence of postoperative infections, pressure ulcer, delirium, and/or depression) was tested using binary logistic regression.[54] To show the adjusted effect of the PREDOCS-programme, significant baseline values were put in a multivariate analysis to compare the influence of baseline values (corrected odds ratio) on the effect of the intervention. A χ^2-analysis was performed to show the differences in groups for the abovementioned four complications separately, patient's risk-assessment, LOS, and mortality-rate. All data were analysed using SPSS 21. Missing data were imputed using multiple imputation by Rubin's rule.[46]

Ethical issues

This study was conformed with the principles outlined in the Declaration of Helsinki[55] and in accordance with the Medical Research Involving Human Subjects Act (*WMO*). In February 2015, the Medical research ethics committee of an academic hospital gave their approval for the multi-centre study. Also, permission was given of the main hospital.

RESULTS

Results are based on 250 patients, 125 in the control-group and 125 in the intervention-group. During the study-period, 69 patients met the eligibility criteria (Figure 2), whereas 50 patients signed informed consent. 19 patients refused participating because they felt no need to or because they felt it was too burdensome. These first 50 patients were allocated to the control-group, while the PREDOCS-programme was not yet implemented fin this hospital during the study-period. To approach the recommended number of patients, it was possible to impute data for another 200 patients.

As shown in Table 1, the median age of all patients was 73.5 (68.8-78.8) years, mostly male gender (77.6%). One quarter of the patients was (physically) disabled. Almost half of the patients underwent a bypass operation (CABG). In the intervention-group more valve operations were performed (24.0% vs. 17.6%), whereas more other cardiac surgeries were found in the control-group (28.0% vs. 18.4%).

Both groups were almost comparable. Only patients' vulnerability as set out by the EuroSCORE was significantly higher in the intervention-group, (1.37 vs. 2.76, p=0.006) and patients from the control-group were in general significantly lower educated (p=0.049).

<<Table 1>>

Primary outcome: incidences of complications

Half of the patients developed complications, most often a depression (34.4%, Table 2). In the control-group, a higher number of patients developed several complications at the same time. In regard to the combined outcome, 64/125 patients who received the PREDOCS-programme developed ≥1 complications versus 61/125 patients in the control group (p=0.704). When corrected for the significant baseline-variables from the univariate analysis, also no significant difference was found between the groups. In the multivariable analysis, a slight not significant positive association was found for the PREDOCS-programme with an OR <1 (0.954, 95% confidence interval 0.556-1.634, Table 3). Only a significant negative association on the combined outcome was found for patients who either underwent a valve operation, or had disabilities, or had an average education level.

The number of the four complications were divided differently among groups. In the intervention-group, patients developed significant less often pressure ulcer (8.8% vs. 20.8%, p=0.013), a depression (30.4% vs. 38.4%, p=0.231), and less infections (8.8% vs 13.6%, p=0.316), but significant more often a delirium (20.0% vs. 9.6%, p=0.033).

When comparing the occurrence of complications to patient's risk measured preoperatively, results showed that 20% of the patients without an increased risk developed a (risk for) delirium in the intervention-group versus 4.8% of the control-group. This was about the same for patients who developed a risk for a depression, but these numbers were even higher in patients without receiving the PREDOCS-programme (28.0% vs. 43.3%). 16.7% (9/54) of the patients from the intervention-group who were at risk were not able to prevent pressure ulcer versus 29.7% (22/74) in the control-group.

<<Table 2>>
<<Table 3>>

Secondary outcomes: LOS and mortality-rate

18.4% of all patients died, of which significantly more patients in the control-group. 16/33 patients who died in the control-group did not achieve the nursing ward postoperatively. In the intervention-group this division was 6/13 patients. Almost 70% of all patients who died, were recorded for the complication depression and 43.5% with pressure ulcer. No further differences were found between groups.

The median number of the length of stay was equal between groups, namely 5(3-6) days.

