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Prospective Cohort Study

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Family caregiver outcomes after participating in a hospital-based family involvement program after major gastrointestinal surgery: a subgroup analysis of a patient preferred cohort study

Selma C.W. Musters, RN, MSc[a,b,*], Sani M. Kreca, RN[a,b], Susan van Dieren, PhD[a,b], Hanneke van der Wal-Huisman, RN, MSc[c], Johannes A. Romijn, MD, PhD[d], Wendy Chaboyer, RN, PhD[f], Els J.M. Nieveen van Dijkum, MD, PhD[a,b], Anne M. Eskes, RN PhD[a,b,e,f,*]; on behalf of the ARTIS Consortium

Background: Engaging families in postsurgical care is potentially beneficial for improving cancer patient outcomes and quality of care. The authors developed a family involvement program (FIP) and in this study, the authors aim to evaluate the impact of the FIP on family caregiver burden and well-being. Moreover, the authors aim to assess the fidelity of the program.

Materials and methods: This is a preplanned subgroup analysis of a patient-preferred prospective cohort study that included family caregivers of patients who underwent major oncological surgery for gastrointestinal tumors. Only patient-nominated family caregivers could participate in the FIP. Caregivers received structured training in fundamental caregiving tasks from healthcare professionals and then actively participated in these tasks. Caregiver burden and well-being were measured four times (at hospital admission, at hospital discharge, and at 1 and 3 months posthospital discharge) using the Caregiver Strain Index + (CSI +) and the Care-related Quality of Life instrument (CarerQoL-7D). The fidelity of the FIP was assessed by recording completion of care activities. In addition, family caregivers were asked whether they would participate in the FIP again.

Results: Most of the 152 family caregivers were female (77.6%), and their mean age was 61.3 years (SD = 11.6). Median CSI + scores ranged between – 1 and 0 and remained below the cutoff point of experiencing burden. CarerQoL-7D results indicated no significant differences in family caregivers' well-being over time. Upon discharge, over 75% of the family caregivers stated that they would recommend the FIP to others. The highest compliance with all fundamental care activities was observed during postoperative days 2–4.

Conclusion: The family caregivers of oncological surgical patients who participated in the FIP exhibited acceptable levels of caregiver burden and well-being. These findings suggest that the FIP is a valuable intervention to equip family caregivers with the skills to navigate the uncertain period following a patient's hospital discharge.

Keywords: caregiver burden, family-centered care, supportive care, surgical oncology

Introduction

Today, many cancer patients' main source of care is family caregivers[1], who undertake various tasks[2] such as assisting with activities of daily living (e.g. feeding, bathing, and dressing patients)[3] and instrumental activities (e.g. managing finances, cooking, and cleaning)[4]. Caregivers may also assume responsibility for monitoring patients' medication and performing complex medical or nursing tasks[5]. This broad range of caregiver responsibilities is frequently linked to physical and emotional strain[2], which could lead to both short-term and long-term problems (e.g. sleep disturbance, anxiety, depression, and

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[a]Department of Surgery, Amsterdam UMC location University of Amsterdam, Amsterdam, the Netherlands, [b]Cancer Center Amsterdam, Treatment and Quality of Life, Amsterdam, the Netherlands, [c]Department of Surgery, University of Groningen, University Medical Center Groningen, the Netherlands, [d]Amsterdam UMC Location University of Amsterdam, Amsterdam, the Netherlands, [e]Faculty of Health, Center of Expertise Urban Vitality, Amsterdam University of Applied Sciences, Amsterdam, The Netherlands and [f]Menzies Health Institute Queensland and School of Nursing and Midwifery, Griffith University, QLD, Australia

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*Corresponding authors. Address: Department of Surgery, Cancer Center Amsterdam, Amsterdam UMC, University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands. Tel.: +312 056 645 65. E-mail: a.m.eskes@amsterdamumc.nl (A.M. Eskes); Department of Surgery, Amsterdam UMC, University of Amsterdam, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands. Tel.: +312 0256 6445 65. E-mail: s.c.musters@amsterdamumc.nl (S.C. Musters).

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financial difficulties)[6]. This strain is associated with family caregivers not feeling adequately prepared to provide care[7]. For example, they often perform medical or nursing tasks for which they have not received training[8]. The first weeks after hospital admission among the most stressful times for most of family caregivers[2].

Nevertheless, a growing body of evidence suggests that family involvement during hospital admission increases the quality of care[9,10]. When family members are involved in transitional care interventions or live near the patient, the number of unplanned readmissions is significantly reduced[11,12]. Moreover, family-centered care benefits family members, as they report greater levels of satisfaction when involved in care[13].

