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ORIGINAL ARTICLE

# Feasibility and effectiveness of an evidence-based intervention bundle to improve peri-operative care of older adults

## *A quality improvement study*

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**BACKGROUND** Maintaining functional status is an essential therapeutic goal in peri-operative care of older adults. Although several recommendations concerning peri-operative management are available, pragmatic approaches to their sustainable implementation are lacking.

**OBJECTIVE** Multiple evidence-based recommendations for peri-operative care of older adults were bundled into a multicomponent intervention and assessed for feasibility and effectiveness.

**DESIGN** A quality improvement study with before–after comparison using a hybrid implementation-effectiveness approach.

**SETTING** University Medical Centre. The trial was conducted from 2017 to 2020, follow-up was 1 week, 1 month and 6 months after surgery.

**PATIENTS** Patients at least 65 years old were scheduled for surgery; excluded: intercranial, ophthalmological, and emergency surgery; planned postoperative stay in the intensive care unit. A total of 720 patients were eligible; 278 patients were recruited, 95 (34) of whom were female.

**INTERVENTIONS** The intervention consisted of a set of recommended measures for peri-operative management of older patients, including pre-operative assessment and measures to manage frailty, malnutrition, polypharmacy, cognitive impairment and delirium. Patients were sequentially assigned to three groups: control (no change from usual care), transition (to implementation of the intervention) and intervention (fully implemented).

**MAIN OUTCOME MEASURES** Feasibility was assessed by determining the level of implementation, and barriers were identified by conducting qualitative interviews with the medical staff. Intervention effectiveness was estimated by Instrumental Activities of Daily Living (IADL; Lawton and Brody, primary clinical outcome) 1 and six months postoperatively. The secondary outcomes included postoperative complications, cognitive performance, quality of life and length of hospital stay.

**RESULTS** The implementation rate was 77%. Pre-operative IADL was 9.9/10 (range 8 to 10; SD 0.4) and 9.7/10 (6 to 10, 0.8) for the control and intervention groups, respectively. There was no statistically significant difference between the groups in IADL (0.07, 95% CI −0.23 to 0.36, $P = 0.66$) and 6 months after surgery (0.01, 95% CI −0.29 to 0.31, $P = 0.95$).

**CONCLUSION** The implementation of evidence-based interventions to improve peri-operative care of older patients showed good feasibility in clinical routine but did not improve patients' functional status, which was already at a high level pre-operatively.

**TRIAL REGISTRATION** ClinicalTrials.gov, Identifier: NCT03325413

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**KEY POINTS**

- A multicomponent intervention of evidence-based measures for peri-operative care of older patients could be implemented in routine clinical practice with good feasibility.
- Most patients aged older than 65 years were still relatively fit, and even if peri-operative geriatric anaesthesia care bundles were applied, there would be no additional benefit to their postoperative outcomes.
- One in five patients experienced a decline in at least one area of functional activity after surgery, and the scope or extent of our peri-operative geriatric anaesthetic care bundle was insufficient to prevent this.

## Introduction

### Problem description

The complexity of ageing and its manifold effects on the physique and psyche, as well as the variety of age-related risk factors, require that older people be recognised as a distinct patient group in the peri-operative setting. Although the postoperative outcomes of older adults are satisfactory with regard to treatment success and survival even after major surgery, aged patients are at an increased risk of adverse outcomes in the mid-term and long-term postoperative course.[1] This applies particularly to patient-centred outcome parameters such as functional status, independence and quality of life.[2] In particular, pre-existing frailty, malnutrition, polypharmacy and cognitive impairment are associated with unfavourable postoperative results.[2,3]

### Available knowledge

Consequently, several evidence-based recommendations have been made for peri-operative management of aged patients.[1,4–6] These include pre-operative assessment of frailty, functional and nutritional status and cognitive performance. Patients with malnutrition are likely to benefit from targeted nutritional supplementation before surgery.[7] Prehabilitation programs and pre-operative breathing exercises have been shown to significantly lower the rate of postoperative pulmonary complications in frail persons.[8] Postoperative delirium prevention is an integral part of good patient healthcare and must be performed throughout the peri-operative course.[4,5] However, in routine clinical practice, the implementation of these recommendations is slow, presumably partly because of unclear objectives and vague instructions. The feasibility and effectiveness of these measures in routine clinical practice have rarely been studied or reported. It is challenging to identify which patients are most likely to benefit from the recommended interventions and what exactly needs to be done to improve their postoperative outcomes. These matters are relevant in view of the increasing number of aged patients undergoing surgery and limited resources in the health system, as implementation of the required measures requires extensive and time-consuming pre-operative assessment and peri-operative management.

### Rationale and aims

In this project, we bundled highly substantiated recommendations for the optimal care of aged patients into a complex multicomponent intervention. Interest was equally focused on both feasibility and effectiveness of the intervention (corresponding to an effectiveness-Implementation hybrid type 2 design).[9] The aim of this study was to test the effects of a complex intervention on relevant patient outcomes and to investigate the quality and extent of implementation and feasibility in routine clinical practice.

## Methods

### Design and context

A pre-post comparison was performed and the participating patients were sequentially assigned to three groups: control (no change from usual care), transition (to implementation of the intervention) and intervention (fully implemented). In this case, usual care was the standard care provided by the compulsory healthcare system. Prior to admission, an anaesthesiological consultation was performed without an extended assessment, in which anaesthesiologically relevant concomitant diseases and medications were recorded. Anaesthesia and intra-operative management were performed at the discretion of a supervising specialist.

Participants were recruited for 6 months in each phase, with the possibility of extending the transition phase to 9 months. The trial was conducted at the University Medical Centre Hamburg, a 1700-bed hospital in a German metropolitan region that treats approximately 90 000 inpatients annually, 40 000 of whom undergo surgery or interventional procedures under anaesthesia.

### Intervention

The intervention comprised evidence-based recommendations of clinical practice guidelines[10–13] concerning the management of frailty, malnutrition, polypharmacy, cognitive impairment and delirium prevention in the pre-operative and intra-operative phases (Table 1, Supplemental file 1, http://links.lww.com/EJAIC/A75). We determined the age threshold for the 'older adult' to be 65 years and set cut-off values for individual components of the measure bundle. The components of the intervention generally recommended for all older patients (e.g. delirium prevention measures) were administered to all participants regardless of the individual risk profile, the other