<<Figure 2>>

DISCUSSION

In measuring the effect of the PREDOCS-programme in patients aged ≥65 years and undergoing cardiac surgery in a general hospital, no differences were found between the intervention and the control-group on the combined incidence of the occurrence of postoperative complications. When corrected for baseline values, only a slight positive association was found for the PREDOCS-programme. This could indicate a protective value of the PREDOCS-programme, but if this is the case, this result was however not significant, possibly due to the reason that this study is underpowered. In the intervention-group significant less pressure ulcer, less infections and fewer patients with a risk for depression were found. Moreover, a significant lower incidence of the complication delirium was found in the control-group.

Few studies are done in this topic of interest. One study assessed an intervention including several phone-facilitated interviews eight weeks before surgery, for patients awaiting a CABG.[56] This study showed a significant reduction in feelings of a possible depression, which is in line with the current study. Another nurse-led programme provided lifestyle counselling and preparation for patients also undergoing a CABG.[57] They found no differences between groups for the measured outcomes and infection rate. Other studies in patients undergoing surgery other than a heart-operation recommend pre-admission education to reduce feelings of anxiety and depression.[58,59] Also it could help to reduce postoperative pain levels after surgery and a greater recall of provided information after discharge.[60] Most of the studies showed that a pre-admission intervention could be beneficial, but could not state it has its effects on preventing all complications like in the PREDOCS-programme. Also, these studies did not especially focus on older patients.

This target group is important while the most vulnerable patients are at risk for complications. Results from this study showed patients who had disabilities or underwent a valve operation, this was negatively associated with the occurrence of complications. The prevalence of aortic-stenosis is namely related to age and minimal invasive techniques make it possible for older patients to undergo a valve operation. Patients who are indicated for a valve operation, could be corresponding with an higher EuroSCORE and a higher mortality rate.[61]

A well-working intervention which does focus on preventing complications in 65+ patients was the so-called POPS-intervention. This is a pro-active multi-disciplinary evidence-based comprehensive geriatric assessment-service with postoperative follow-through for at-risk elective orthopaedic patients, which was developed using the MRC-framework. The intervention led to reduced incidences for i.a. pneumonia, delirium, pressure ulcer, and poor pain-control. Also there were fewer delayed discharges relating to medical complications and a reduced LOS of 4.5 days.[62] The PREDOCS-programme showed no

differences in patient's LOS an and a perchance effect of the intervention. It could be worthwhile to explore the working elements of this POPS-intervention and eventually adopt these into the PREDOCS-programme to improve the intervention. This with special attention for preventing a delirium, while significant more patients had this complication in the intervention-group.

It could be hard to determine effects after a short period of rolling out the intervention. Therefore the results of this study should be interpreted with caution while it needs time to implement the intervention effectively. Besides, data from 50 patients were supplemented with imputed data of 200 patients. Together with the fact that the calculated number of 464 patients was not achieved, this led to an underpowered study in which it was not possible to determine a significant effect in case there is an effect. In this dataset, complications occurred in approximately 50% of the patients (48.8% versus 51.2%), which is more than the previous performed study.[13] In a sample of 1,761 patients, 36.0% of the patients had ≥1 complication. Possibly this is biased by the effect of the imputation. This also applies to the number of days between the PREDOCS-programme and operation. Only patients were included when electively planned at least two to five weeks before their operation, but it was found the median number was ten days, with a minimum of one day. This has its negative consequences for the reliability of findings. Besides imputation of cases, for many missing values multiple imputation was needed to cause no selection-bias. While most of the measurements for this study were in accordance to the hospital's protocol, apparently nurses did not screen every patient for complications. The results of this study could therefore be under or overestimated. For a good insight in the number of complications in older patients after cardiac surgery, it would be recommended to aim for a higher compliance-rate, also to improve the external validity. The exact findings will be found at the end of the trial.