When involving family caregivers, training is essential to ensure high-quality care[14,15]. According to a meta-analysis of randomised controlled trials, training and skill development can reduce caregiver burden[16]. Using the time in hospital to train family caregivers can support them in the transition to home and prepare them for their caring role after discharge. Therefore, we developed a family involvement program (FIP) in which family caregivers were trained, during patients' hospital admission, to perform fundamental care activities.[17–20]. We then undertook a prospective cohort study investigating the FIP's effect on unplanned readmissions, patients' physical outcomes (e.g. complications), and health services outcomes among adult patients undergoing oncological gastrointestinal surgery. We found a significant reduction in patients' home care need (*submitted*). However, a decrease in such needs suggests greater family involvement in postdischarge care, possibly resulting in increased caregiver burden.

In this study, we aimed to evaluate family caregiver outcomes after participation in a hospital-based FIP following patients' major gastrointestinal surgery and to assess family caregivers' burden and their well-being up to 90 days after discharge. In addition, we aimed to evaluate the fidelity of the FIP.

Methods

Study design

We conducted a preplanned subgroup analysis of a subset of the participants in a multicentre prospective cohort study results of ARTIS-1. The study protocol, the [results of ARTIS-1 Blinded during review] study and other scientific work regarding the development of the FIP and qualitative evaluations of patient and family caregiver experiences have been published elsewhere.[17–20] The program was implemented in two academic hospitals across multiple wards for gastrointestinal oncology surgery in the Netherlands.

Participants

This study included family caregivers (≥18 years) of patients undergoing major oncological surgery for gastrointestinal tumors. The definition of a family caregiver was broad, encompassing both relatives and close friends. Each patient could nominate up to three caregivers for the FIP. The caregivers needed to assist in fundamental care during hospitalization, committing to a minimum of 8 h daily for at least 5 days after surgery. Proficiency in reading and writing Dutch language was necessary for receiving information through a mobile application. Caregivers were ineligible if they required professional care themselves.

HIGHLIGHTS

- A substantial group of cancer patients undergoing surgery receive care through family caregivers; however, patients' families often lack necessary skills and training.
- A family involvement program has the potential to involve family caregivers in care and show acceptable levels of caregiver burden and caregiver's well-being.
- The program could be a valuable intervention to equip family caregivers with the necessary skills to navigate the uncertain period following a patient's discharge from the hospital.

Intervention

In the multicomponent FIP, nurses trained family caregivers in fundamental care activities, involving hands-on participation during hospitalization and bedside teaching (Textbox 1). The *Mantelzorg* mobile app provided written information, step-by-step guides, and material requirements for each task. For caregivers without smartphones, a paper-based form was available. Family caregivers, patients, and healthcare professionals set shared goals based on the patients' care needs and the family caregivers' personal goals. Family caregivers were allowed to be present during medical ward rounds and ask questions. Caregivers could also receive training in optional care activities such as wound dressing, and managing drains or injections.

Textbox 1

Fundamental care activities performed by family caregivers.

Three times a day

- Assisting with patient mobilizing, which is defined as getting a patient out of bed (i.e. sitting out of bed and ambulation).
- Encouraging oral intake and providing companionship during meals (i.e. breakfast, lunch, and dinner) and ensuring that patients are seated at the table when meals are served.
- Stimulating patients to perform breathing exercises (i.e. coughing and deep breathing).
- Supporting active orientation of patients by providing specific time-related, place-related, and person-related information in the context of the present day and engaging in daily discussions on real-world subjects (e.g. news).

Two times a day

- Assisting in oral care (brushing teeth and using mouthwash).

*Table previously published in Musters *et al.*[20]

Outcomes

The main outcomes of this study were the FIP's effects on caregiver burden and well-being. Additionally, the fidelity of the intervention was assessed.

Caregiver burden

Caregiver burden was measured using the Caregiver Strain Index+ (CSI+) at hospital admission, hospital discharge, 30 days after discharge, and 90 days after discharge[21]. The CSI+ ranges from −5 to 13, and a score ≥7 indicates that a family caregiver has experienced substantial strain[21]. Subjective caregiver burden outcomes included self-rated burden scores, measured using a visual-analog scale (VAS ranging from 0 ‘not straining at all’ to 10 ‘too much straining’) at discharge and 30 and 90 days after discharge[22]. Moreover, perseverance time (i.e. whether caregivers were anticipated to maintain their care tasks for a duration of more than 6 months) was included as an outcome of this study[23]. For objective caregiver burden, we measured the intensity of informal care, which included the number of hours spend on household activities, personal patient care, and practical support of the patient in the last week, at 30 and 90 days after discharge[24]. Family caregivers’ health statuses were measured using a VAS with start-points and endpoints of ‘worst possible health’ and ‘best possible health’, and use of professional home care was measured[24].