**Table 1** Components and handling of the intervention bundle

| Intervention | Indication | Assessment of indication | Administration |
|---|---|---|---|
| High-protein nutritional supplement 2× daily until surgery | Malnutrition<br>Frailty | MNA ≤11 points or albumin deficiency (serum)<br>LUCAS-FI: prefrail or frail | Via pharmacy, intake at home and patient diary documentation |
| Iron supplementation (1× intravenous administration) | Iron deficiency, anaemia and surgery with estimated bleeding risk ≥10% | Criteria defined by Patient Blood Management program[11] | Iron infusion in outpatient clinic |
| Physical exercise daily until surgery | Frailty<br>Reduced grip strength<br>Reduced mobility<br>Reduced endurance | LUCAS-FI: prefrail or frail<br>Vigorometer: 50% below age-adapted standard value<br>Timed up&go test: ≤20 s<br>1 min sit-to-stand test: age-adapted cut off[22] | Physical home-based training without aids; beginning at study enrolment until scheduled surgery. Daily breathing exercise, endurance training (e.g. climbing stairs, cycling, walking) alternating every other day with muscle strengthening training (e.g. leg extension, abdominal and back muscles). Intensity should be 5 to 6 on the 10-item Borg scale, corresponding to: 'I'm breathing fast and deeply and my heart is beating strongly and faster, but I can still hold a conversation'. Instruction by medical staff, instruction brochure, individual target agreement and patient diary documentation |
| Medication optimisation | Multimedication, potentially inadequate medication | At least five substances in long-term medication. At least one substance in long-term medication listed as PIM[12,13] | Medication analysis by hospital pharmacist, recommendations for medication changes for primary care physician |
| Carbohydrate loading | Always | | Apple juice or sweet tea offered at prescribed times |
| Involving confidants in pre-operative patient education | Always, if confidants available | | Offer of an additional appointment with confidants |
| Delirium prevention education | Always | | Education about delirium, information brochure |
| Availability of glasses, hearing devices and dentures in the OR | Always | | Bringing respective items from ward or admission into OR |
| Patient warming | Always | | Thermal blankets |
| Use of peri-operative pain catheters whenever possible | Always | | Development of a standard operating procedure for aged patients, training of anaesthesiologists |
| Monitoring anaesthesia depth by processed electroencephalogram using bispectral index (BIS) and avoidance of BIS values below 30 | Always | | |
| Avoidance of PIM in the perioperative phase whenever possible | Always | | |

LUCAS-FI, longitudinal Urban Cohort Age Study – functional index; MNA, Mini Nutritional Assessment; OR, operating room; PIM, potentially inadequate medication.

components were applied only if there was a specific indication present, that is, nutritional supplementation was given only to malnourished patients. The sequence and administration of the interventions are shown in Fig. 1.

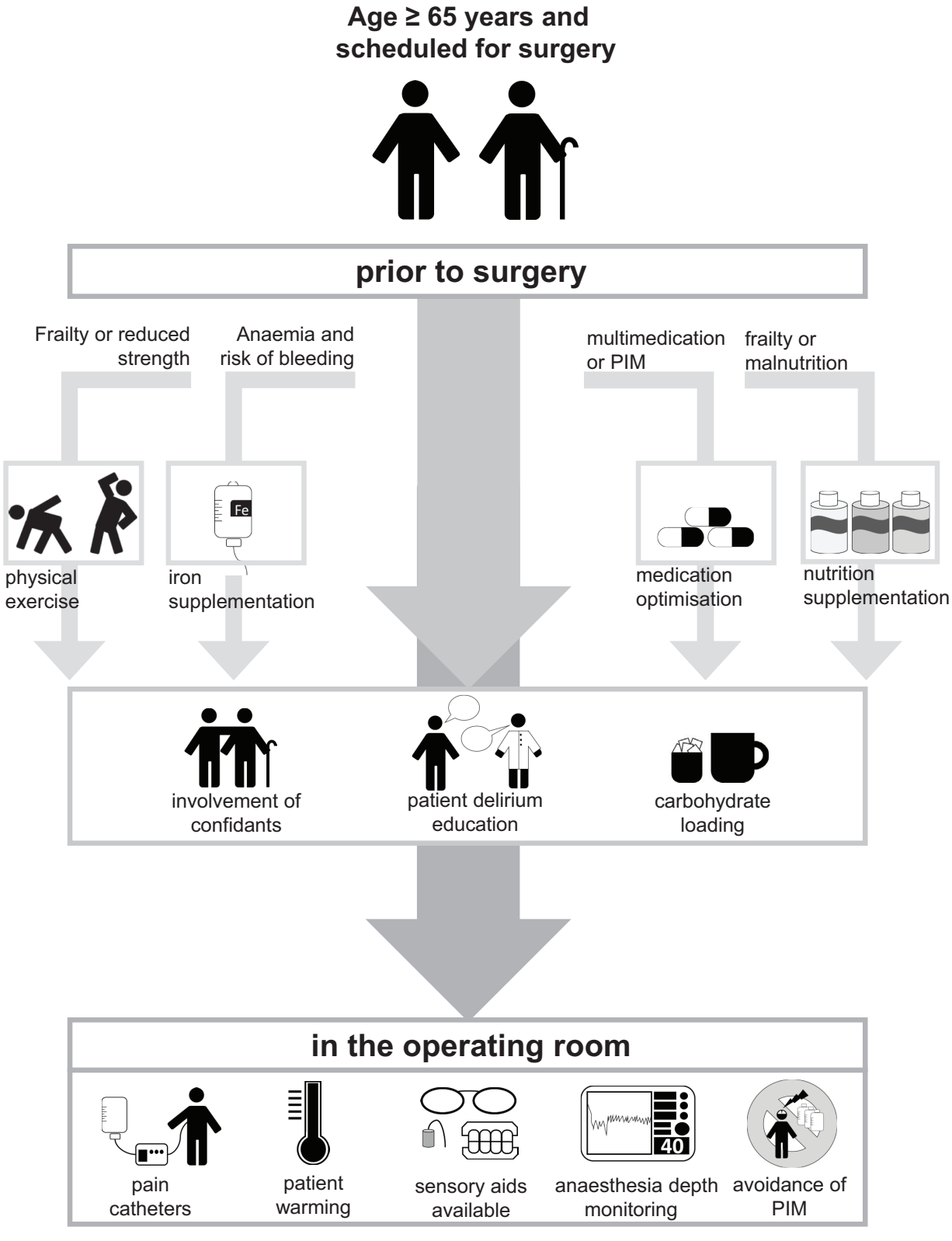
## Study and development of the intervention

The feasibility of implementing the intervention in the day-to-day routine of the clinic, with limited time and personnel resources and a reasonable amount of training, was an essential criterion for the development of the intervention. It was tested in a hybrid design combining an exploratory assessment of its implementation and effectiveness.[10,14] As it was envisaged that some components of the intervention could not be fully implemented in routine clinical practice at once, a transition phase was defined between the control and intervention phases. In order to be able to adapt the intervention to the needs and specificities of the practitioners and hospital routines, the staff involved were regularly interviewed regarding practicability, adherence and acceptance. To enhance the implementation of the intervention, regular training and education sessions were conducted with clinical personnel in the different work areas involved. A contact person from our research group was available to the clinical staff in case of inquiries or difficulties with any intervention. The intervention was developed and managed by an interdisciplinary team consisting of three anaesthesia specialists, three psychologists, one nurse, two residents, two physiotherapists and a pharmacist. The team was advised by geriatric specialists and visceral surgery specialists. An overview of the project setup is shown in Fig. 2.

## Participants and timing of data collection

Patients aged at least 65 years old who were scheduled for elective surgery were eligible for enrolment. Exclusion criteria were scheduled for cranial, ophthalmological and emergency surgery; less than 5 days to operation and an anticipated postoperative hospital stay of less than 24 h. Patients with a planned postoperative stay in the