Furthermore, the study shows the most occurring complication is a risk for developing a depression. Also most of the patients who died, were labelled for this complication. The influence of this complication on the mortality-rate however cannot be stated. It was a shortcoming that the used GDS2-15 questionnaire was not validated for older cardiac surgery patients. This two-question part of the questionnaire was tested in a primary care setting, not especially for older patients but showed a high sensitivity for patients aged 65+. The questionnaire could probably give therefore sufficient indication for measuring the risk for a depression in this sample. However, incidences could be overestimated while patients were only measured for their risk of developing a depression, because it takes time to determine a depression, since the patient should have depressive feelings for at least two weeks.[63] Patients who received the PREDOCS-programme had less often a risk for a depression, which is in accordance with the abovementioned[56] and other studies.[65,65]

Possibly the attention for the psychosocial wellbeing makes patients more aware, which helps to prevent the occurrence of a depression.

Another limitation was the chosen baseline-variable education-level. This is a common proxy to compare groups for their cognitive capacity. It was found that an average education-level (lower vocational, vocational education) was negatively associated with postoperative complications. Several patients told however that they learned during their working career, while the study population was mostly retired and only went to primary school or did not go to school at all. Therefore it is questionable whether this was the right proxy to measure patient's learning ability and the value of this finding.

Furthermore, it was not possible to follow patients during their whole hospital-stay which consisted also a limitation. The subjected hospital is one of the key hospitals in the Netherlands and many patients transfer back to their own hospital, mostly from the third postoperatively day. The first days post-surgical, lab results could be deviant (like C-reactive protein and leucocytes) due to an inflammatory response post-surgical,[66] which makes it difficult to determine the presence of an infection. It could be possible that an infection was detected later, which could lead to underreporting from the number of infections. However, this chance was equal for both groups and probably did not cause differences between groups.

Some recommendations can be made. The study showed only few patients from the intervention-group with an increased risk for pressure ulcer developed this complication. A large percentage of patients however who were not labelled as having an increased risk for a depression and delirium before surgery, developed these complications. This result could be found by chance or could probably be due to the fact the PREDOCS-programme did not distinct correctly for an increased risk or patients did not follow the provided advices well. However, a gap exists between the performance of the intervention and hospital-admission, while the execution of the third step of the PREDOCS-programme (how the patient with an increased risk had worked in the home-situation with the given advices) was not recorded. It is therefore difficult to determine and troublesome to assign the results of the study to the effects of the PREDOCS-programme. When the patient is admitted to the hospital preoperatively, re-screening the risks for developing complications could be beneficial in order to reassess patient's risk and eventually perform in hospital interventions for this, like consulting a social-worker.

Also, it could be worthwhile to explore the effects of this pre-admission intervention like the PREDOCS-programme on women. The PREDOCS-programme contains tailored education to prepare preoperative patients well, so probably anxious patients could have benefit from the intervention. Reasons to refuse participating were mostly because they thought the study was too burdensome caused by their anxiety for the heart-operation. From

the eligible approached patients, remarkably 9/46 men refused participating versus 6/20 female patients. An earlier performed study determined the need for social services in patients at pre-admission for elective surgery. It was found aging females who lived alone required most support from social-workers and had the longest LOS.[67] In general, more men than women underwent cardiac surgery.[68] In this study 77.6% of the patients were men, so the results are mostly generalizable to male patients.

Probably due to the effect of the underpowered sample-size, we could not find a significant effect of the PREDOCS-programme. Results are uncertain and exact effects will be found at the end of the trial.