Caregiver well-being

Family caregivers’ well-being was measured using the Care-related Quality of Life instrument (CarerQoL-7D)[25]. This instrument contains five negative and two positive dimensions concerning the provision of informal care. In addition, the Care-related Quality of Life-Visual Analog Scale (CarerQoL-VAS), with a visual-analog scale ranging from 0 ‘completely unhappy’ to 10 ‘completely happy’, was employed[25].

Fidelity of the FIP

Using a mobile app, we collected the mean percentage of fundamental and optional care activities performed by family caregivers in the first 5 days after surgery. The app included a daily diary that allowed caregivers to check boxes indicating task completion and gave them the option to add written comments. We also recorded the number of caregivers staying overnight in patients’ rooms, verified by ward nurses and researchers.

FIP program outcomes

In addition to the outcomes documented in the study protocol[20] we collected the following FIP program outcomes: number of family caregivers who would recommend the program to others and number of caregivers who would participate in the program again. We used a numeric rating scale to evaluate transition from hospital to home, overall hospital satisfaction, and FIP severity.

Other measures

On the day of admission, family caregivers were asked to complete the baseline questionnaire in the app. The following baseline variables were collected: sex, age, highest level of formal education, and patient and family caregiving relationship prior to admission[24]. In addition, household composition, (un)paid work, monthly net household income and number of family caregivers per patient were reported in the app[24]. Finally, the following baseline characteristics of patients participating in the FIP-arm of the ARTIS-1 study were collected: sex, age, WHO score, type of surgery, use of professional home care prior to admission, and health status (measured using a visual-analog scale ranging from 0 ‘worst possible health’ to 10 ‘best possible health’)[24].

Statistical analyses

We summarized family caregivers’ baseline characteristics using descriptive statistics. Continuous variables were presented as means with SDs or medians with inter quartile ranges (IQRs), according to the distribution of the variables. Categorical variables were presented as numbers and frequencies (%) for dichotomous data. Statistical analyses were conducted using R software (version 3.6.2; R Foundation for Statistical Computing).

To assess potential differences at baseline, discharge, and 30 and 90 days after discharge, we used a repeated measures ANOVA for normally distributed continuous outcomes and Friedman tests for non-normally distributed outcomes. Post-hoc analyses or Wilcoxon rank tests with Bonferroni correction were performed for significant differences. For dichotomous outcomes, we applied Cochrane’s Q and post-hoc McNemar tests with Bonferroni correction if differences were significant.

Ethical considerations

The Medical Ethics Review Committee (METC) of the Amsterdam UMC reviewed the study and concluded that the Medical Research Involving Human Subject Act did not apply (W19_497#20.015). Patients and family caregivers provided verbal and written informed consent. This study is reported according to the Strengthening the Reporting of Cohort Studies in Surgery (STROCSS) criteria[26].

Results

Family caregiver characteristics

This study comprised 152 family caregivers who participated in the ARTIS-1 study, which included 302 patients (FIP: $n=152$ and $n=149$ usual care). Most family caregivers were female (77.6%), and most patients in the FIP group were male (72.4%; Table 1). The mean family caregiver age was 61.3 years ($SD=11.6$), and the mean patient age was 65.3 ($SD=9.9$). Two patients nominated more than one family caregiver for the FIP (Table 1).

Outcomes

Family caregiver burden

Median CSI+ scores varied significantly over time (i.e. at baseline, discharge, and 30 and 90 days; Fig. 1) but consistently remained below the cutoff point of 7, indicating a manageable level of burden. Notably, substantial increases occurred from baseline to discharge [mean difference (MD): 0.89, $P<0.01$] and from baseline to 30 days after discharge (MD: 1.40, $P<0.01$). Between 30 and 90 days after discharge, scores significantly decreased (MD: –1.06, $P<0.01$). Similarly, self-rated burden scores differed significantly across time points: increases were observed from baseline to discharge (MD: 1.54, $P<0.01$) and from baseline to 30 days after discharge (MD: 0.86, $P<0.01$). Self-rated burden scores decreased between discharge and 90 days after discharge (MD: –1.38, $P<0.01$) and between 30 and 90 days after discharge (MD: –0.70, $P<0.01$). At discharge, 38.2% of family caregivers indicated that they anticipated being able to continue providing care for more than 6 months (Table 2). After 90 days, over half of the family caregivers indicated a perseverance time of more than 6 months. A significant 18.4% increase occurred between discharge and 30 days after discharge ($P<0.01$), with a subsequent 4.6% decrease between 30 and 90 days after discharge ($P<0.01$). Upon hospital admission, family caregivers had an average health status score

Table 1

Baseline characteristics family caregivers and patients.

