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Postoperative Complications and Mobilization Following Major Abdominal Surgery With Versus Without Fitness Tracker-based Feedback (EXPELLIARMUS)

A Student-led Multicenter Randomized Controlled Clinical Trial of the CHIR-Net SIGMA Study Group

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Objective: To determine whether daily postoperative step goals and feedback through a fitness tracker (FT) reduce the rate of postoperative complications after surgery.

Background: Early and enhanced postoperative mobilization has been advocated to reduce postoperative complications, but it is unknown whether FT alone can reduce morbidity.

Methods: EXPELLIARMUS was performed at 11 University Hospitals across Germany by the student-led clinical trial network SIGMA. Patients undergoing major abdominal surgery were enrolled, equipped with an FT, and randomly assigned to the experimental (visible screen) or control intervention (blackened screen). The experimental group received daily step goals and feedback through the FT. The primary end point was postoperative morbidity within 30 days using the Comprehensive Complication Index (CCI). All trial visits were performed by medical students in the hospital with the opportunity to consult a surgeon-facilitator who also obtained informed consent. After discharge, medical students performed the 30-day postoperative visit through telephone and electronic questionnaires.

Results: A total of 347 patients were enrolled. Baseline characteristics were comparable between the 2 groups. The mean age of patients was 58 years, and 71% underwent surgery for malignant disease, with the most frequent indications being pancreatic, colorectal, and hepatobiliary malignancies. Roughly one-third of patients underwent laparoscopic surgery. No imputation for the primary end point was necessary as data completeness was 100%. There was no significant difference in the CCI between the 2 groups in the intention-to-treat analysis (mean ± SD CCI experimental group: 23 ± 24 vs. control: 22 ± 22; 95% CI: −6.1, 3.7; $P = 0.628$). All secondary outcomes, including quality of recovery, 6-minute walking test, length of hospital stay, and step count until postoperative day 7 were comparable between the 2 groups.

Conclusions: Daily step goals combined with FT-based feedback had no effect on postoperative morbidity. The EXPELLIARMUS shows that medical students can successfully conduct randomized controlled trials in surgery.

Keywords: early ambulation, fitness trackers, students, medical, general surgery, postoperative complications, quality of life, randomized controlled trial, enhanced recovery after surgery, patient-reported outcome measures

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Annually, more than 300 million surgeries are performed worldwide,[1] with complications occurring in up to every sixth person who receives major surgery.[2,3] Complications occur even more frequently in major abdominal surgeries, including pancreatic, hepatobiliary, colorectal, and upper gastrointestinal operations.[4–6] Postoperative complications have major implications for patients and the health care system, as they are associated with mortality, reduced quality of life, and increased costs. Nonsurgical complications constitute a substantial part of the overall postoperative morbidity and can potentially be reduced by perioperative interventions.[7,8]

Postoperative mobilization has been postulated to decrease postoperative complications in abdominal surgery and is part of the enhanced recovery after surgery guidelines[9,10] albeit with little evidence.[11,12] Furthermore, mobilization is no trivial aspect of the postoperative course, as recent research suggests that enforcing early mobilization targets requires substantial staff time, and lack of manpower is a main barrier to this practice.[13] Furthermore, many patients fail to achieve common mobilization targets in major abdominal surgery.[14]

Fitness trackers (FT) are a promising tool to improve postoperative mobilization as they have the potential for real-time continuous feedback rather than irregular feedback by health care professionals, allowing an objective, validated outcome measurement of physical activity and a reduction in staff time and manpower to enforce mobilization targets, thereby increasing the cost-effectiveness of mobilization interventions.[15] However, the results of FT use in hospitalized patients are conflicting.[16] Although studies have shown a positive correlation between early enhanced mobilization and recovery,[17] few trials have investigated whether FT-based interventions can independently improve the postoperative course. In addition, most studies have focused on physical activity metrics, such as step

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counts, rather than directly investigating the effect on postoperative complications.[18–22] In summary, the effects of FT-based interventions on complications have not yet been studied in high-quality randomized trials.

Therefore, the objective of the EXPELLIARMUS trial was to determine whether daily postoperative step goals and feedback through a fitness tracker about these step goals reduce the rate of postoperative complications following elective major abdominal surgery.