IMPLICATIONS FOR PRACTICE

- Results from the multi-centre trial are needed to draw conclusions from the effect of the pre-admission intervention PREDOCS-programme;
- Effective elements of another well-working multidisciplinary intervention could be incorporated into the PREDOCS-programme to improve to the effect of a pre-admission intervention for preventing complications;
- Preoperatively re-screening patient's risk for postoperative complications could be beneficial to measure the effect of a pre-admission intervention.
- Preoperatively and during the patient's hospital stay, more attention should be paid to the psychosocial well-being of patients for prevention a depression;
- To provide insight in the number of complications after cardiac surgery, nurses should aim for a higher compliance-rate for screening postoperative complications;

FIGURES AND TABLES

	T_1	T_2	T_3	T_4
Centre I	0	I	I	I
Centre II	0	0	I	I
Centre III	0	0	0	I

	T_1	T_2		T_3	T_4
n control-group	0 *(Pre-test)*	0 *(Pre-test)*			
			Implementation of the PREDOCS-programme		
n intervention-group				I *(Post test)*	I *(Post test)*

Fig. 1. Design current pre-post study in relation to trial with stepped-wedge design

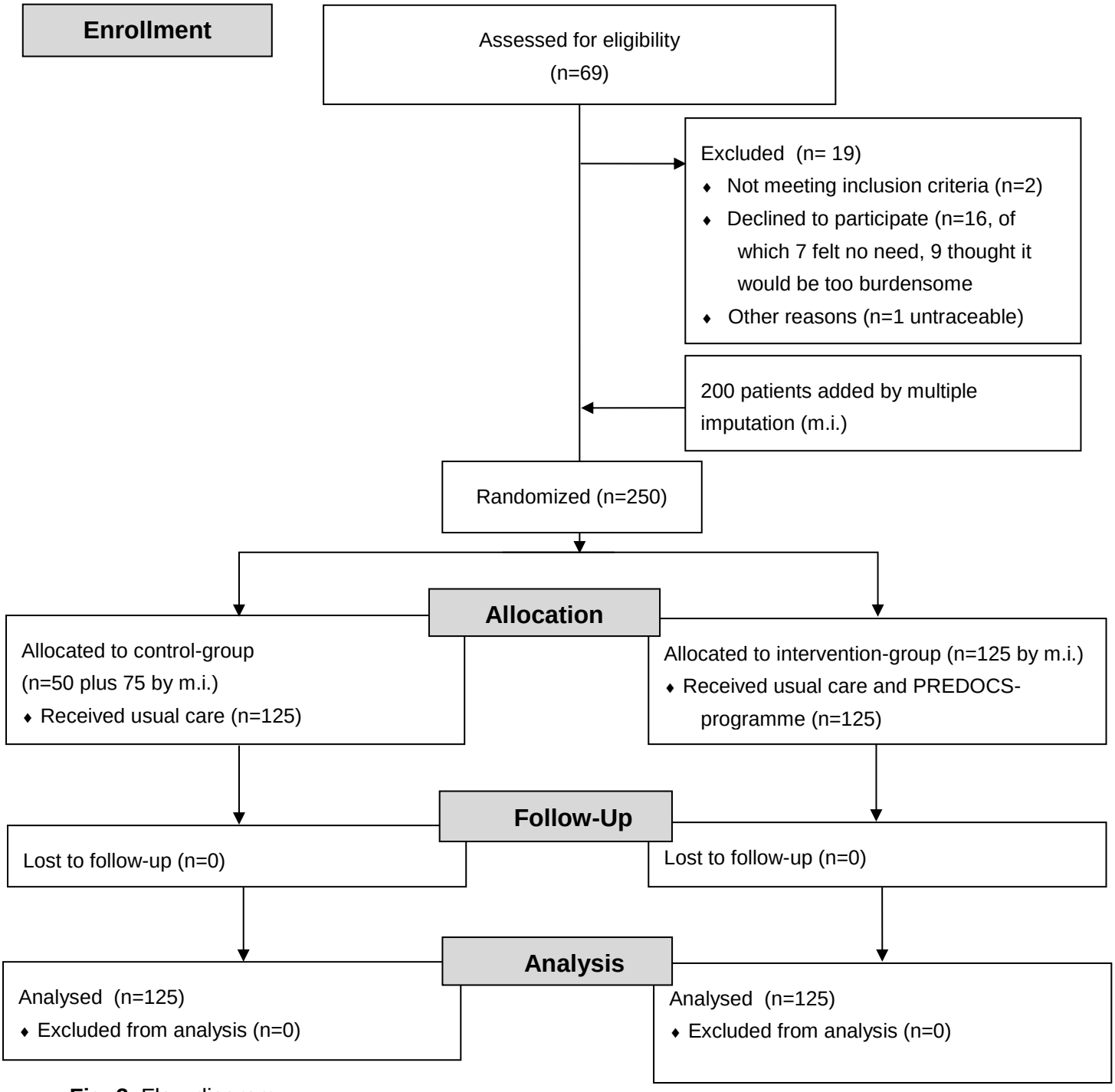

Fig. 2. Flow diagram

Table 1. Baseline characteristics

	All (n=250)	Control-group (n=125)	Intervention-group (n=125)	p-value
General				
Age[a]	73.5 (68.6-78.8)	73.4 (68.6-79.2)	73.8 (69.5-78.6)	0.544
Gender (men)	194 (77.6%)	99 (79.2%)	95 (76.0%)	0.649
BMI[a]	26.78 (24.22-29.21)	26.95 (23.99-29.76)	26.64 (24.45-28.87)	0.465
Days between PREDOCS and OK[a]	-	-	10 (1-27)	
Social status				
Marital status (without partner)	83 (33.2%)	46 (36.8%)	37 (29.6%)	0.283
Living status (living alone)	94 (37.6%)	52 (41.6%)	42 (33.6%)	0.240
Depending on care[b]	31 (12.4%)	14 (11.2%)	17 (13.6%)	0.701
Educational level[c]				***0.049****
