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Active involvement of family members in postoperative care after esophageal or pancreatic resection: A feasibility study

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ABSTRACT

Background: Active involvement of relatives has the potential to improve postoperative patient outcomes by prevention of complications sensitive to basic care and unplanned readmissions. The aim of this study was to assess the feasibility of a program in which relatives participated in postoperative care.
Methods: A pragmatic feasibility trial conducted at the surgical ward of a University hospital in the Netherlands. Patients undergoing esophageal or pancreatic resection with a relative who was willing and able to participate formed the intervention group ($n = 20$). A control group ($n = 20$) received usual postoperative care.
The program consisted of the following: (1) information; (2) shared goal setting; (3) task-oriented training; (4) participation in basic care, focusing on mobilization, breathing exercises, cognitive activities and oral hygiene; (5) presence of relatives during ward rounds; and (6) rooming-in.
Feasibility criteria were adherence to basic care, caregiver burden, and satisfaction of patients, family, and healthcare professionals.
Results: All participants completed the program. Patients in the intervention group mobilized more (estimated difference for walking 170 meters per day, $P = .037$, and for sitting 109 minutes per day, $P < .001$), and showed more adherence to breathing exercises (estimated difference per day 1.4, $P = .003$), oral hygiene (estimated difference 1.52, $P = .001$), and cognitive activities (estimated difference 2.6, $P < .001$). Relatives'Care-Related Quality of Life instrument score did not deteriorate over time ($P = .64$); 96% of relatives would recommend the program and 92% felt better prepared for discharge. Patients in the intervention group were more satisfied with hospital admission. Healthcare professionals valued the program positively.
Conclusion: This program is feasible and is positively appreciated by patients, family, and healthcare professionals. Patients following the program showed more adherence to basic care activities.

Introduction

Hospitalization for a major surgical procedure is a stressful event for patients.[1,2] Healthcare professionals (HCPs) may underestimate that hospital discharge can be equally stressful.[3] This can be caused by the number of unplanned hospital readmissions, ranging from 8% to 30% in surgical patients with highest readmission rates for patients undergoing major abdominal surgery.[4,5] Not only do these unplanned readmissions have a huge impact on patients' lives, but they also lead to increased healthcare demands and costs.[6,7]

A substantial part of unplanned readmissions is thought to be preventable, for instance by improving transition of care.[8,9] Nowadays, family members are more and more involved in providing care at home.[10] However, they are often not trained to provide care.[11] For elective surgical patients, the postoperative phase is an unused opportunity to teach family members the required skills. Therefore, we developed a program in which family members of adult surgical patients actively participate in postoperative care.

In pediatric wards involvement of parents is often standard,[12] but relatives of adult patients are often side-tracked during hospital admission.[13] Although engagement of patients and their

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families in care has been recommended to improve quality of care and patient safety, rigorous evidence for the effectiveness of this strategy is lacking.[14–16]

For surgical patients, reducing postoperative complications is key in quality and safety improvement. This is especially true for patients undergoing resection for a malignant or premalignant esophageal or pancreatic lesion as complication rates in these patients are high, and a delay in recovery may also lead to a delay in adjuvant treatment.[17–19] Many postoperative complications are considered to be potentially preventable, including delirium, pneumonia, urinary tract infections, pressure ulcers, and malnutrition.[20,21] Basic care activities, such as early mobilization, breathing exercises, oral hygiene, eating together, and cognitive measures are known to reduce the risk of these complications.[20–25] Although simple, these basic care activities are prone to be missed and are an important target for improvement.[15]

We hypothesize the benefit of our family involvement program to be 3-fold: first, more confident and skilled relatives, potentially improving transition of care; second, a higher patient satisfaction; and third, more adherence to basic care activities, potentially reducing postoperative complications. Possible drawbacks of this program include a higher caregiver burden and a time demand for hospital staff.

The aim of this study was to assess the feasibility of our program by measuring the following: (1) patients' adherence to basic care activities during hospitalization; (2) caregiver burden; and (3) appreciation of the program by patients, family members, and HCPs.

Methods

Study setting and design

This was a pragmatic, preference-based feasibility study carried out at the surgical ward in a 1,000-bed university hospital (Amsterdam University Medical Center, location Academic Medical Center, the Netherlands). The Medical Ethics Review Committee of the Amsterdam UMC (location Academic Medical Center) reviewed the study protocol and concluded that the Medical Research Involving Human Subject Act does not apply to this study (reference number W17_067#17.085). The study was conducted in accordance with the CONSORT extension for pilots and feasibility studies.[26] Both patients and their family members gave written informed consent for the study.