The EXPELLIARMUS trial was carried out by the Student-Initiated German Medical Audit (SIGMA) study group of the Clinical Trial Network CHIR-*Net* (see the Methods section). Planning, execution, analysis, and publishing were conducted by trained medical students under the supervision of academic surgeons based on the principles of research-based learning. To our knowledge, this is the first student-led multicenter randomized controlled trial in the world.

METHODS

Study Design

EXPELLIARMUS is a multicenter randomized controlled superiority trial with 2 parallel study groups conducted according to the published trial protocol.[15] The trial is reported according to the current CONSORT guidelines,[23] and no changes to the methods have been made after trial commencement.

Participants

Patients were screened preoperatively and recruited to the trial at least on the day before surgery. Informed consent was obtained from all patients scheduled for elective surgery. Inclusion criteria were as follows:[15] (1) patients scheduled for elective major abdominal surgery defined as procedures expected to last more than 2 hours or with an anticipated blood loss greater than 500 mL; (2) ability to understand the character and individual consequences of the clinical trial; (3) open or laparoscopic or robotic surgery, or any variant (laparoscopic-assisted, hybrid procedures, etc.); (4) written informed consent; and (5) age ≥ 18 years. In addition, the following intraoperative/postoperative inclusion criteria were defined: (1) expected postoperative stay in the intensive care or intermediate care ward for less than 4 days; (2) no planned reoperation within 30 days; and (3) confirmed major abdominal surgery (defined as procedures expected to last more than 2 hours, or with an anticipated blood loss greater than 500 mL).

Exclusion criteria were: (1) American Society of Anesthesiologists (ASA) grade > 3, (2) preoperative immobility or inability to walk unaided, (3) participation in another interventional trial with the interference of intervention and outcome of this study, (4) expected postoperative stay in the intensive care or intermediate care ward ≥ 4 days, (5) planned reoperation within 30 days after the index operation, and (6) planned abdominal-thoracic operations (2-field surgeries).

Setting

The EXPELLIARMUS trial was initiated, conducted, analyzed, and reported by the Student-Initiated German Medical Audit (SIGMA) study group (www.sigma-studies.org). SIGMA is a Germany-wide, student-led clinical research network affiliated with CHIR-Net, the clinical trial network of the German Society of Surgery (www.chir-net.de).[24] SIGMA offers medical students the opportunity to participate in student-led clinical research under the supervision of academic surgeons. Participating medical students were trained in workshops to acquire theoretical and practical know-how to independently conduct the EXPELLIARMUS trial and act as peer teachers for fellow students.[25] Data analyses, interpretation, and reporting were performed by student members under the auspices of the statisticians and CHIR-Net facilitators.

The study was conducted at the following university hospitals: Berlin, Frankfurt, Freiburg, Göttingen, Hamburg, Hanover, Heidelberg, Kiel, Mannheim, Munich (Ludwig-Maximilians-University) and Ulm. The EXPELLIARMUS trial was approved by the responsible, independent Ethics Committees (primary ethic vote Heidelberg February 27, 2019; reference S-099/2019) and was registered with the German Clinical Trials Register (DRKS00016755) on March 6, 2019. Patients were recruited between June 2019 and October 2021 and were followed up until 30 days after surgery (last-patient-out 22nd November 2021).[15]

Description of Experimental Intervention

Patients were fitted with a wearable fitness tracker (ActiGraph GT9X Link, ActiGraph, ProCare, Groningen, Netherlands) on their dominant wrist or, if that was not possible, on the nondominant wrist or if that was not possible on any other part of the body for the duration of their postoperative stay until discharge or a maximum of 30 days. They were motivated to achieve their daily step goals using real-time visual feedback from their tracker. Interprofessional care teams were also responsible for the patients' daily step improvement as part of their local standard of care.

The predefined step goals/instructions (mobilization protocol) were as follows:

(1) "Please ambulate/mobilize as much as possible and allowed by your doctors."
(2) "Please take more steps than the previous postoperative day."
(3) "Your daily step goal should be 4000 or more steps. Do not worry if you do not reach this goal immediately."
(4) "You should reach this 4000-step target latest on postoperative day 5 in the case of laparoscopic surgery or on postoperative day 8 in the case of open surgery."