Low	82 (32.8%)	50 (40.0%)	32 (25.6%)	***0.022****
Mediate	78 (31.2%)	36 (28.8%)	42 (33.6%)	0.495
High	90 (36.0%)	39 (31.2%)	51 (40.8%)	0.147
Vulnerability				
EuroSCORE II[a]	2.15 (1.21-4.07)	1.37 (1.17-3.57)	2.76 (1.31-7.56)	***0.006****
Disabilities[d]	64 (25.6%)	33 (26.4%)	31 (24.8%)	0.597
Resources[e]	183 (73.2%)	89 (71.2%)	94 (75.2%)	0.406
Type of operation				0.278
CABG[f]	113 (45.2%)	55 (44.0%)	58 (46.4%)	0.799
Valve[g]	52 (20.8%)	22 (17.6%)	30 (24.0%)	0.275
Combined CABG + valve	27 (10.8%)	13 (10.4%)	14 (11.2%)	1.000
Other cardiac surgery[h]	58 (23.2%)	35 (28.0%)	23 (18.4%)	0.099
Pressure ulcer at admission	6 (2.4%)	3 (2.4%)	3 (2.4%)	1.000
Days postoperative nursing ward[a]	5 (3-6)	5 (3-6)	5 (3-6)	0.081
Discharge direction				0.019
Home	106 (42.4%)	50 (40.0%)	56 (44.8%)	0.443
Transmission to another hospital	93 (37.2%)	39 (31.2%)	54 (43.2%)	0.067
Rehabilitation centre	3 (1.2%)	2 (1.6%)	1 (0.8%)	1.000
Nursing home	2 (0.8%)	1 (0.8%)	1 (0.8%)	1.000
Died	46 (18.4%)	33 (26.4%)	13 (10.4%)	***0.002****

* Significance level with p-value <0.05
[a] Median and IQR were calculated. In all other variables frequencies and percentages were calculated;
[b] Depending on care: receiving informal care from family care giver or other care givers;
[c] Education level: low= primary school, secondary school; mediate= lower vocational, vocational education; high= higher vocational, university;
[d] Disabilities: deaf, physically disabled;
[e] Resources: glasses, hearing aid, stick/walker, insoles, wheelchair;
[f] CABG: Coronary Artery Bypass Graft
[g] Valve operation: repairing/replacement of the mitral valve/aortic valve/tricuspid valve
[h] Other cardiac surgery: rhythm surgery (combined with CABG/valve operation), minimal invasive cardiac surgery (heartport procedures), septal myectomy (morrow procedure), tricuspid valve replacement.