Family caregivers	**(*n* = 152)**	
Sex, female (*n*, %)	118	77.6
Age[a] (mean, SD)	61.3	11.6
Highest level of formal education[ab] (*n*, %)		
Lower education	24	15.8
Medium education	63	41.4
Higher education	53	34.9
Relationship with patient[a] (*n*, %)		
Spouse	122	80.3
Other[c]	19	12.5
Number of family caregivers per patient (*n*, %)		
1	150	98.7
> 1[d]	2	1.4
Family caregiver has partner (*n*, %)	144	94.7
Children[a] (*n*, %)	113	74.3
Children living at home family caregiver[a] (*n*, %)	22	14.5
Paid work[a] (*n*, %)	34	22.4
Unpaid work[a] (*n*, %)	14	9.2
Monthly net Income[a] (*n*, %)		
< €1.000 euro	3	2.0
€1.000–€1.999 euro	55	36.2
€2.000–€2.999 euro	37	24.3
€3.000–€3.999 euro	14	9.2
€4.000–€4.999 euro	4	2.6
≥ €5.000 euro	21	13.8
I do not know or I do not want to state this	6	3.9
Family caregiving prior admission[a] (*n*, %)		
No	99	65.1
Yes, <1 month prior admission	7	4.6
Yes, between 1 month and 1 year prior admission	24	15.8
Yes, > 1 year prior admission	8	5.3
Patient and family caregiver sharing household[a] (*n*,%)	97	63.8
Patient can be left alone[a]		
No, patient needs continuous surveillance	4	2.6
Yes, but not for more than 1 hour	2	1.3
Yes, patient can easily be left alone for several hours (or more)	111	73.0
Sex, male (*n*, %)	110	(72.4)
Age (mean, SD)	65.3	(9.9)
WHO performance status (*n*, %)		
0	107	(70.4)
1	35	(23.0)
2	10	(6.6)
Type of surgery (*n*, %)		
Pancreatic surgery	59	(38.8)
Esophageal surgery	54	(35.5)
Peritoneal surgery	12	(7.9)
Liver surgery	12	(7.9)
Gastric surgery	10	(6.6)
Colorectal surgery	3	(2.0)
Other[e]	2	(1.3)
Use of professional home care prior admission[a] (*n*, %)	17	11.2
Health status of patient, VAS (mean, SD)	6.3	(2.1)

n, number; WHO performance status, World Health organization performance status.

[a] Missing values occurred for these variables and ranged between 7.2 and 27.0% with an outlier for variable paid work (63.2%) and for variable unpaid work (73.7%).

[b] Lower education level includes primary education plus the first three years of senior general secondary education (HAVO) and pre-university secondary education (VWO); prevocational secondary education (VMBO) including lower secondary vocational training and assistant's training (MBO-1). Medium education level include upper secondary education (HAVO/VWO), basic vocational training (MBO-2), vocational training (MBO-3), and middle management and specialist education (MBO-4). Higher education level include associate degree programmes, higher education (HBO/WO) Bachelor programmes; 4-year education at universities of applied sciences (HBO); Master degree programmes at universities of applied sciences and at research universities (HBO, WO); and doctoral degree programmes at research universities (WO).

[c] Other types of relationship with patient include parent, child, other family member and friend.

[d] 1 patient had 2 family caregivers and another patient had three family caregivers.

[e] Type of surgery includes: Pancreatic surgery includes: pancreatic tail resection, pylorus sparing pancreatico-duodenectomy, classic whipple, pancreas corpus resection; gastric surgery includes: esophageal and gastric cardiac resection, subtotal gastrectomy, total gastrectomy; liver surgery includes: left- and right hemihepatectomy; colorectal surgery includes: left hemicolectomy, sigmoid colectomy, protectomy with ileostomy; peritoneal surgery includes: HIPEC, abdominoperineal resection; other surgeries include: bile duct resection.

of 8.2 (SD = 1.2); after 90 days, the average score was 7.4 (SD = 1.3). A significant decrease was observed between baseline and 30 days after discharge (MD: 0.70, $P < 0.01$).