**FIGURE 1** Outline of the intervention.



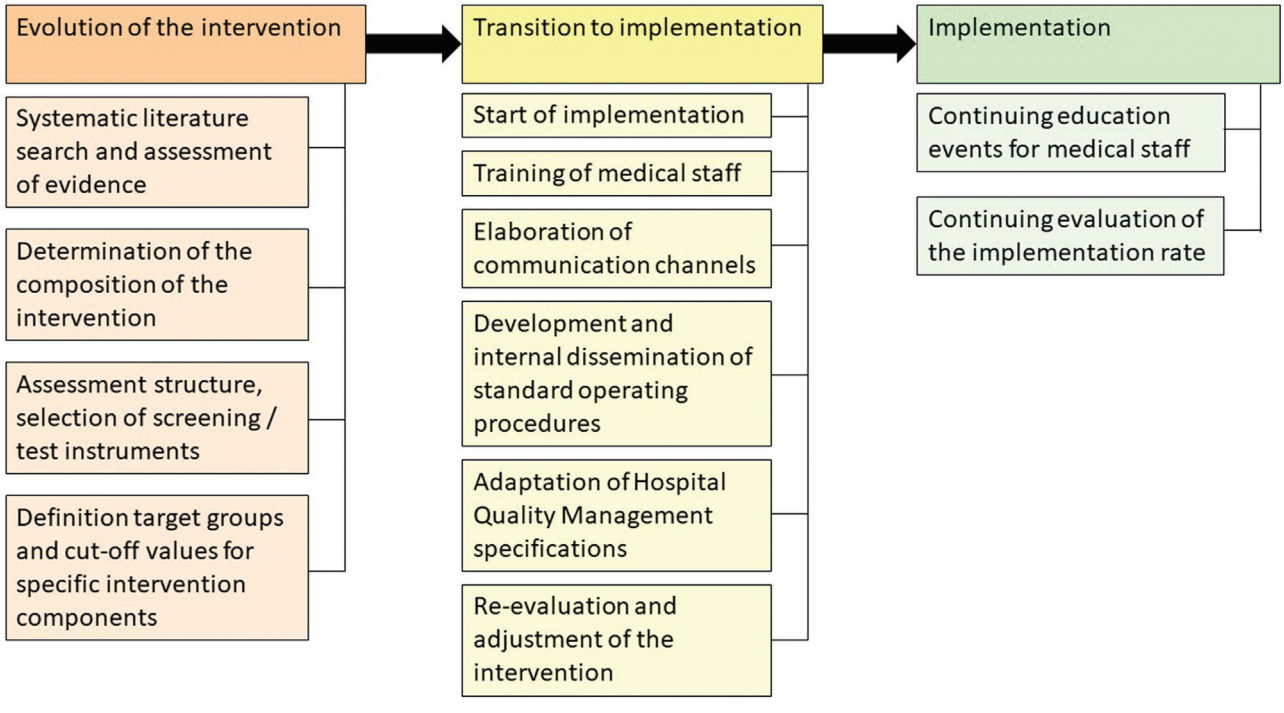
intensive care unit (ICU) were excluded, as we believe that further postoperative course of ICU and non-ICU patients differs to such an extent that a direct comparison without subgrouping would not be advisable. Further exclusion criteria were illiteracy, insufficient command of the German language, severe and uncorrected visual or hearing impairment, mental disability (anticipated difficulties with adherence to the intervention), psychosis, illicit drug use or benzodiazepine abuse. Eligible patients were contacted by the study staff during their visit to the anaesthesiologic outpatient clinic. The time points for data collection were pre-operatively (T0), 1 week (T1), as well as 1 month (T2) and 6 months (T3) postoperatively. Participants were invited to the hospital for data collection at follow-up appointments T2 and T3. All tests were performed by anaesthesiologists who were part of the study team, study nurses or medical graduate students. The tests were performed according to an a priori defined scheme, and the staff was trained before the first test was performed. This training was provided by the principle investigators and was based on the implementation recommendations of the test manufacturers wherever available.

## Measures

The implementation rate of the components of the intervention was determined as the number of cases in which the intervention was fully delivered divided by the number of cases in which it was indicated. Treatment fidelity was documented either through direct assessment or by surveying patients and clinical personnel using a standardised checklist. Medical staff and patients were interviewed about their acceptance of and adherence to the intervention and their perception of feasibility at several points in time. Patients were asked to maintain a patient diary of home interventions; patient diaries were later evaluated by the study team.

The primary clinical outcome was functional status, measured by Instrumental Activities of Daily Living (IADL).[15] The secondary outcomes included postoperative complications[16] until 6-month follow-up (assessed by patient record while in hospital and patient interview on follow-up visits), cognitive performance 1 and 6 months after surgery [Dementia Detection test (DemTect),[17] Test for Attentional Performance (TAP), Trail Making Test (TMT)[18]], occurrence of postoperative delirium [from medical record: Nursing Delirium Screening Scale (NuDesc) applied routinely by nursing staff; questioning of patients, caregivers and confidants for reported delirium symptoms; screening by the study team from postoperative days 0 to 5 every 8 h using the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU),[19] development of frailty [Longitudinal Urban Cohort Age Study – functional index (LUCAS-FI)[20]], health-related quality of life [Short Form 12 (SF-12)[21]], length of hospital stay, further mobility, strength and endurance (1-min sit to stand test,[22,23] timed up and go[24] and grip strength[25]) as well as mental health [depressive and anxiety symptoms (Geriatric Depression Scale GDS)[26]].

**FIGURE 2** Project setup and implementation process.



### Analysis

The sample size was determined to investigate the feasibility of the implementation of the intervention and examine its effectiveness in an exploratory manner. In this regard, we aimed to detect design factors rather than outcomes, such as intervention components failing to be administered, patients dropping out of the study or patient-reported outcome measures being misinterpreted.[27] We powered the study to observe events with an occurrence probability of 10%, with a confidence of 95% in each group. Concerning effectiveness, we required 80 participants in each group (240 in total) to be able to detect a small to moderate effect (Cohen's *d* of 0.4) with rather low attrition or a moderate effect (Cohen's *d* of 0.5) with high attrition.

The baseline characteristics of the participants in each group and treatment fidelity of the multicomponent intervention were investigated using descriptive statistics. The effect of the intervention on outcomes at 1 and 6 months after surgery was analysed using linear mixed models. The intervention, time point of measurement, interaction between the intervention and time point of measurement and baseline level of the analysed outcome were added as fixed covariates, whereas the effects of the responsible operating department and the individual on the intercept were modelled as random. We performed an intention-to-treat analysis and considered the observed group differences in age, sex and smoking status as potentially clinically relevant. Therefore, these variables were included in all analyses as covariates. The potential influence of the coronavirus pandemic was considered by including a binary time-varying indicator (measurement before or during the pandemic) in the models. Outcomes without repeated measurements were analysed using Kruskal–Wallis and Pearson's $\chi^2$ tests.

To use all available data to compare the intervention with the control, we modelled the intervention variable as continuous in the main analysis. The control phase was coded as 0, the intervention phase as 1 and the transition phase as a value between 0 and 1, depending on the time point of inclusion of the patient in the study. A participant included at the very beginning of the transition (directly after the control phase) received a value very close to 0, a participant at the very end of the transition (directly before the intervention phase) received a value very close to 1, and so on. This procedure allowed us to include cases from the transition period in the evaluation by merging the three original groups into two. This is mathematically equivalent to a segmented regression frequently used in interrupted time-series designs,[28] assuming that no temporal effects are present (i.e. the linear slope of change is zero) in the control and intervention phases (but are freely estimated in the transition phase) and no immediate effects (i.e. changes in the intercept) are present when moving from one phase to another. In the sensitivity analysis, we treated the intervention as an unordered categorical variable and compared the control only with the intervention.

Missing data were handled by multiple imputations following established guidelines.[29] Differences were considered statistically significant when the alpha error probability was less than 0.05. As this was a pilot study, no adjustments were made for multiple testing. All analyses were performed using IBM SPSS Statistics version 25 (IBM Corp., Armonk, New York, USA).