Table 2. Incidence of complications postoperatively

	Control-group n/total	(%)	PREDOCS-group n/total	(%)	p-value[a]
Complication-rate					
Infection	17/125	(13.6%)	11/125	(8.8%)	0.316
No increased risk	11/95	(11.6%)	8/107	(7.5%)	0.450
Increased risk	6/30	(20.0%)	3/18	(16.7%)	1.000
Pressure ulcer	26/125	(20.8%)	11/125	(8.8%)	***0.013****
No increased risk	4/51	(7.8%)	2/71	(2.8%)	0.400
Increased risk	22/74	(29.7%)	9/54	(16.7%)	0.135
(Increased risk) delirium	12/125	(9.6%)	25/125	(20.0%)	**0.033***
No increased risk	5/105	(4.8%)	21/105	(20.0%)	**0.002***
Increased risk	7/20	(35.0%)	4/20	(20.0%)	0.479
Increased risk depression	48/125	(38.4%)	38/125	(30.4%)	0.231
No increased risk	39/90	(43.3%)	26/93	(28.0%)	**0.044***
Increased risk	9/35	(25.7%)	12/32	(37.5%)	0.438
Number of complications					
≥1 complication	61/125	(48.8%)	64/125	(51.2%)	0.800
One complication	34/125	(27.2%)	46/125	(36.8%)	0.136
Two complications	13/125	(10.4%)	15/125	(12.0%)	0.841
Three complications	13/125	(10.4%)	3/125	(2.4%)	***0.020****
Four complications	1/125	(0.8%)	0/125	(0%)	1.000
Mortality-rate					
Achieve postoperative ward	16/33	(48.5%)	6/13	(46.2%)	
Labelled with infection	8/33	(24.2%)	5/13	(38.5%)	0.548
Labelled with pressure ulcer	15/33	(45.5%)	5/13	(38.5%)	0.920
Labelled with delirium	3/33	(9.1%)	2/13	(15.4%)	0.927
Labelled with depression	22/33	(66.7%)	10/13	(76.9%)	0.745

[a] p-value: χ^2-analysis with Yates' continuity correction
* Significance level with p-value <0.05

Table 3. Influence of PREDOCS-programme on combined outcome

	OR (CI)[a]	p-value
Univariate analysis		
Random group	1.101 (0.670-1.808)	0.704[b]
Multivariable analysis		
Random group (Adjusted for significant variables from univariate analysis below)	0.954 (0.556-1.634)	0.863
Disabilities	2.383 (1.268-4.475)	0.007
Valve operation	2.236 (1.045-4.782)	0.038
Average education level	2.145 (1.196-3.847)	0.010