Description of Control Intervention

Patients were also fitted with a wearable fitness tracker (ActiGraph GT9X Link; ActiGraph, ProCare, Groningen, Netherlands) for the duration of their postoperative stay until discharge or a maximum of 30 days. They received no feedback through their tracker (blackened display) and were allowed to mobilize at will. The patients were supported by interprofessional care teams according to local standards, but no specific recommendations were provided.

Trial Visits and Informed Consent

Trials visits were performed as described previously.[15] Medical students screened and informed potential patients about the trial. Thereafter, informed consent was obtained from surgeons at the participating trial sites. Baseline data were collected during visit 1. Visit 2 was used to collect surgical data. Primary and secondary outcome parameters were assessed on postoperative days 2, 4, 6, and 8 (visit 3-6) as well as on discharge (visit 7) and 30 days after surgery (visit 8). Visits 1-7 were performed in the hospital by the medical students, while visit 8 was usually performed by the medical students through telephone

interviews and electronic questionnaires (PROMs). In case patients were still in the hospital 30 days after surgery, visit 8 was also performed in person at the hospital.

Primary End Point

Postoperative morbidity was set as the primary end point to assess the efficacy of the intervention using fitness trackers. Postoperative morbidity was quantified using the comprehensive complication index (CCI) within 30 days of the index operation. CCI calculates the overall morbidity for an individual patient on a scale from 0 (no complication) to 100 (death).[26,27]

Secondary End Points

The following secondary objectives of the clinical trial were prespecified to further characterize the success of the intervention: (1) number of steps for each postoperative day (POD) until POD 8 or discharge whatever comes first measured through the FT; (2) quality of recovery according to quality of recovery-15 at baseline and on POD 4 (or at discharge whatever comes first);[28,29] (3) activity data (using the wearable device for each POD until discharge or a maximum of 30 days) including metabolic equivalent of tasks (MET) rates, light/moderate physical activity, and sedentary bouts; and (4) health-related quality of life measured using the EORTC QLQ-C30 at baseline, on POD 6 and 8 (or discharge, whatever comes first). Although the health-related quality of life measure EORTC QLQ-C30 has been developed and validated for patients with cancer, it is the most comprehensive tool to cover aspects of postoperative recovery that are important to patients and experts;[30] (5) 6-minute walking test on POD 6 (or discharge, whatever comes first); (6) Time (in days) until return of bowel function measured using the GI-2 score defined as "The patient has tolerated solid intake (no vomiting) for 24 hours AND has passed stool";[31] (7) Postoperative pulmonary complications according to the Melbourne group score during hospital stay;[7] (8) Deep vein thrombosis until POD 30; (9) Pulmonary embolism (PE) until POD 30; (10) Length of hospital stay in days (from day of surgery until day of discharge after index operation); (11) Discharge destination from the acute hospital ward (home, rehabilitation facility, nursing home, or other hospital); (12) Pain scores according to the numeric rating scale on POD 2, 4, and 6 at rest and during movement; (13) Postoperative unintended falls/collapses until day of discharge. There were no changes in trial outcomes after the trial commenced.

Sample Size Calculation

The sample size calculation was based on the primary end point "CCI within 30 days after the index operation." Assumptions were based on the literature:[26,27,32] a decrease of 10 points in the CCI was considered relevant by patients and clinicians, and a conservative SD of 20 was assumed. The primary end point was tested simultaneously in the subgroup of patients who underwent minimally invasive surgery and the subgroup of patients who underwent open surgery with an expected ratio of occurrence in patients of 1:1 using a 2-sided t-test. Therefore, the overall 2-sided significance level of $\alpha = 0.05$ was adjusted by Bonferroni correction, yielding $\alpha = 0.025$ for each of the 2 subgroups. Thus, to achieve a power of 80%, a sample size of $n = 156$ (78 per group) had been recruited per subgroup, with a total required sample size of the trial of $n = 312$ (156 per therapy group). To compensate for drop-outs and loss-to-follow-up, another 10% of patients were randomized, leading to a total sample size of $n = 348$ (174 per group).