Study population

Consecutive patients undergoing elective pancreatic or esophageal resection with an expected hospital stay of ≥5 days were eligible for inclusion. Patients received an invitation to participate and written information about the study at the outpatient clinic, a few weeks before surgery. Patients who had a relative available and willing to participate were eligible for inclusion. Up to 3 relatives per patient were allowed to participate. Group allocation was preference based, meaning that when a patient and his or her relative wanted to participate in the program, they were allocated to the intervention group, and when a patient or his or her relatives did not want to participate in the program (but gave consent for observation in the control group) they were allocated to the control group.

Patients were excluded from participation when they had irresectable disease during surgery, or when they required prolonged observation (>48 hours) at the intensive care unit (ICU) directly after surgery because these scenarios precluded active participation.

Description of the intervention

The family involvement program was developed by a multidisciplinary team including nurses, doctors, a physician assistant, a physiotherapist, and a specialist in quality improvement. The development process and rationale of this program are described elsewhere in further detail (Eskes et al, unpublished data, April 2019). The program comprised multiple components, which are summarized in Table I.

Relatives were asked to participate in care, focusing on basic care activities (oral hygiene, early mobilization, breathing exercises, and cognitive activities). During their participation, relatives were coached by a qualified nurse. All activities were supervised until the nurse judged the relative able to carry out that activity alone. Before the trial period, nurses received training to prepare them for this coaching role.

Two rooms were refurnished to create a more homely atmosphere, with an extra bed for rooming in. Patients gave explicit consent to the presence of their family members during ward rounds. The program started the first day after surgery and was continued until hospital discharge or up to 2 weeks after surgery. If severe complications necessitated ICU admission, the program was ended because this setting and the clinical condition of the patient precluded active participation.

Table I
Components of the family involvement program

Component	Description	When?
Information	Family members received oral and written information on basic care activities	Before hospital admission
Task-oriented training	Family members were coached by a qualified nurse; activities were supervised until the nurse judged the family member able to carry out the activity alone	Daily
Joint goal setting	Nurse, patient and family member all partake in joint goal setting	Daily
Hands-on participation in care	Oral hygiene	2 times per day
	Mobilization (sitting in a chair or walking around)	3 times per day with increasing daily goals
	Breathing exercises	Aim: every awake hour; registered 3 times a day
	Cognitive activities	3 times a day
	Optional extra activities*	Tailored to the patients' needs and caregivers' skills
Presence at morning rounds	Family members were invited to be present at medical ward rounds	Daily
Rooming in	Family members were present for at least 8 hours per day and were invited to stay for up to 24 hours per day with the opportunity to sleep in the hospital.	Daily

* Optional extra activities included wound dressing, caring for abdominal drains, nasogastric and jejunal tubes, and administration of tube feeding and medication.