### Ethical considerations

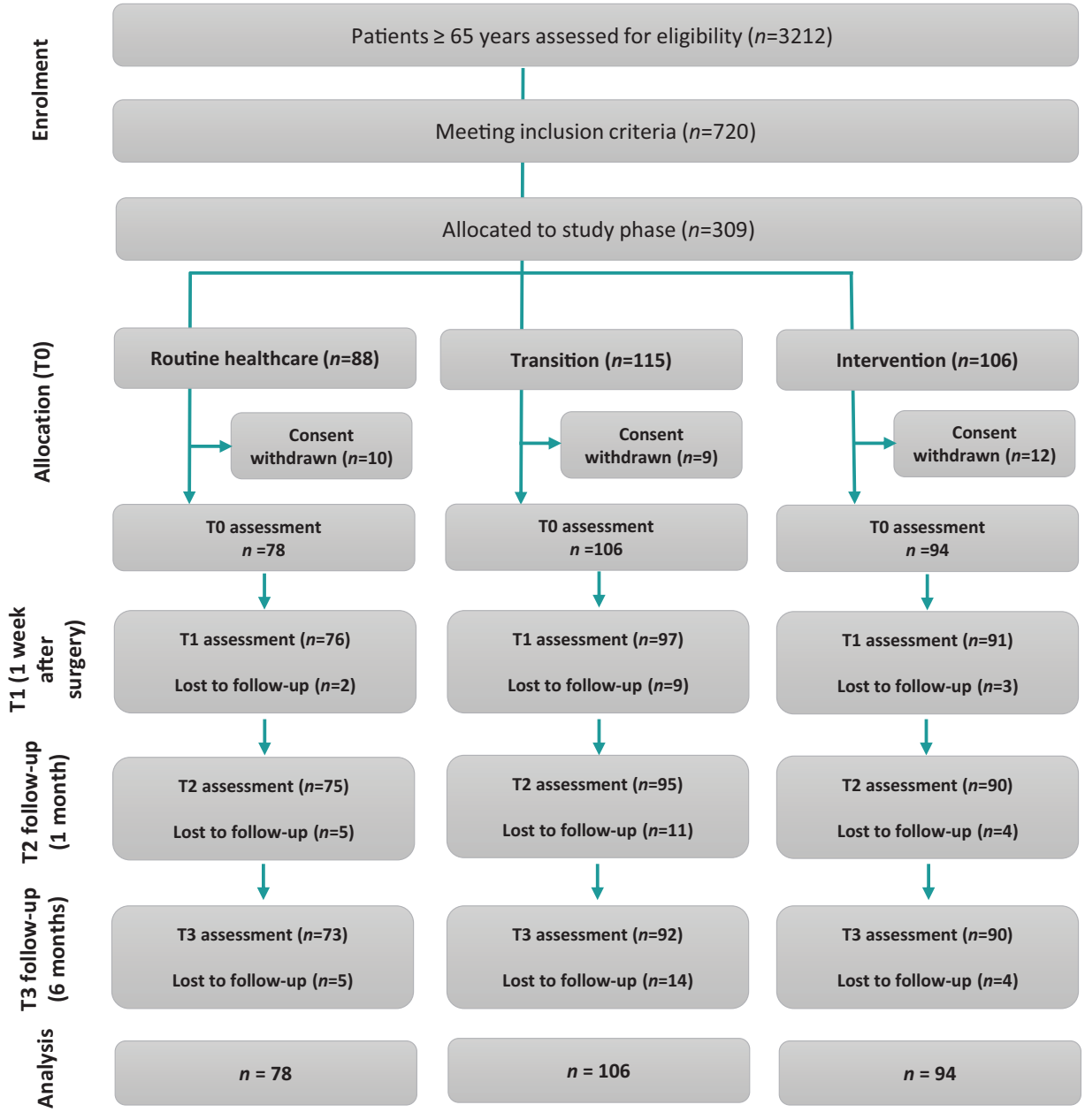
The study was registered at ClinicalTrials.gov prior to recruitment (NCT03325413; 30 October 2017). Informed written consent was obtained from all participants, and ethical approval of the study (PV5596; 8 September 2017) was provided by the ethics committee of the Hamburg Chamber of Physicians. This study was conducted in accordance with the principles of Good Clinical Practice and the guidelines of the Helsinki Declaration. Methodological details are reported in a publicly available study protocol.[10] This manuscript adheres to SQUIRE guidelines.[30]

## Results

### Participants

The first participant was recruited in November 2017. The control phase ran until May 2018, and the transition phase ran until January 2019. As establishing the operational requirements for some interventions took longer than expected, the transition phase had to be extended several weeks beyond the original schedule. Consequently, the final number of cases exceeded the planned sample size. The intervention phase was completed in September 2019 and the last follow-up was completed in May 2020. Of the 3212 patients screened for eligibility, 720 fulfilled the inclusion criteria and 309 agreed to participate in the study, representing a participation rate of 43% (Fig. 3). A personal interview and test (approximately 45 min) were required for study enrolment. The majority of patients who were unable to participate in the study despite meeting the inclusion criteria had further appointments immediately after the anaesthesia consultation and were unable to make time for enrolment testing. In other cases, inclusion, which in most cases had to be ad hoc, could not be carried out for personnel reasons (no free study personnel available), or patients had already been included in other intervention studies. Thirty-one patients withdrew their consent during the study or did not undergo the planned procedure; therefore, baseline data from 278 patients were available. Follow-up data were collected from 255 participants (91.5% of the patients with baseline data). Overall, a completion rate of 83% was achieved and 90% of the enrolled patients were included in the analysis. The average time from study enrolment to surgery was 13 days [standard deviation (SD) = 25.1]. At enrolment, 33 and

**FIGURE 3** Patient flow chart.




29% of the study participants (intervention and control group, respectively) were prefrail and 5 and 9%, respectively, were classified as frail. Seventeen percent and 9%, respectively, presented with a slight cognitive impairment. The sample characteristics are listed in Table 2 and Supplemental Table 3 (http://links.lww.com/EJAIC/A72).[31]

## Feasibility of the intervention and barriers to implementation

The steps involved in the implementation of each intervention are listed in Table 3. The average implementation rate was 77%. Interventions that achieved an implementation rate below 70% included continuous patient warming (68%), use of hearing devices within the operating room until anaesthesia induction and in the recovery room (41%), continuous processed electroencephalogram (pEEG)-guided anaesthesia (23%), involvement of confidants during preoperative patient education (16%) and pre-operative medication adjustment (0%). All other interventions of the bundle achieved implementation rates between 70 and 100% and were considered feasible (Table 4). The interventions which were carried out by the patients themselves, showed a high level of acceptance