Family caregiver well-being

The CarerQoL-7D results indicated no significant differences in family caregivers' well-being over time (i.e. at baseline, discharge, and 30 and 90 days; Table 1). Family caregivers had an average CarerQoL-VAS score of 7.4 (SD = 1.6) at the beginning of the FIP; after 90 days, this score remained the same (MD: 7.4; SD = 1.4). However, post-hoc analysis revealed differences between scores at hospital admission and discharge (MD: – 0.47; $P = 0.03$) and between scores at discharge and 30 days after discharge (MD: 0.42; $P < 0.01$).

FIP program outcomes

Upon discharge, over 75% of family caregivers stated that they would recommend the FIP to others, and 69.1% reported that they felt better prepared to return home (Table 1). However, family caregivers assigned a median score of 5.0 (IQR: 2.0–7.0) when evaluating the transition from the hospital to home. The median score for overall hospital satisfaction was 9.0 (IQR: 8.0–9.0), both at the time of discharge and 30 days after discharge.

Fidelity outcomes

Figure 2 presents the average percentages of fundamental care activities carried out by family caregivers. The highest adherence to all mandatory care activities was observed during postoperative days 2 to 4. Overall, assistance in oral care had the highest fidelity percentage (range: 44.1–72.0%). By contrast, the fidelity percentage was found for assistance in patient mobilization (range: 22.9–47.0%). Detailed descriptions of caregivers' fidelity regarding mobilization (i.e. minutes of sitting, minutes of walking, and meters of walking), optional care activities, and rooming-in are reported in the Supplementary File (Supplemental Digital Content 1, http://links.lww.com/JS9/C403), (Supplemental Digital Content 2, http://links.lww.com/JS9/C404), (Supplemental Digital Content 3, http://links.lww.com/JS9/C405).

Discussion

This preplanned subgroup analysis of an FIP in which family caregivers participated in postoperative care activities showed acceptable levels of caregiver burden and no clinically relevant changes in caregivers' well-being. Moreover, family caregivers were involved in the majority of both fundamental and optional care activities. As the postoperative days proceeded, family caregivers' roles increased, possibly because they felt more confident in their skills. Furthermore, this evaluation demonstrated

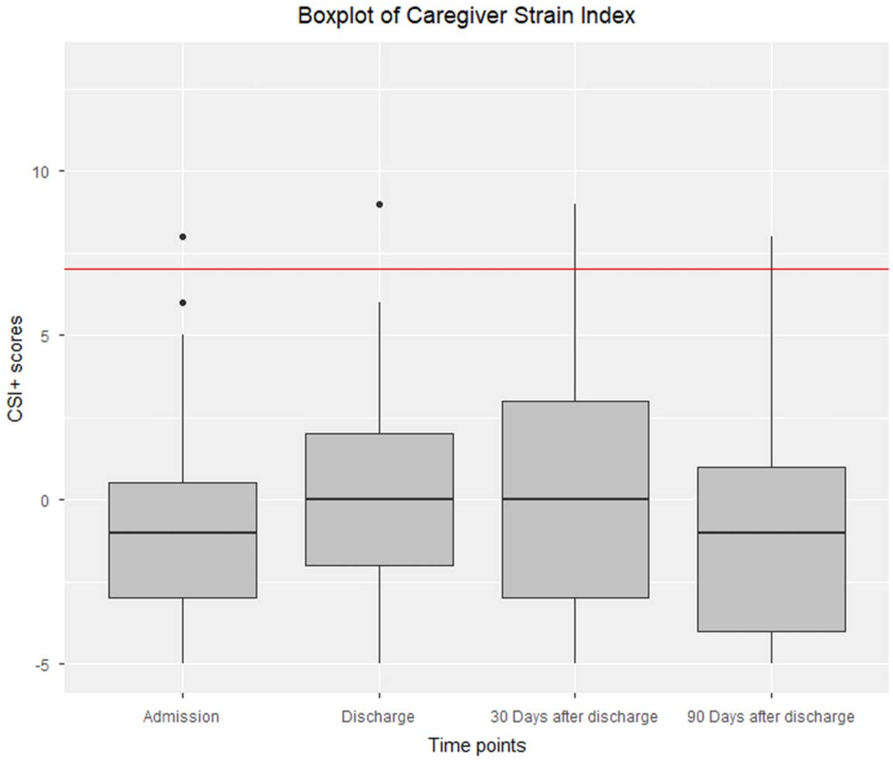

Figure 1. Boxplot of Caregiver Strain Index. Caregiver Strain Index plus (CSI +) scores of family caregivers during the study period. Horizontal line represents cut-off score of experiencing caregiver burden. Missing values ranged between 13.8 and 34.9%.

family caregivers' overall positive experience with hospital admission. Most caregivers reported that they would recommend the FIP to others.