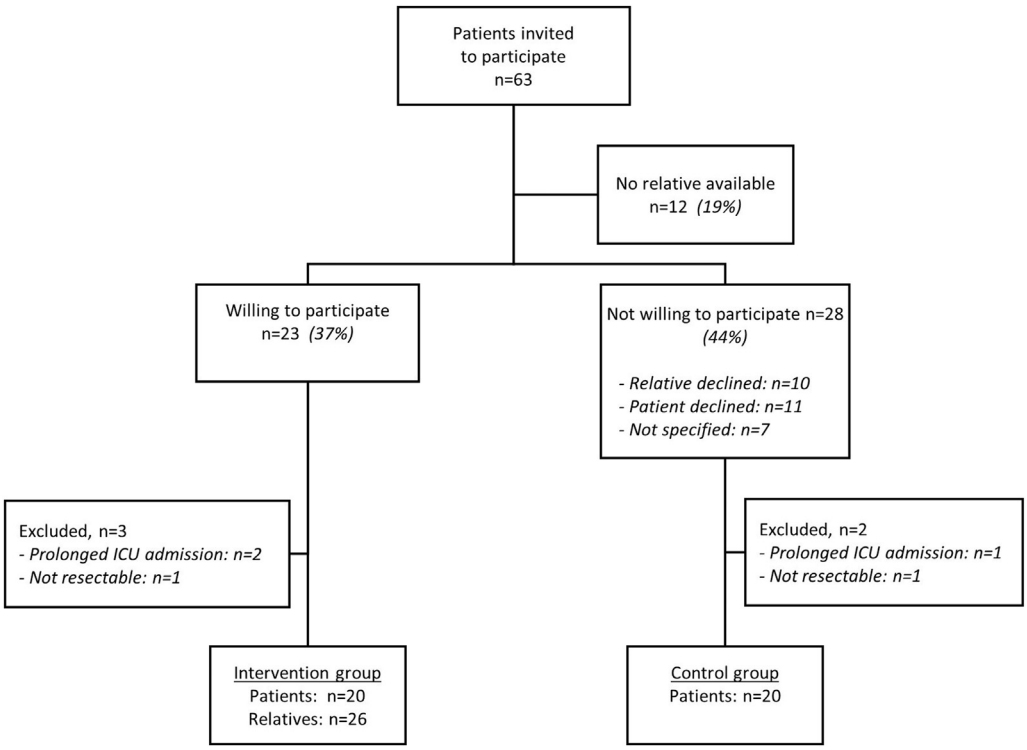


Fig 1. Flow diagram of participant inclusion.

Usual care

The control group received care as usual, meaning that all care was delivered by HCPs. Postoperative care in our wards is based on the enhanced recovery after surgery principles, pursuing early mobilization with day-to-day targets and early enteral intake (oral or per jejunal feeding tube). Normal standards were applied in the control group, including liberal visiting hours (11:00 AM to 9:00 PM). Rooming-in was possible if desired, but relatives did not participate in care.

Outcomes and data collection

The primary outcome was difference in patient-delivered care concerning the basic care set that relatives participated in (mobilization, oral hygiene, breathing exercises, and cognitive measures). Participating relatives kept a log recording all care activities delivered to the patient (eg, the amount of meters walked or the number of times breathing exercises were performed). The researchers (AMS or RvL) checked this log every 3 days to ensure data accuracy. For the control group the investigators (AMS or RvL) kept this log by visiting the patients on a daily basis.

Secondary outcomes included caregiver burden and satisfaction of patients, relatives, and HCPs. Patients in both groups, and participating relatives, completed questionnaires at baseline, discharge, and 3 weeks after discharge. Caregiver burden was measured using the Care-related Quality of Life instrument (Care-rQol-7d). This validated questionnaire assesses 2 positive (fulfilment and support) and 5 negative domains (relational problems, mental health problems, problems combining daily activities, financial problems, and physical health problems), resulting in a score from 0 to 100, a higher score representing favorable outcome.[27] It also contains a visual-analogue scale for happiness (score from 0–10).

A digital survey was held amongst all doctors and nurses toward the end of the trial period. This survey included questions regarding time investments, workload, opinions toward the program, and suggestions for improvement. All evaluations and experiences of the authors were used to formulate recommendations for the implementation of family involvement programs.

Data on clinical outcomes were retrieved from patient charts at the end of follow-up. This included overall morbidity ($\leq$90 days of surgery), complications sensitive to basic care (pneumonia, delirium, urinary tract infections, pressure ulcers, and malnutrition[20]), duration of stay, and unplanned hospital readmissions ($\leq$30 days of discharge).

Sample size and power analysis

Because this was a feasibility study and no data were available from literature to determine an expected effect for a power calculation, the sample size was established at 40 patients (20 patients and their relatives in the intervention group, and 20 patients in the control group). A post-hoc power analysis with 20 patients per group, a power of 80% and a 2-sided significance level of 0.05 resulted in an effect size of 0.9.

Statistical analysis

Statistical comparison for categorical data was made using a χ^2 test or Fisher exact test, as appropriate. Data with a normal distribution were compared using an independent Student *t* test, otherwise a Mann-Whitney *U* test was performed.

The primary outcome of delivered care was analyzed using a linear mixed-effects model for repeated measurements for continuous outcomes (meters walked and minutes sitting upright). Covariance structures were compared using a maximum likelihood method. The Akaike's Information Criterion was used to determine the best fitting covariance structure, after which a restricted

Table II
Baseline characteristics of patients and participating relatives

	Patients					Relatives	
	Intervention group N = 20		Control group N = 20		*P* value	N = 26	
	N	%, SD	N	%, SD		N	%, SD
Age (mean, SD)	64.9	9.5	62.8	8.9	.48	55	
Male	13	65	16	80	.29	7	27
ASA classification							
I	3	15	1	5	.50		
II	13	65	13	13			
III	4	20	6	30			
Medical history							
Hypertension	8	40	10	20	.53		
Pulmonary (COPD, asthma)	3	15	4	20	.68		
Cardiac	4	20	3	15	.68		
Diabetes	2	10	4	20	.38		
History of delirium	0	0	0	0	>.99		
Dementia	0	0	0	0	>.99		
ECOG performance score							
0	14	70	12	60	.78		
1	5	25	7	35			
2	1	5	1	5			
Living situation							
Independent at home	20	100	20	100	>.99		
Type of surgery							
Minimally invasive esophagectomy	10	50	10	50	.54		
Minimally invasive pancreatic surgery	9	45	7	35			
Open pancreatic surgery	1	5	3	15			
Surgery for malignancy	18	90	17	85	.63		
Relation to the patient							
Partner						17	65
Child						9	35
Highest level of education							
Secondary school						7	27
Post-secondary nonacademic						13	50
Academic						6	23
Work-situation							
Full-time paid work						9	35
Part-time paid work						9	35
Retired						6	23
Unemployed						2	8
Informal caregiver prior to hospital admission						2	8
Self-reported health status* (mean, SD)						8.2	±0.8