Randomization and Assignment of Intervention

The random assignment of patients to one of the 2 comparable study groups was achieved using a centralized web-based tool (www.randomizer.at). The concealment of the randomization scheme was guaranteed using an online program. The trial participants and investigators did not have access to the randomization schedule. Block randomization with variable block sizes was performed on the day of surgery at the time of skin closure or later if all intraoperative inclusion criteria were fulfilled. Randomization was stratified according to the type of surgery (laparoscopic vs. open). Surgeries, including laparoscopic-assisted or hybrid procedures, were considered laparoscopic interventions. Conversions from laparoscopic to open surgery were classified as open procedures. Randomization was performed by authorized trial personnel (investigator, medical student, or designated representative) only.

Blinding

Neither the patients nor the outcome assessors were blinded to the intervention, as this was not feasible and contradicted the pragmatic nature of the trial. However, because the primary and secondary end points are objective, the risk of bias is limited.

Statistical Analysis

For the examination of the primary end point "CCI within 30 days after the index operation," the hypotheses that were assessed for each subgroup (minimally invasive or open) in the primary analysis were as follows: H0: $\mu 1 = \mu 2$ versus H1: $\mu 1 \neq \mu 2$, where $\mu 1$ and $\mu 2$ denote the mean CCI in the control and intervention groups, respectively. The significance level was set to 2-sided $\alpha = 0.025$ per subgroup test. Due to the stratified randomization and relatively large number of centers in relation to the sample size, the inclusion of centers as a random effect was used.[33] Therefore, the primary end point was examined in the respective subgroup (minimally invasive or open) using a linear mixed model, including the center as the random intercept and the group as the fixed effect. The primary analysis was conducted based on the full analysis set according to the intention-to-treat (ITT) principle and comprised all patients in the group they were randomized to. In the ITT analysis, missing data for the primary outcome variable were replaced by using multiple imputations, which took the covariates treatment group and center into account by applying the fully conditional specification method.[34] The per-protocol (PP) set consisted of all patients treated per-protocol, and no missing data were imputed. An additional mobility population (MP) consisted of all patients who were randomized, had no reoperation within 30 days, and had not been in the intensive or intermediate care ward for ≥ 4 days during the first postoperative week. For the full analysis set, all baseline values and secondary outcomes were evaluated descriptively, and descriptive *P* values were reported together with 95% confidence intervals (CI) and mean with SD for the corresponding effects. Therefore, secondary end points were evaluated descriptively using regression models, including group as a fixed effect and center as random intercept, as specified for the primary end point. In further exploratory analyses, the association between variables and primary and secondary outcomes was assessed. Subgroup analyses were also conducted. The safety analysis included the calculation of frequencies and rates of complications together with 95% CI. All analyses were performed using SAS version 9.4 and R version $> 4.0.0$.

Patient data were obtained using electronic case report forms entered into the REDCap electronic data capture

system.[35] Data security was ensured by restricting access to authorized and trained study members. Based on a study-specific data validation plan, queries were created in the case of missing or implausible data entry, which had to be clarified by the study investigators and medical students to enhance the validity of data collection. Data were obtained from patients or their medical records.

RESULTS

Participants

From June 2019 to October 2021, 347 patients were successfully enrolled across 11 trial centers. After randomization, 174 and 173 participants were allocated to the experimental and control groups, respectively. A CONSORT flow diagram is shown in Figure 1. Of the ITT population, 150 had to be excluded from the PP analysis because of reoperations within 30 days (n = 3), no major surgery performed (n = 1), and discontinuous use of tracker until discharge and/or major protocol violation (n = 146). For MP analysis, the open and laparoscopic subgroups consisted of 160 and 89 participants, respectively.