These quantitative findings about caregiver burden align with our previous qualitative interview study, in which we evaluated the experiences of 12 family caregivers who participated in the FIP.[19] In the qualitative study, caregivers reported positive experiences with the opportunity for physical proximity and the opportunity to be involved in all elements of the healthcare process.[19] In addition, caregivers discussed the concept of burden, which was evident in their experiences of exhaustion and anxiety.[19] Nevertheless, they indicated that the program's positive effects outweighed its burden.[19] These findings correspond to the quantitative data collected from a much larger group of families in the present analysis. While levels of burden changed significantly over the study period, the changes were not considered to be clinically relevant. For example, the family caregivers' CSI + scores changed significantly over time but remained below the cutoff point of experiencing burden.

While a CSI + score can be helpful to diagnose significant burden, it remains uncertain whether it accurately reflects caregiver burden[27]. Caregivers do not perceive all CSI + items equally problematic[27]. Therefore, we added the self-rated burden scale to the study. This scale considers overall positive and negative effects by asking caregivers how burdened they feel when caring for or accompanying the patient. We observed equal levels of self-rated burden at the beginning of the FIP and 90 days after discharge, indicating that burden was in an acceptable range.

Despite acceptable short-term outcomes, caregivers' well-being continues to be a point of concern, as it is widely recognized that the burden among caregivers of cancer patients is high[28]. Burden is particularly severe in caregivers of pancreatic cancer patients[2]. This burden is likely to increase as family caregivers' roles will expand[29] with the expected rise in the number of cancer patients[30], global healthcare shortages[31], and the shift from in-hospital recovery to home-based recovery[32]. Therefore, an FIP is a useful approach to prepare caregivers for their roles. As suggested by a review of randomised controlled trials of caregiver interventions, practical skill training might be more effective for caregivers than psychosocial support or educational information in alleviating patient symptoms[8,14].

Strengths and limitations

We used multiple instruments to measure burden and well-being, collecting data at various times during hospitalization and up to 90 days after discharge, when the highest level of burden is expected[2]. However, our findings have some limitations. First, caregiver burden levels might be underestimated because caregivers tend to hide negative emotions, as indicated in the literature[33]. Nonetheless, we gained in-depth information about caregiver experiences with the FIP in our qualitative study, wherein acceptable levels of burden were mentioned.[19] Second, family caregivers may have

Table 2

Family caregiver outcomes.

Family involvement program ($n=152$)	Admission	At discharge	30 days after discharge	90 days after discharge	*P*
Family caregiver burden					
Self-rated burden, NRS (median, IQR)	2 (1–4)	4 (2–6)	3 (1–6)	2 (1–4)	$<0.01^{ab}$
Perseverance time, ≥6 months (*n*, %)	–	58 (38.2)	86 (56.6)	79 (52.0)	$<0.01^{cd}$
Household activities, hours/week (median, IQR)	–	–	7.0 (2.0–15.0)	4.0 (0.0–8.0)	$<0.01^{e}$
Personal care for patient, hours/week (median, IQR)	–	–	2.0 (0.0–7.0)	0.0 (0.0–2.0)	$<0.01^{e}$
Practical support for patient, hours/week (median, IQR)	–	–	3.0 (1.0–7.0)	0.0 (0.0–3.0)	$<0.01^{e}$
Health status of family caregiver, VAS (mean, SD)	8.2 (1.2)	8.0 (1.5)	7.7 (1.2)	7.4 (1.3)	$<0.01^{fg}$
Well-being					
CarerQoL-7D (mean, SD)	80.0 (10.9)	81.4 (11.0)	78.7 (12.3)	79.8 (11.5)	0.09^{f}
CarerQoL-VAS (mean, SD)	7.4 (1.6)	7.6 (1.3)	7.3 (1.5)	7.4 (1.4)	$<0.01^{fg}$
Fip program outcomes					
Family caregiver would recommend program to others (*n*, %)	–	116 (76.3)	115 (75.7)	95 (75.7)	0.22^{c}
Family caregiver felt better prepared with program (*n*, %)					–
Better prepared	–	105 (69.1)	–	–	
Less prepared with program	–	1 (0.7)	–	–	
No difference with program	–	12 (7.9)	–	–	
Family caregiver would participate in program again (*n*, %)		118 (77.6)	118 (77.6)	97 (63.8)	0.37^{c}
Transition to home, NRS (median, IQR)	–	5.0 (2.0–7.0)	–	–	–
Severity of the FIP, NRS (mean, SD)	–	4.1 (2.7)	4 (2.9)	3.5 (2.8)	0.09^{f}
Overall hospital satisfaction, NRS (median, IQR)	–	9.0 (8.0–9.0)	9.0 (8.0–9.0)	–	0.78^{e}