ASA, American society of Anesthesiologists; *COPD*, chronic obstructive pulmonary disease; *ECOG*, Eastern Cooperative Oncology Group; *VAS*, visual analogue scale.
* Score on a scale of 0 to 10.

maximum likelihood method was used to estimate parameters. Change in caregiver burden over time was also analyzed using a linear mixed-effects model. Delivered care with binary outcomes (oral hygiene, breathing exercises, and cognitive measures) were analyzed using a generalized estimation equation. Data were analyzed using SPSS software, version 24.0.0.1 (IBM Corp., Armonk, NY).

Results

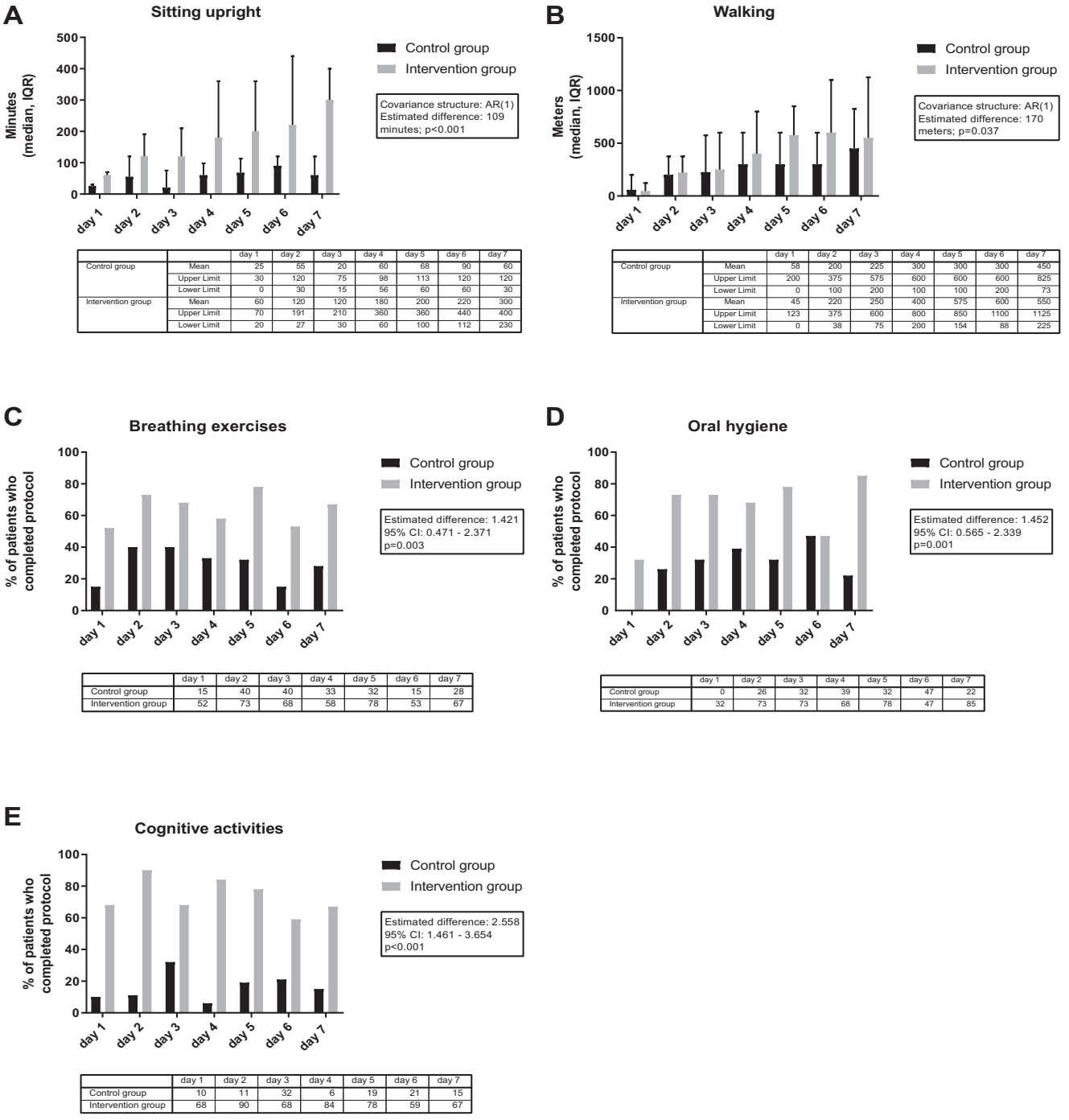
Inclusion

Between March and October 2017, a total of 63 patients were assessed for eligibility (Fig 1). Twelve patients did not have any relatives and were therefore unable to participate. Of 28 patients who declined participation, the first 20 consecutive patients were enrolled in the control group. Five patients were excluded from participation because of direct admission to the ICU after surgery ($n = 3$) or irresectable disease ($n = 2$). In total, 20 patients and 26 relatives were included in the intervention group; 4 patients had 2 participating relatives and 1 patient had 3 participating relatives. No patient or relative was lost to follow-up. Follow-up ended on December 7, 2017.

Groups were comparable regarding age, sex, medical history, and type of surgery (Table II). All patients lived independently at home before hospital admission. The majority of participating relatives were female (19 out of 26, 73%). They were either the partner (17 out of 26, 65%) or child (9 out of 26, 35%). Only 8 relatives (31%) had no work obligations: 6 were retired (23%) and 2 were unemployed (8%).

Patient-delivered care

Patient-delivered care is presented in Fig 2. The estimated difference in sitting upright was 109 minutes per day in favor of the intervention group ($P < .001$). The estimated difference in walking was 170 meters per day in favor of the intervention group ($P = .037$). Patients in the intervention group more often performed breathing exercises (estimated difference per day: 1.4, 95% confidence interval [CI], 0.5–2.4; $P = .003$), oral hygiene (estimated difference 1.5, 95% CI, 0.6–2.3; $P = .001$), and