Baseline Data

The control and experimental groups were statistically comparable in all clinical aspects except for gender, type of malignancy, ASA status, and previous abdominal surgeries (Table 1). However, these differences are clinically irrelevant to the research question. For example, the ASA classification was clinically comparable in both groups, as the experimental group had fewer patients who met the criteria for ASA I (7% control group vs. 2% interventional group), while the control group included more patients with ASA III (49% control group vs. 42% interventional group). The distribution of cancer types differed slightly between groups, with a higher proportion of pancreatic malignancies (25% experimental vs. 22% control group, $P = 0.043$) and sarcoma (5% experimental vs. 1% control group, $P = 0.043$) and more colorectal cancer in the control group (24% vs. 16% experimental group, $P = 0.043$). Importantly, physical fitness measured using the Duke Activity Status Index was

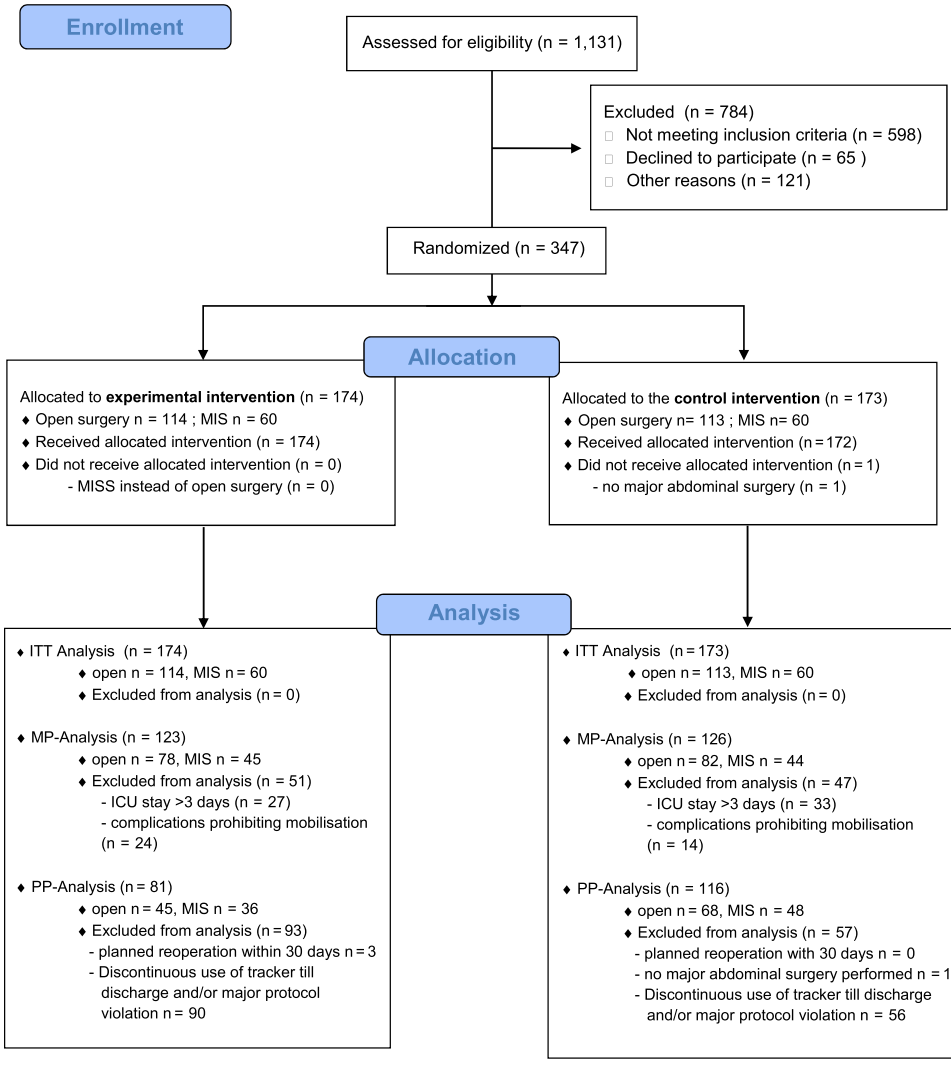

FIGURE 1. CONSORT Flow Diagram of the EXPELLIARMUS trial. ITT indicates intention-to-treat; MIS, minimally invasive surgery; MP, mobility population; PP, per-protocol.