[a] OR=Odds Ratio, CI= Confidence Interval

[b] uncorrected p-value

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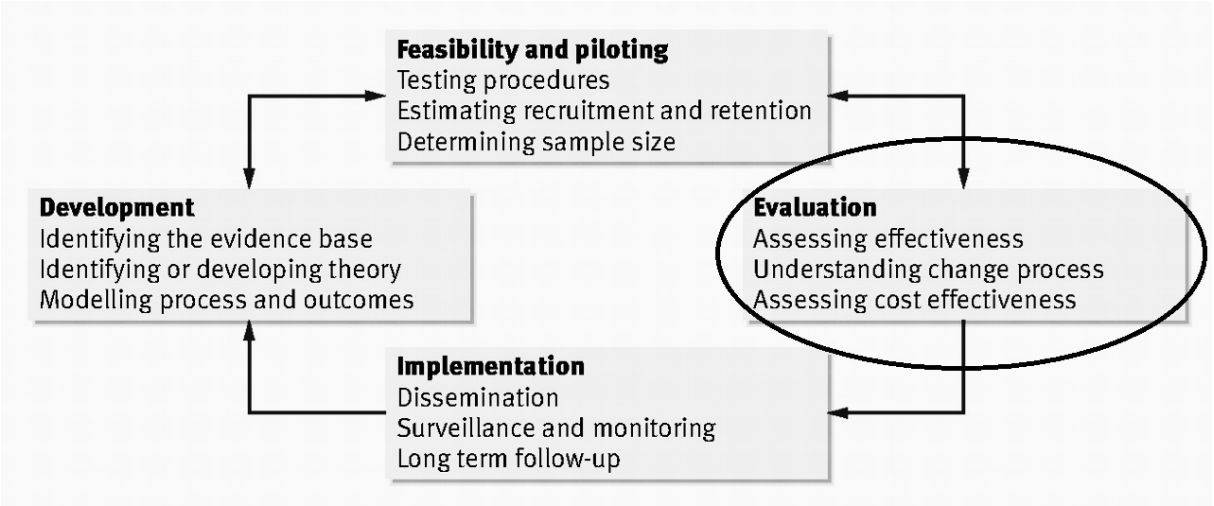
SUPPLEMENTARY DATA

1. MRC-framework

Guideline for developing complex interventions[30,31]