**Table 2** Sample characteristics

| | Control ($n = 78$) | Intervention ($n = 94$) |
|---|---|---|
| Age (years) | 74.9 ± 5.3 [65 to 87] | 72.1 ± 5.3 [65 to 87] |
| Sex | | |
| Male | 49 (63) | 63 (67) |
| Female | 29 (37) | 31 (33) |
| Formal education | | |
| 10 to 13 years | 28 (36) | 37 (39) |
| ≤10 years | 50 (64) | 57 (61) |
| Social situation | | |
| Still working | 17 (22) | 15 (16) |
| Living at home | 77 (99) | 93 (100) |
| Care dependent | 2 (2) | 0 (0) |
| Sensory impairment | 46 (59) | 61 (62) |
| Nikolaus-Score[a] (0 to 25) | 17.94 ± 2.1 [13 to 21] | 17.81 ± 2.36 [9 to 22] |
| Specialty | | |
| Urology | 43 (55) | 43 (46) |
| General | 13 (17) | 10 (11) |
| Oral and maxillofacial | 7 (9) | 6 (6) |
| Gynaecology | 9 (12) | 16 (17) |
| ENT surgery | 3 (4) | 14 (15) |
| Trauma | 1 (1) | 4 (4) |
| Vascular | 0 (0) | 1 (1) |
| Endoscopy | 1 (1) | 0 (0) |
| Hepatobiliary | 1 (1) | 0 (0) |
| Reconstructive | 0 (0) | 0 (0) |
| BMI (kg body weight height $m^{-2}$) | 25.5 ± 4.6 [14 to 44] | 26.6 ± 5.2 [18 to 48] |
| Smokers | 11 (14) | 27 (29) |
| Comorbidities | | |
| Cancer | 32 (41) | 32 (34) |
| Arterial hypertension | 42 (54) | 53 (56) |
| Coronary heart disease | 9 (12) | 6 (6) |
| Chronic kidney disease KDIGO I/II and III/IV | 57 (73)/21 (27) | 70 (71)/20 (20) |
| COPD | 4 (5) | 5 (5) |
| Depression | 6 (8) | 4 (4) |
| Diabetes | 10 (13) | 13 (14) |
| Medication | | |
| Antihypertensives | 41 (53) | 49 (52) |
| Diuretics | 12 (15) | 11 (12) |
| Beta blockers | 26 (33) | 30 (32) |
| Statins/fibrates | 20 (26) | 27 (29) |
| CNS active | 10 (13) | 20 (21) |
| ASA score | | |
| I | 2 (3) | 6 (6) |
| II | 33 (42) | 52 (55) |
| III | 43 (55) | 35 (37) |
| IV | 0 (0) | 0 (0) |
| POSPOM score (0 to >51 points) | 24.4 ± 3.9 [12 to 35] | 22.6 ± 3.7 [15 to 31] |
| 10.8 ± 1.1 [9 to 14] | 11.2 ± 1.1 [9 to 14] | 10.8 ± 1.1 [9 to 14] |
| Points from comorbidities (0 to 4) | 3.2 ± 2.5 [0 to 11] | 2.1 ± 2.3 [0 to 8] |
| Points from surgery (0 to 22) | 10 ± [0 to 16] | 9.7 ± 2.6 [6 to 10] |
| Frailty scoring (LUCAS-FI) | | |
| Not frail | 48 (62) | 58 (62) |
| Prefrail | 26 (33) | 27 (29) |
| Frail | 4 (5) | 8 (9) |
| Cognition scoring (Demtect) | | |
| Appropriate | 64 (82) | 84 (89) |
| Slightly impaired | 13 (17) | 8 (9) |
| Suspected dementia | 1 (1) | 2 (2) |
| Nutrition scoring (MNA-SF) | | |
| Normal | 34 (44) | 55 (59) |
| At risk for malnutrition | 41 (52) | 35 (38) |
| Malnutrition | 3 (4) | 3 (3) |
| Type of anaesthesia | | |
| TIVA | 24 (31) | 31 (33) |
| Balanced | 36 (46) | 49 (52) |
| GA and neuraxial | 9 (12) | 7 (7) |
| Neuraxial only | 8 (10) | 3 (3) |
| Other | 1 (1) | 4 (4) |
| Surgery time (min) | 90.1 ± 83.9 [7 to 423] | 93.2 ± 86.2 [5 to 497] |

Data are given as number (%) or mean ± SD [range]. BMI, body mass index; CNS, central nervous system; COPD, chronic obstructive pulmonary disease; ENT, ear-nose-throat-medicine; KDIGO, Kidney Disease: Improving Global Outcomes; POSPOM, Pre-operative Score to Predict Postoperative Mortality. [a]Nikolaus-Score: the test looks at the respondent's social situation. It is made up of 4 sections and examines the respondent's social contacts and activities, housing situation and economic circumstances.

(Table 4, Supplemental Table 5, http://links.lww.com/EJAIC/A74). A substantial difficulty in implementing pre-operative medication adjustment was the complex process needed to achieve a change in medication; the pharmaceutical recommendation needed to be communicated with the general practitioner prescribing the medication, who needed to contact the patient and initiate a change in the permanent medication. The time remaining until surgery was often too short for this sequence to follow. Other barriers were a lack of knowledge about potentially inadequate medication among anaesthetists and hurdles in communication at the interface with the outpatient sector (between hospital-based physicians and general practitioners). With regard to the involvement of confidants, the nonexistence or unavailability of relatives was a major barrier; in other cases, patients were not willing to postpone an already-planned appointment to allow family members or confidants to participate. Concerning monitoring of anaesthesia depth, almost all anaesthetists questioned claimed to avoid too deep anaesthesia; however, pEEG was often not implemented. The reasons attributed to this are the supposedly high costs of the necessary EEG electrodes and, in some cases, a low perceived benefit. Challenges to implementing the intervention to maintain sensory aids on the patient until the induction of anaesthesia were concerns from patients and nurses that these items might be misplaced in the operating area. Hygiene issues about taking patients' belongings into the operating theatre also played a role, especially not only for nurses in the ward but also for the transport staff who brought patients to the operating theatre.

## Effectiveness

At the time of inclusion, no significant differences were observed between the control and intervention groups (Table 2). Participants' functional status, as measured by IADL, had a mean above 9.4 points on a scale from 0 (low-functioning) to 10 (high-functioning) in all groups across all time points (Table 5, Supplemental Table 2, http://links.lww.com/EJAIC/A71). The clinically minimal important change in the IADL score has been reported at 0.5 points.[32] This threshold was not reached when average differences (pre-operative − postoperative) of IADL scores between the intervention and control groups were compared at 1 and 6 months after surgery [adjusted (i.e. controlled for covariates) mean difference T1 : 0.07, 95% confidence interval, −0.23 to 0.36, $P = 0.66$; T3 : 0.01, 95% confidence interval, −0.29 to 0.31, $P = 0.95$, see Supplemental Table 2, http://links.lww.com/EJAIC/A71]. There were no statistically significant between-group differences in secondary outcomes (Table 5, supplemental table 4, http://links.lww.com/EJAIC/A73). The sensitivity analysis (Supplemental Table 1, http://links.lww.com/EJAIC/A70) confirmed these findings. Regarding individual IADL items in the overall population, taking the control, implementation and intervention groups together, 27 (10%) and 24 (9%) patients showed improvement in at least one activity domain at 1 and 6 months after surgery, respectively, whereas 49 (18%) and 39 (14%) patients experienced deterioration in an