CarerQoL-7D, Care-related Quality of Life instrument-7 Dimensions; CarerQoL-VAS, Care-related Quality of Life-Visual Analog Scale; FIP, Family Involvement Program; IQR, Inter Quartile Range; n, number; NRS, Numeric Rating Score; SD, Standard Deviation; VAS, Visual Analog Scale.

Missing values occurred for all variables and ranged between 7.9 and 34.2% with an outlier for variable severity of the FIP (38.8%) and variable family caregivers' health status 90 days after discharge (61.8%).

[a] Friedman test.

[b] Post-hoc analysis: Wilcoxon rank test including Bonferroni correction of $P<0.0083$.

[c] Cochrane's Q test.

[d] Post-hoc analysis: McNemar test including Bonferroni correction of $P<0.02$.

[e] Wilcoxon signed rank test.

[f] Repeated measures ANOVA.

[g] Post-hoc analysis: pairwise difference including Bonferroni correction of $P<0.0083$.

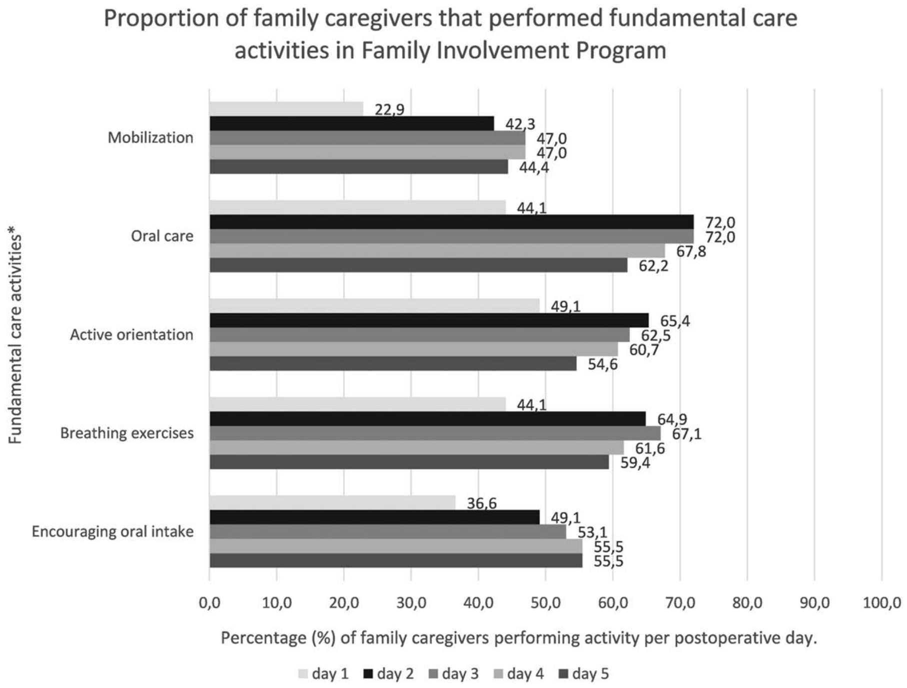

Figure 2. Proportion of family caregivers that performed fundamental care activities in Family Involvement Program. Caption: Proportion of family caregivers that performed fundamental care activities per postoperative day during the Family Involvement Program. * Family caregivers needed to perform the fundamental care activities three times daily, with the exception of oral care, which was performed two times a day. The percentages presented in Figure 2 represent the average values across three (or two) distinct moments.

underreported the fundamental and optional care activities they performed. We assumed that a care activity had not been performed if not registered in the app. However, family caregivers did not always find the time to register activities; furthermore, following the first five postoperative days, some patients were able to perform the care activities independently and no longer required assistance. Finally, considering that we only included patients and family caregivers who could read and write Dutch, our study population may lack diversity, which could affect the generalizability of the study. However, this remains a presumption, as we did not collect data on participants' cultural backgrounds and health literacy levels.