		day 1	day 2	day 3	day 4	day 5	day 6	day 7
Control group	Mean	25	55	20	60	68	90	60
	Upper Limit	30	120	75	98	113	120	120
	Lower Limit	0	30	15	56	60	60	30
Intervention group	Mean	60	120	120	180	200	220	300
	Upper Limit	70	191	210	360	360	440	400
	Lower Limit	20	27	30	60	100	112	230

		day 1	day 2	day 3	day 4	day 5	day 6	day 7
Control group	Mean	58	200	225	300	300	300	450
	Upper Limit	200	375	575	600	600	600	825
	Lower Limit	0	100	200	100	100	200	73
Intervention group	Mean	45	220	250	400	575	600	550
	Upper Limit	123	375	600	800	850	1100	1125
	Lower Limit	0	38	75	200	154	88	225

	day 1	day 2	day 3	day 4	day 5	day 6	day 7
Control group	15	40	40	33	32	15	28
Intervention group	52	73	68	58	78	53	67

	day 1	day 2	day 3	day 4	day 5	day 6	day 7
Control group	0	26	32	39	32	47	22
Intervention group	32	73	73	68	78	47	85

	day 1	day 2	day 3	day 4	day 5	day 6	day 7
Control group	10	11	32	6	19	21	15
Intervention group	68	90	68	84	78	59	67

Fig 2. Patient-delivered care. (A) Sitting upright (in minutes), (B) walking (in meters); (C) breathing exercises; (D) oral hygiene; (E) cognitive activities. AR(1), first-order autoregression.

cognitive activities according to protocol (estimated difference 2.6, 95% CI, 1.5–3.7; $P < .001$) compared with patients in the control group.

Caregiver burden

No relative dropped out of the program. Over time, mean score on the CarerQoL-7d (baseline: 86 ± 9, hospital discharge: 84.5 ± 10.4, and 3 weeks after discharge: 83.3 ± 14.4, $P = .637$) and mean score on the visual-analogue scale happiness (baseline: 7.5 ± 1.1, discharge: 7.1 ± 1.5, and 3 weeks after discharge: 7.2 ± 1.6, $P = .268$) for participating relatives did not decrease (Fig 3). When asked to rate the burden of the program on a scale from 0 to 10 (0 being not burdensome at all, 10 being very burdensome), median score was 3 (IQR 0–5).