**Table 3** Implementation process and evolution of interventions

| Intervention | Steps to implementation |
|---|---|
| High-protein nutritional supplement 2× daily until surgery | Selection of a prescribable nutritional supplement:<br>- with highest available protein content<br>- suitable for everyday use even for people with cognitive impairment (no complex measuring of quantities)<br>- suitable for patients with diabetes mellitus<br>clarification of the procedure for patients with impaired renal function |
| Iron supplementation (1× intravenous administration) | Implementation of the Patient Blood Algorithm (pre-operative management of iron deficiency).<br>Definition of surgical procedures with a with estimated bleeding risk ≥10%.<br>Determination of the modalities of a pre-operative iron infusion (facilities, monitoring, patients' admission status, cost coverage). |
| Physical exercise daily until surgery | Systematic literature review of prehabilitation training models.<br>Development of a prehabilitation program with the following requirements:<br>- safe for frail patients to perform independently at home<br>- training intensity can be evaluated independently by the patient<br>- endurance training and muscle strengthening feasible for mobility impaired patients.<br>Preparation of a training manual.<br>Education of study staff in instructions for training.<br>Formulation of a training agreement and training protocol.<br>Re-evaluation and adjustments of training instructions during the transition phase according to patient feedback. |
| Medication optimisation | Training of anaesthesiologists (continuing education event): analysis of patient medication with regard to criteria for multimedication and PIM.<br>Establishment of a pharmaceutical consultation service for anaesthetists during pre-operative anaesthesiologic evaluation.<br>Defining a standardised procedure for contacting primary care physician with recommendations for medication changes. |
| Carbohydrate loading | Training of nursing staff (continuing education event) to administer apple juice or sweet tea to patients the evening before and prior to surgery.<br>Informing of patients during pre-operative anaesthesiologic evaluation, handing out a patient brochure with respective information. |
| Involving confidants in pre-operative patient education | Where possible, patients were called before the scheduled pre-operative anaesthesiologic evaluation and asked to bring a confidant with them to the interview.<br>If patients came without confidants, they were offered an additional appointment together with a family member. |
| Delirium prevention education | Patient education during pre-operative anaesthesiologic evaluation and handing out of a brochure on delirium and delirium prevention.<br>Continuing education event for anaesthesiologic staff on delirium and delirium prevention. |
| Availability of glasses, hearing devices and dentures in the OR | Installation of a safe locker for patients' belongings in the operating theatre.<br>Instruction of ward and operating theatre staff as well as transport staff on the necessity of taking patient property into the operating theatre. |
| Intra-operative anaesthesiologic management | Preparation of a checklist for intra-operative procedures in patients at least 65 years of age. This consisted of the following elements: *'1. always use prewarming/always use BIS (values >20)/if relaxation is needed, use short-acting muscle relaxants/avoid: benzodiazepines, additional sedatives when regional anaesthesia can be sufficient, repetitive doses of muscle relaxants and anticholinergic medication. 2. If sensoric aids are needed, do not remove until induction of anaesthesia and return immediately when patient arrives at the PACU'*. Contact details of study staff were provided on the checklist.<br>Development of a standard operating procedure for aged patients (including pre-operative management and assessment and intra-operative procedures as well as analgetic management), continuing education events for anaesthesiologists. |

IADL item over the same period (Supplemental Figure 1, http://links.lww.com/EJAIC/A69). Patients with frailty were affected by IADL deterioration to a much higher degree than patients who were fit (23 vs. 3% at 1 month, 11 vs. 3% at 6 months after surgery; Fig. 4).

## Discussion

### Summary

In this project, we compiled a concept for the perioperative care of older adults adapted to the patient's individual risk profile. Single recommended measures that have been shown to be beneficial for postoperative outcomes in older adults[5,6,8] were bundled into a multicomponent intervention. This intervention bundle was implemented in routine clinical practice and was evaluated for feasibility and effectiveness.

We considered the intervention to be feasible but found that it did not improve IADL neither one month nor six months postoperatively in patients aged ≥ 65 years in a German metropolitan region.

### Feasibility

Most components of the intervention could be implemented at a degree between 70 and 100%, which was rated as 'good' following our clinical experience and in comparison with the reported results of other implementation projects.[33] However, a cut-off point for when implementation is considered 'successful' is not defined; this can only be assessed based on the specific clinical context.[34] In this setting, the main obstacles encountered during the implementation process were structural barriers, such as difficult communication pathways between hospital-based physicians and general practitioners, which made it almost impossible to pass on information in a timely manner. Lack of perception of the benefit of the intervention by medical staff has been an obstacle to implementation to some extent. Time to surgery was

**Table 4** Implementation of the intervention in clinical routine practice

| Pre-operative phase | Participants with present indication for a respective intervention (intervention group) | Participants, in which an indicated intervention was realised (intervention group) |
|---|---|---|
| Nutrition supplementation | 46 (49) | 45 (98) |
| Iron supplementation | 1 (1) | 1 (100) |
| Physical exercise | 62 (66) | 63 (100) |
| Medication adjustment | 35 (37) | 0 (0) |
| Carbohydrate loading | | |
| Eve before surgery | 92 (98) | 73 (79) |
| 2 h preoperatively | 92 (98) | 72 (78) |
| Involvement of confidants | 94 (100) | 15 (16) |
| Patient delirium education | 94 (100) | 73 (78) |
| Intra-operative phase | | |
| Dentures used in OR | 41 (45) | 30 (73) |
| Dentures used in PACU | 41 (45) | 29 (71) |
| Glasses used in OR | 59 (64) | 47 (80) |
| Hearing aids used in OR | 17 (19) | 7 (41) |
| Patient warming | 92 (100) | 62 (68) |
| Pain catheter applied | 43 (47) | 32 (74) |
| BIS-guided anaesthesia according to protocol | 56 (61) | 18 (23) |
| PI[a] medication avoided | 92 (100) | OR[b] 71 (77)<br>PACU[c] 83 (90) |

Numbers and percentages of patients are reported. $n = 94$ for pre-operative, $n = 92$ for intra-operative phase. OR, operating room; PACU, postanaesthetic care unit. [a] PI, potentially inadequate (e.g. Atropine, Pethidine, Tramadol, Dimenhydrinate).

another barrier; it was challenging to reach patients sufficiently early, as routinely, anaesthesiologists were usually involved only shortly before a planned operation. As some intervention components comprised prehabilitation measures, the time between enrolment and surgery might have been too short to impact the postoperative outcome. In our setting, the average time from study enrolment to surgery was 13 days. Other studies found that prehabilitation combining breathing exercises with resistance and endurance training, as in our protocol, proved effective, even if applied over a shorter period of time, the same applies for preo-perative nutritional supplementation.[7,35]

Overall, the achieved implementation rate of 77% might not be outstanding but nevertheless satisfactory. It is known that the sustainable implementation of interventions is extremely laborious and slow.[36] Based on our experience, we do not believe that geriatric care bundles can be expected to achieve a higher implementation rate in routine clinical practice under real-world conditions.

## Effectiveness

The intervention bundle applied here did not improve patients' functional status after surgery. Were patients in our setting too young and too fit to benefit from a perioperative geriatric anaesthesia concept? There is no uniform definition for when a person is considered old. Within the range of 65 to 87 years, our population sample corresponded to an age group that would be referred to as aged in general and gerontological understanding. The prevalence of frailty, malnutrition and cognitive impairment in the cohort studied was consistent with that observed by other authors in comparable samples.[37,38] The POSE trial, a large multicentre study, has recently shown that even very elderly patients in Europe still maintain a high functional status, with a frailty prevalence below 15%, and more than 60% of octogenarians being functionally independent.[39] In line with this, most patients in our study consistently scored high on IADL. The IADL remains the gold standard for measuring functional abilities in geriatric assessment, and its use is widely recommended.[40] Nevertheless, IADL does not appear to be the optimal instrument for measuring changes in functional status in fit older people who are not in need of care, as its sensitivity seems too low, resulting in distinctive ceiling effects. With study participants being predominantly cognitively unimpaired and fit, an instrument with a more sensitive graduation of functional status, such as the Functional Independence Measure (FIM), might have reflected more subtle changes.[41] It has been shown that an adjusted IADL score might reveal more information about functional decline or improvement in fit elderly cohorts.[42] Focusing on the gradations of the single IADL items, it appeared that 18 and 14% of the patients had a decline in at least one instrumental activity at 1 and 6 months postoperatively, respectively. Comparable data were obtained from the POSE trial, where one in five patients developed a deterioration of functional state after surgery.[39]