Implications for clinical practice and future research

The FIP was a valuable intervention to equip family caregivers with skills to navigate the uncertain period following a patient's discharge from hospital. While some literature suggests that informal care can be highly demanding, the family caregivers who participated in our FIP were able to strike a balance between addressing the patients' needs and fulfilling their own. This program should be implemented in other settings and hospitals, with awareness that participation is voluntary and cannot be forced upon family caregivers. Furthermore, it is crucial to emphasize that while family involvement is encouraged, it is not a substitute for professional care, as monitoring patient safety and caregiver burden remains important. Training and coaching family caregivers requires a time investment from healthcare professionals. Most benefits are likely to occur in the home setting, for example, a reduction in home care needs (submitted).

In future research, it is important to be aware that interventions like the FIP should ensure a more representative and comprehensive sampling of the study population. This comprehensive sampling encompasses factors such as age, gender, socioeconomic status, health literacy levels, and cultural background. Expanding eligibility criteria not only enhances research ethics but also ensures that study findings are relevant and impactful for diverse communities. Furthermore, informed consent procedures should be tailored to different health literacy levels, including the use of multimedia resources such as short videos in addition to traditional paper-based information. Our next step is to conduct a stepped wedge study focusing on the implementation of the FIP in other settings and hospitals, which will take these items into account.

Conclusion

While caregiver burden levels varied over the study period, this subgroup analysis demonstrated that patients' family caregivers experienced acceptable levels of burden. Family caregivers' wellbeing also varied over the study period but remained within an acceptable range for each of the time points measured. Furthermore, our findings indicate that family caregivers can carry out fundamental and optional care tasks, indicating the program's efficacy. Moreover, our findings show that family caregivers would participate again and would recommend the program to others. This suggests that a FIP is a valuable intervention to equip family caregivers with the skills to navigate the uncertain period following a patient's discharge from the hospital. The FIP promotes increased family engagement in postdischarge care while mitigating negative effects on family caregivers' burden and well-being.

Ethical approval

The Medical Ethics Review Committee (METC) of the Amsterdam UMC (location AMC), Amsterdam, The Netherlands reviewed the study and concluded that the Medical Research Involving Human Subject Act did not apply to this study (W19_497#20.015).

Consent

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in- Chief of this journal on request.

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Author contribution

L.L.: data collection, data analysis or interpretation, and writing the paper; S.Q., Q.X., and K.L.: provision of study materials, data collection, data analysis, or interpretation; Y.Y., Y.Z., S.Y., and J.C.: provision of study materials, writing – review and editing; B.X.: provision of study materials and supervision; W.Y. L.: study concept or design, supervision, and writing – review and editing; W.Z.: study concept or design, project administration, supervision, and writing – review and editing.

Conflicts of interest disclosure

The authors declare no conflicts of interest.

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Guarantor

Weiping Zhou.

Data sharing statement

Participant data is available upon reasonable request from the corresponding author.

Provenance and peer review

None.

Presentation

None.

Members of the ARTIS-consortium

Marc G.H. Besselink MD PhD, Amsterdam UMC location University of Amsterdam, Department of Surgery, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands; Chris A. Bakker RN, Amsterdam UMC location University of Amsterdam, Department of Surgery, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands; Rosanna van Langen MSc, Amsterdam UMC location University of Amsterdam, Department of Surgery, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands; Charlotte Heidsma MD PhD, Amsterdam UMC location University of Amsterdam, Department of Surgery, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands; Marjan Ouwens RN, Amsterdam UMC location University of Amsterdam, Department of Surgery, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands; Marie-José Hendriks RN, Amsterdam UMC location University of Amsterdam, Department of Surgery, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands; Barbara L. van Leeuwen MD PhD, Department of Surgery, University of Groningen, University Medical Center Groningen, Hanzeplein 1, 9713 GZ Groningen, the Netherlands; Maarten de Jong RN, Department of Surgery, University of Groningen, University Medical Center Groningen, Hanzeplein 1, 9713 GZ Groningen, the Netherlands; Rommy Hoekstra RN, Department of Surgery, University of Groningen, University Medical Center Groningen, Hanzeplein 1, 9713 GZ Groningen, the Netherlands; Reggie Smith RN, Amsterdam UMC location University of Amsterdam, Department of Surgery, Meibergdreef 9, 1105 AZ Amsterdam, the Netherlands; Marthe Schreuder MD PhD.

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