Patients' and caregivers' satisfaction with care

On a scale from 0 to 10 (0 being completely dissatisfied, 10 being completely satisfied), patients in the intervention group rated their

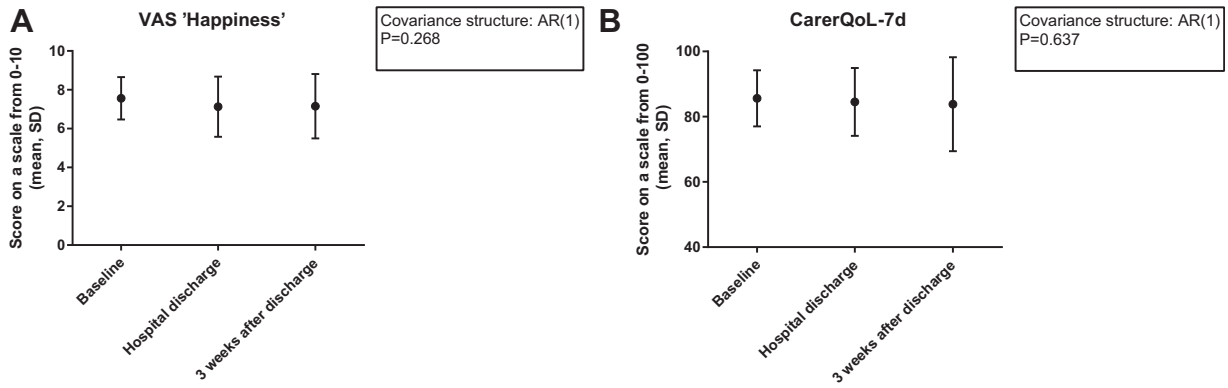


Fig 3. Caregiver burden of participating relatives. (A) Mean visual-analogue scale happiness, measured at baseline, at hospital discharge, and 3 weeks after discharge. (B) Mean score at CarerQol-7d measured at baseline, at hospital discharge, and 3 weeks after discharge. AR(1), first-order autoregression.

Table III
Clinical outcomes

	Intervention group N = 20		Control group N = 20	
	N	%, SD	N	%, SD
Overall mortality[*]	0	0	0	0
ICU admission	2	10	2	10
Overall morbidity[*,†]	11	55	11	55
No. of patients with ≥1 complications sensitive to basic care	3	15	6	30
Pneumonia	0	0	3	15
Delirium	1	5	1	5
Malnutrition	3	15	2	10
Urinary tract infection	0	0	1	5
Pressure ulcers	0	0	0	0
Postoperative LOS in days (median, range)	11	5–29	13	6–48
Use of homecare facility after discharge	5	25	6	30
Unplanned readmission[‡]	4	20	7	35
Duration of first readmission in days (median, range)	4.5	2–12	7	4–13

LOS, length of stay; *SSI*, surgical site infection.
[*] Within 90 days of surgery.
[†] including minor complications.
[‡] within 30 days of hospital discharge.

hospital admission with a median of 9 (IQR 8–10) versus a median of 7 (IQR 7–8) by patients in the control group ($P = .004$). Relatives rated the hospital admission with a median of 9 (IQR 8–10). When asked if they would attend the program again in the future, 96% of relatives (25 out of 26) and 100% of patients in the intervention group (20 out of 20) stated they would. Also, 96% of relatives (25 out of 26) and 100% of patients (20 out of 20) stated they would recommend the program to others.

All patients in the intervention group experienced emotional support because of the increased presence of their relatives. Also, 95% of patients (19 out of 20) and 92% of relatives (24 out of 26) thought that the transition toward home was positively influenced by their attendance to the program.

Doctors' and nurses' valuation of the program

The survey among doctors yielded a response rate of 51% (23 out of 45). When asked about time investment during ward rounds, 48% (11 out of 23) felt no extra time was needed, 48% felt it took a little more time, and 4% (1 out of 23) felt it took substantially more time. None of the doctors answered that the presence of a relative during rounds was obstructive, 79% (18 out of 23) thought their presence to be of additional value, whereas 21% (5 out of 23) were neutral about this.

The survey among nurses yielded a response rate of 65% (42 out of 65). When asked about time investment, a majority stated that taking care of a patient with a relative participating to the program took a little less (23 out of 42, 55%) or a lot less time (5 out of 42, 12%) compared with normal patient care. Seven nurses (17%) felt that taking care of these patients took a little more time; the remaining 7 (17%) were neutral. A majority of nurses (26 out of 42, 62%) thought the workload for these patients to be reduced to some extent.