Our results show that patients over the age of 64 years in a large city in northern Germany are predominantly independent and fit. Nevertheless, a small proportion of these patients also experienced loss of function. Therefore, it is important to pre-operatively identify patients who are at risk. Our results show that this selection can have a high threshold. This indicates that even more efforts are needed when assessing the demands and outcomes of older adults to identify the 15 to 20% who will effectively

**Table 5** Results of the main effectiveness analyses

| Outcome | Observed | | Estimated | | | |
|---|---|---|---|---|---|---|
| | control M ± SD; *n* | Intervention M ± SD; *n* | Control EMM (SE) | Intervention EMM (SE) | AMD (95% CI) | *P* |
| Functional status (IADL, scaled 1 to 10)) | | | | | | |
| Baseline | 9.92 ± 3.9; 78 | 9.71 ± 0.81; 94 | N/A | N/A | N/A | N/A |
| One-month follow-up | 9.46 ± 1.36; 65 | 9.56 ± 0.98; 84 | 9.52 (0.11) | 9.59 (0.10) | 0.07 (−0.23 to 0.36) | 0.66 |
| Six months follow-up | 9.78 ± 0.60; 70 | 9.65 ± 1.02; 85 | 9.70 (0.11) | 9.70 (0.11) | 0.01 (−0.29 to 0.31) | 0.95 |
| Frailty status (LUCAS-FI, risks/resources, scaled 0 to 6) | | | | | | |
| Baseline | 0.94 ± 1.34; 78/3.18 ± 1.31; 78 | 0.86 ± 1.13; 93/3.25 ± 1.29; 93 | N/A | N/A | N/A | N/A |
| 6-months follow-up | 0.80 ± 1.11; 70/3.28 ± 1.39; 72 | 0.80 ± 1.24; 87/3.27 ± 1.39; 88 | 0.72 (0.12)/3.24 (0.10) | 0.73 (0.12)/3.26 (0.10) | 0.004 (−0.33 to 0.34)/0.02 (−0.26 to 0.30) | 0.98/0.88 |
| Cognitive performance (Dementia Detection Test, scaled 10 to 18) | | | | | | |
| Baseline | 14.97 ± 2.59; 78 | 15.73 ± 2.48; 94 | N/A | N/A | N/A | N/A |
| One-month follow-up | 15.58 ± 2.29; 62 | 15.96 ± 2.45; 84 | 15.83 (0.20) | 15.82 (0.19) | −0.01 (−0.55 to 0.54) | 0.99 |
| Six-months follow-up | 15.04 ± 2.80; 71 | 16.00 ± 2.61; 83 | 15.42 (0.19) | 15.81 (0.20) | 0.40 (−0.14 to 0.94) | 0.15 |
| Alertness (Test of Attentional Performance, *T*-score) | | | | | | |
| Baseline | 49.92 ± 12.26; 78 | 42.54 ± 8.53; 94 | N/A | N/A | N/A | N/A |
| One-month follow-up | 49.61 ± 10.63; 67 | 41.13 ± 8.11; 84 | 45.31 (1.20) | 43.13 (1.14) | −2.18 (−5.42 to 1.07) | 0.19 |
| Six months follow-up | 48.58 ± 10.60; 71 | 41.73 ± 10.21; 80 | 43.37 (1.20) | 42.37 (1.17) | −1.00 (−4.29 to 2.29) | 0.55 |
| Executive function (Trail Making Test B/A) | | | | | | |
| Baseline | 2.44 ± 0.77; 78 | 2.58 ± 1.03; 94 | N/A | N/A | N/A | N/A |
| One-month follow-up | 2.46 ± .97; 66 | 2.54 ± .97; 83 | 2.47 (0.11) | 2.48 (0.11) | 0.02 (−0.29 to 0.32) | 0.92 |
| Six months follow-up | 2.83 ± 1.62; 71 | 2.46 ± 1.10; 83 | 2.70 (0.11) | 2.43 (0.11) | −0.27 (−0.58 to 0.04) | 0.09 |
| Stamina (1-Minute-Sit-to-Stand Test, number of repetitions) | | | | | | |
| Baseline | 24.25 ± 5.43; 67 | 28.63 ± 9.04; 81 | N/A | N/A | N/A | N/A |
| One month follow-up | 24.43 ± 5.9; 49 | 26.77 ± 9.28; 64 | 25.79 (0.69) | 25.63 (0.67) | −0.16 (−2.04 to 1.72) | 0.84 |
| Six months follow-up | 23.67 ± 7.3; 61 | 27.94 ± 7.72; 72 | 26.11 (0.68) | 26.218 (0.65) | 0.11 (−1.73 to 1.95) | 0.91 |
| Mobility (Timed Up&Go, seconds) | | | | | | |
| Baseline | 7.69 ± 2.23; 77 | 8.12 ± 3.19; 92 | N/A | N/A | N/A | N/A |
| One-month follow-up | 7.23 ± 1.99; 61 | 7.44 ± 3.08; 80 | 8.06 (0.60) | 8.36 (0.56) | 0.30 (−1.31 to 1.91) | 0.72 |
| Six months follow-up | 7.81 ± 1.95; 68 | 7.81 ± 8.31; 81 | 7.92 (0.59) | 8.53 (0.56) | 0.61 (−0.98 to 2.19) | 0.45 |
| Grip strength (Vigorometer, kg) | | | | | | |
| Baseline | 33.05 ± 9.93; 77 | 36.83 ± 10.21; 93 | N/A | N/A | N/A | N/A |
| One month follow-up | 33.84 ± 10.53; 66 | 36.78 ± 9.72; 80 | 35.60 (0.37) | 35.26 (0.36) | −0.34 (−1.35 to 0.67) | 0.51 |
| Six months follow-up | 33.69 ± 10.60; 70 | 27.01 ± 10.71; 77 | 35.49 (0.37) | 35.30 (0.38) | −0.19 (−1.22 to 0.85) | 0.72 |
| Health-related Quality of Life (Short Form-12, physical/psychological domain) | | | | | | |
| Baseline | 41.75 ± 9.52/47.39 ± 9.32; 42 | 39.64 ± 11.88/47.53 ± 11.05; 55 | N/A | N/A | N/A | N/A |
| One month follow-up | 38,55 ± 10.02/47.04 ± 8.83; 51 | 40.47 ± 10.14/47.95 ± 8.84; 59 | 40.43 (0.97)/50.63 (0.98 | 41.19 (0.96)/51.55 (0.95) | 0.76 (−1.91 to 3.34)/0.92 (−1.76 to 3.59) | 0.58/0.50 |
| Six months follow-up | 38.31 ± 8.61/49.46 ± 7.94; 37 | 41.59 ± 11.59/49.80 ± 9.00; 52 | 41.13 (1.02)/51.55 (0.95) | 42.35 (1.00)/51.99 (1.03) | 1.22 (−1.58 to 4.02)/0.55 (−2.27 to 3.38) | 0.61/0.28 |
| Depression (Geriatric Depression Scale, scaled 0 to 15) | | | | | | |
| Baseline | 5.62 ± 1.68; 76 | 5.34 ± 1.56; 94 | N/A | N/A | N/A | N/A |
| One month follow-up | 5.36 ± 1.40; 73 | 5.50 ± 1.54; 90 | 5.29 (0.12) | 5.59 (0.12) | 0.30 (−0.03 to 0.64) | 0.08 |
| Six months follow-up | 5.50 ± 1.56; 73 | 5.50 ± 1.58; 89 | 5.45 (0.12) | 5.64 (0.12) | 0.19 (−0.15 to 0.53) | 0.28 |

| Outcome parameters without repeated measurements | Observed averages | | Intervention vs. control/mixed model | | |
|---|---|---|---|---|---|
| | Control | Intervention | Adj. effect | 95% CI | *P* |
| Length of inpatient stay (days) | 7.0 ± 7.67 [1 to 48] *n* = 71 | 5.76 ± 5.95 [1 to 42] *n* = 91 | −0.61 | −2.49 to 1.26 | ≤0.52 |
| Postoperative complications | 27 (35%) *n* = 78 | 24 (25.5%) *n* = 94 | −0.10 | −0.26 to 0.06 | ≤0.21 |