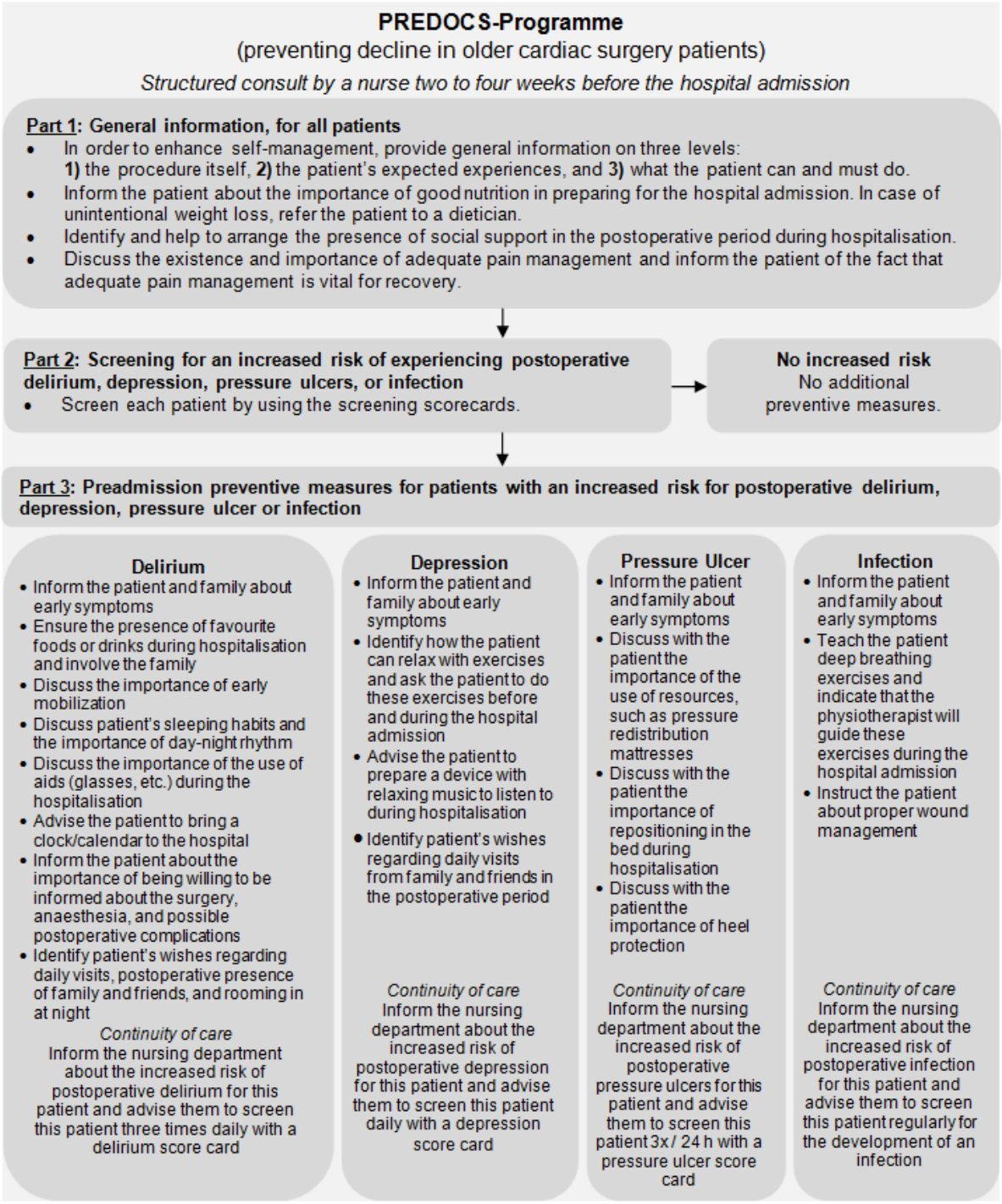


2. Study-procedures

	-2-5 weeks before operation	-1 day	0[a]	+1 day	+2 day	+3 day	+4 day until discharge from hospital	File research
Treatments of groups								
All groups	Obtain i.c.[b]							
Intervention-group	PREDOCS-programme							
Control-group		Usual care						
Moments of measurements in all groups								
Infection								
Pressure ulcer								
Delirium								
Depression								

[a] cardiac surgery and stay at ICU (Intensive Care Unit), MC (Medium Care) or PACU (Post Anaesthesia Care Unit)
[b] i.c. = informed consent

3. PREDOCS-programme[28]



4. Screening scoring cards to measure an increased risk for a postoperative complication[38]:

Delirium Risk Score Card Points	
Experienced delirium previously	2
Alzheimer's diagnosis	2
Uses a stick or walker	2
Logistic EuroSCORE* risk above 20%	1
Receives support from family/friends (informal care) when living alone or not actively supported by the partner	1
Age over 70 years	1
History of stroke and/or TIA	1
Use of benzodiazepines	
Total (an increased risk of delirium is 3 or higher)	

Depression Risk Score Card Points	
Use of insoles	3
Deaf	2
Female	1
Use of benzodiazepines	1
Total (an increased risk of depression is 2 or higher)	

Pressure Ulcer Risk Score Card Points	
History of tricuspid insufficiency	5
Physically limited*	3
Logistic EuroSCORE risk* above 20%	2
Use of fraxiparin	2
Renal impairment	1
Total (an increased risk of pressure ulcer is 3 or higher)	

Infection Risk Score Card Points	
History of tricuspid insufficiency	3
Logistic EuroSCORE* risk above 20%	2
Use of diuretics	2
Total (an increased risk of infection is 3 or higher)	

*) The European System for Cardiac Operative Risk Evaluation (EuroSCORE) was developed in the eighties for predicting 30-day mortality after cardiac surgery. In the meantime, with improved cardiac surgery techniques, the mortality rates have been minimised. Currently, frail patients can undergo a cardiac surgery procedure with a low mortality risk, but they can have an increased risk of postoperative complications such as delirium, depression, pressure ulcer, and infection. In several studies, the EuroSCORE has been validated for predicting a prolonged intensive care unit (ICU) stay for patients scheduled for cardiac surgery. Prolonged (ICU) stay is then used as a proxy for complications occurring during surgery and intensive care unit stay.[69]

**) In the development study for this scorecard, the patient was assessed for a disability. The response categories were: 'deaf', 'blind', 'physically limited', and 'intellectual disability'. Physically limited appeared to be predictive for the occurrence of a postoperative pressure ulcer.