Patient outcomes

Three out of 20 patients (15%) in the intervention group and 6 out of 20 (30%) in the control group had one or more complications sensitive to basic care (Table III). No patient in the intervention group developed a pneumonia, versus 3 out of 20 patients (15%) in the control group.

Median postoperative duration of stay was 11 days (range 5–29 days) in the intervention group and 13 days (range 6–48 days) in the control group. Four out of 20 patients (20%) in the intervention group were readmitted ≤30 days of discharge, versus 7 out of 20 patients (35%) in the control group.

Discussion

Active involvement of family members is an unused strategy with the potential to improve quality of care for adult surgical patients. This study showed that our family involvement program is feasible, resulting in increased adherence to basic care activities, without increasing caregiver burden. Participating family members, patients, and HCPs all valued this program positively.

Before our study, many surgeons and residents working on our surgical ward were hesitant toward the presence of relatives during ward rounds, fearing for privacy issues and longer ward rounds because of extra questions. At the end of the trial period, attitudes of HCPs toward family presence during ward rounds shifted and were predominantly positive. Advantages of family presence during rounds include a better understanding of the clinical course, an opportunity for shared decision-making, and the provision of extra information to the physician.[28–30] In pediatric patients, family

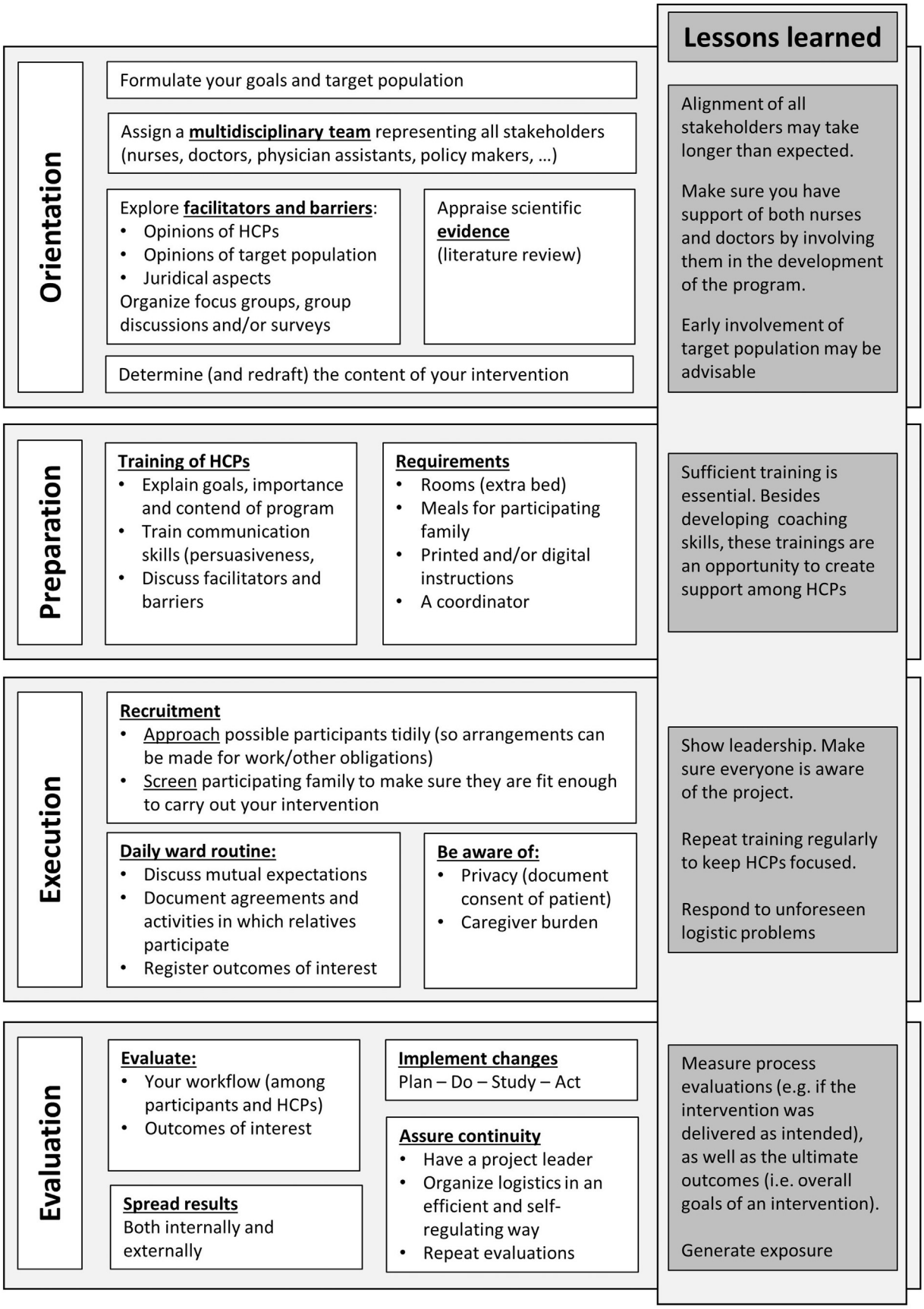


Fig 4. Recommendations for the implementation of family involvement initiatives. *HCPs*, healthcare professionals.