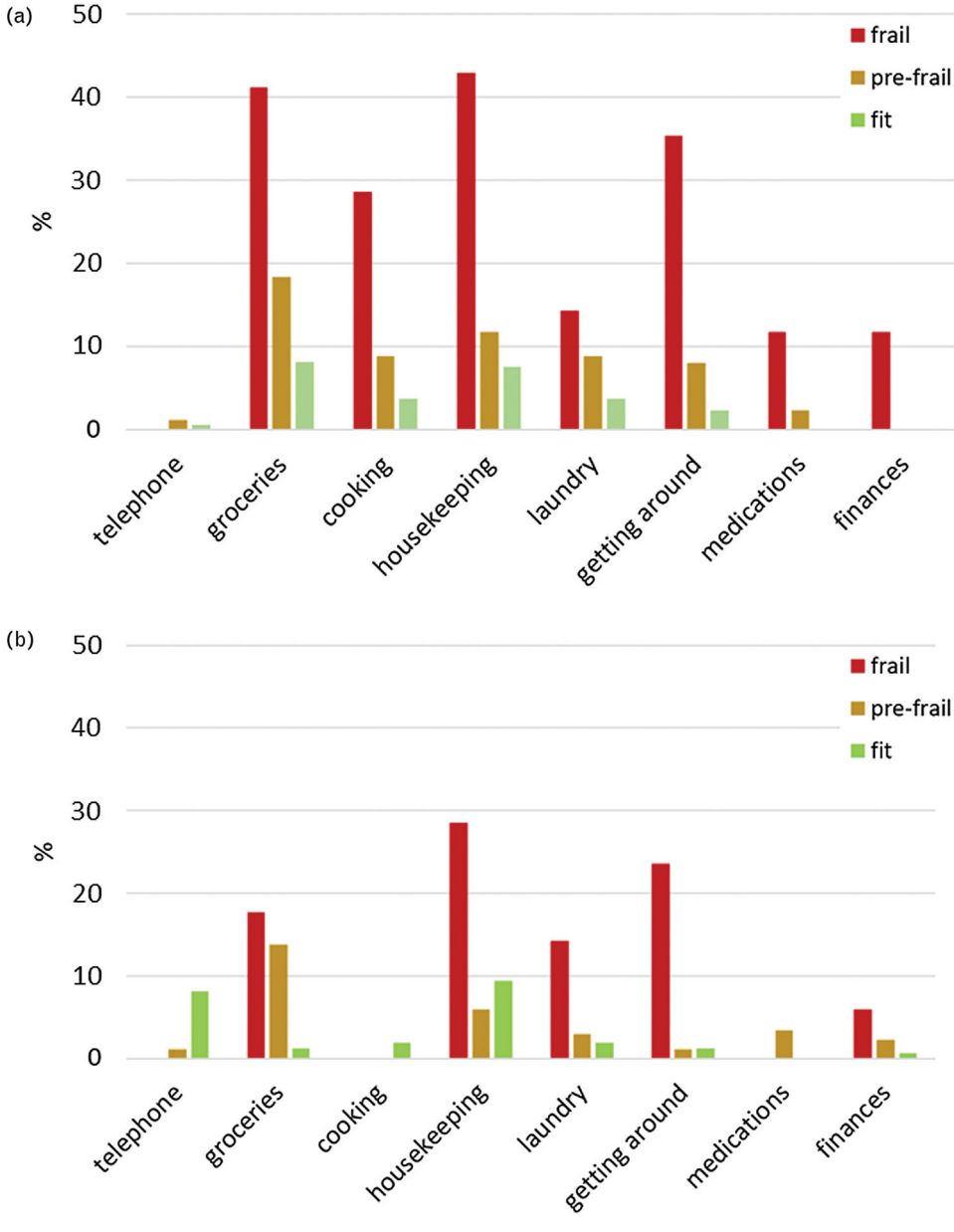
AMD, adjusted mean difference; CI, confidence interval; EMM, estimated marginal mean; IADL, Instrumental Activities of Daily Living; LUCAS-FI, Longitudinal Urban Cohort Age Study – functional index; M, mean; *n*, sample size; SD, standard deviation; SE, standard error. Stamina: average norm values for adults at ≥65years = 25 repetitions; mobility (Timed Up&Go): ≤10 s = completely unrestricted; 10 to 19 s = less mobile, but still unrestricted; 20 to 29 s = limited mobility; >30 s = severe mobility restriction. Grip strength: norm values for adults at ≥65years: ♂ 34 kg; ♀ 10 kg. Geriatric Depression Scale: cut-off (depressive disorder likely) at ≥6 points.

benefit from geriatric anaesthesia care bundles. There is room for speculation as to whether a comprehensive geriatric anaesthetic care concept, which goes well beyond the scope and provision of our intervention and is delivered fully, but only to the most vulnerable and frail patients, might be more effective than delivering a little less to a broader range of older patients.

## Limitations

Our findings should be interpreted with caution because of some limitations. To avoid contamination effects between the groups, a pre-post design was chosen instead of being randomised. Therefore, time effects, which could not be controlled for, could have impacted the results of the study. For example, the follow-up period for a proportion of the intervention group coincided with the onset of the COVID-19 pandemic conditions. As a pilot study, the focus was primarily on the feasibility and exploratory investigation of effectiveness. Although our sample size was substantial and comparable to other confirmatory trials,[43,44] this may have resulted in our study being underpowered to show effectiveness for

**FIGURE 4** Deterioration of Instrumental Activities of Daily Living 1 and 6 months after surgery depending on frailty. Shown are data from all groups combined; the percentages of fit, prefrail and frail patients reporting at least one deterioration in at least one IADL domain (a) 1 (T2) and (b) 6 (T3) months after surgery. IADL, Instrumental Activities of Daily Living.



our primary outcome because of heterogeneity and the fitness of the patients. Importantly, many frail and burdened elders declined to participate in the study because they considered the follow-up appointments and extensive assessment too strenuous. This selection bias is a well known phenomenon in clinical trials involving older adults and leads to an overrepresentation of fit patients in the cohort studied.[45] As the most vulnerable patients are likely to benefit most from geriatric care bundles, this selection of an above-average fit cohort may lead to an underestimation of the effect of the intervention. Selection was also based on the invasiveness of the procedure, as planned postoperative intensive care treatment was excluded. Furthermore, data on postoperative delirium should be interpreted with caution. The CAM-ICU, which was chosen in our setting for practicability reasons, has not been developed for use in non-ICU wards. Therefore, the actual delirium rate may have been underestimated. The study was performed at an urban university medical centre. The patient population and institutional context may have had specific aspects that are not necessarily transferable to other settings (Supplemental Table 4, http://links.lww.com/EJAIC/A73).

## Conclusion

Our results suggest that elderly patients in a central European metropolitan region are still relatively fit and mostly achieve a good postoperative functional outcome. Nevertheless, up to one-fifth of elderly patients may experience postoperative functional decline. A bundle of evidence-based interventions to improve peri-operative care showed good feasibility in clinical routine but did not further improve patients' functional status.

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