presence during rounds is much more standard of care than in adult patients and has therefore been studied more.[28]

Interventional programs focusing on active, hands-on participation of family are particularly scarce and mostly focus on rehabilitation in stroke patients.[16,31,32] Furthermore, a study in patients with heart failure and a study in geriatric patients both found lower readmission rates after in-hospital training of family members.[33,34] Our study was not powered to detect differences in clinical outcomes, but also showed a trend toward lower readmission rates in the intervention group.

The readmission rate in this study was relatively high compared with previous studies of this patient population.[19] This may be due to the fact that we recorded unplanned readmissions within 30 days after hospital discharge while previous studies recorded unplanned readmissions within 30 days of surgery. The small sample size may also have contributed to the higher incidence of readmissions. Furthermore, patients in the control group appeared to mobilize very little in this study. On average, they sat in a chair 55 minutes per day and walked 260 meters per day. Accordingly, several observational studies have established that hospitalized patients (even those who are perfectly capable of mobilizing) spend most of the day in bed.[35–37] Engaging relatives showed an effective strategy to promote mobility in our study.

Providing care to a loved one with a chronic illness may cause distress in family caregivers.[38] However, the status of physical dependency in surgical patients is generally temporary. In this study, we observed no increase in caregiver burden of participating relatives. Similarly, several studies training family members of acute stroke patients found no increase or even a decrease in caregiver burden.[31,32,39] Moreover, increased presence of a loved one can reduce anxiety and provide comfort for the patient.[31,34,40]

Besides the small sample size inherent to a pilot study, this study has several limitations. First, the nature of the intervention did not allow blinding of patients or outcome assessors. Because nurses were aware of the ongoing study, it is possible that they put extra effort in certain care aspects. Patients who participated in the control group received global information about the study, possibly making these patients more focused on basic care as well. This may have resulted in between-group contamination. Despite this possible confounding, a significant difference in adherence to basic care activities was observed. Post-hoc power analysis showed a large effect size of 0.9. Despite this we found significant differences in adherence to basic care activities between the intervention group and the control group, suggesting that the between-group differences were large and variance in the data was low. Second, patients in the control group declined participation in the intervention group, presumably introducing selection bias. We know from literature that a strong social support system has a positive influence on health status.[41] In future follow-up trials aiming to assess the effect of family involvement on clinical outcomes, selection bias should be minimized by randomization.

Attention to patient- and family-centered care has increased in recent years.[13,14] The Joint Commission International has incorporated the involvement of patients and their families in patient education, care planning, and shared decision-making in their accreditation standards, emphasizing that partnerships between HCPs, patients, and their families are mutually beneficial.[42] Involving family members in care requires changes in daily ward routine. For nurses, these changes are most noticeable: they must adapt a more coaching role, requiring specific skills and knowledge. Training HCPs is therefore essential in implementing such initiatives. Training in communication skills is most important because patients and families often perceive staff communication as inadequate and disconnected.[43] Our recommendations for the implementation of initiatives to promote family involvement are summarized in Fig 4. In particular, we learned that roles and expectations must be clearly defined and agreements should be well documented.

In future research, special attention should be paid to cost-effectiveness of family involvement. Socioeconomic costs of family caregivers, for example by loss of working days, should be weighed against the benefits from lower healthcare costs. This program is explicitly not intended to cut costs by lowering numbers of nursing staff because this would compromise quality of care.[44,45] Involving family members should be seen as an extension to standard care, not as a replacement. Because this program could reduce nurse workload by delegating simple tasks to family members, nurses may be allowed to spend their time and attention on more complex aspects of nursing care.

Active involvement of family members in postoperative care is feasible and is positively appreciated by patients, relatives, nurses, and doctors. This program leads to better adherence to basic care activities and promotes patient- and family-centered care. A large-scale study with a rigorous design is needed and is currently being prepared (Netherlands Trial Registry NTR7611) to assess the effectiveness of this program on clinical outcomes such as postoperative complications and hospital readmissions.

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Conflicts of interest/Disclosure

None

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