TABLE 1. Demographic and Baseline Data

	Control (N (%) or mean ± SD)	Experimental (N (%) or mean ± SD)	Total (N (%) or mean ± SD)	*P*
Age (y)	58 ± 14	59 ± 13	58 ± 14	0.403
BMI (kg/m^2)	26 ± 6.5	26 ± 6.1	260 ± 6.3	0.754
Sex	—	—	—	0.036
Female	72 (42)	92 (53)	164 (47)	—
Male	101 (58)	82 (47)	183 (53)	—
ASA classification status	—	—	—	0.011
ASA III	85 (49)	73 (42)	158 (46)	—
ASA II	76 (44)	98 (56)	174 (50)	—
ASA I	12 (7)	3 (2)	15 (4)	—
DASI	41 ± 15	39 ± 16	40 ± 16	0.211
Indication for surgery - Malignancy	121 (70)	124 (71)	245 (71)	0.787
Type of cancer	—	—	—	0.043
Other	12 (7)	14 (8)	26 (7)	—
Colon cancer	22 (13)	14 (8)	36 (10)	—
Rectal cancer	19 (11)	14 (8)	33 (10)	—
Pancreatic malignancy	38 (22)	43 (25)	81 (23)	—
Hepatobiliary malignancy	18 (10)	18 (10)	36 (10)	—
Gastric malignancy	10 (6)	12 (7)	22 (6)	—
Sarcoma	2 (1)	9 (5)	11 (3)	—
Neoadjuvant treatment for tumor disease	37	36	36	0.818
Indication for surgery - Benign	52 (30)	50 (29)	102 (29)	0.787
Other	30 (18)	37 (21)	67 (20)	—
Obesity (adiposity)	7 (4)	3 (2)	10 (3)	—
Urological disease	5 (3)	2 (1)	7 (2)	—
CED	10 (6)	8 (5)	18 (5)	—
Smoking	—	—	—	0.530
Former smoker	53 (31)	60 (34)	113 (33)	—
Active-smoker	30 (17)	34 (20)	64 (18)	—
Non-smoker	90 (52)	80 (46)	170 (49)	—
Alcohol consumption	—	—	—	0.338
Yes, rarely (less than once a week)	61 (35)	54 (31)	115 (33)	—
Yes, occasionally (~once a week)	34 (20)	35 (20)	69 (20)	—
Yes, often (daily, almost daily)	21 (12)	14 (8)	35 (10)	—
No	57 (33)	71 (41)	128 (37)	—
Previous abdominal surgeries	57	69	63	0.023
Medical comorbidities	135 (78)	130 (75)	265 (76)	0.466
Patients with current medication	76	77	76	0.777

ASA indicates American Society of Anesthesiologists; BMI, body mass index; CAD, coronary artery disease; CI, confidence interval; CED, chronic inflammatory bowel disease; DASI, Duke Activity Status Index.

comparable at baseline (experimental, 39 ± 16 vs. control, 41 ± 15; $P = 0.211$).

Comparing open versus laparoscopic subgroups, the indication for open surgery was malignancy in 78% of cases compared with 57% in laparoscopic surgery. The proportion of male patients was also higher in the open subgroup (58% vs. 43%). Within the laparoscopic subgroup, the experimental group was significantly older than the control group (mean ± SD: 59 ± 14 vs. 54 ± 15, $P = 0.042$). In this subgroup, all otherwise healthy patients defined by ASA classification status I were randomly allocated to the control group (18% vs. 0% interventional group, $P = 0.002$), whereas the experimental group had a larger proportion of ASA III patients (48% vs. 43% control group, $P = 0.002$).

Surgery and Perioperative Data

The 2 groups had similar procedural parameters such as blood loss, operative time, and access routes (open vs. laparoscopic) (Table 2). In the subgroup of patients who underwent open surgery, hepato-biliary-pancreatic surgery was performed most frequently (55%), followed by colorectal surgery (15%) and multivisceral resection (14%). In contrast, colorectal surgery (47%) was performed more frequently in the laparoscopic subgroup, followed by hepato-biliary-pancreatic (23%) and upper gastrointestinal surgery (21%). Overall, hepato-biliary-pancreatic surgery was the most frequent type of surgery (44%), followed by colorectal (26%) and upper gastrointestinal surgery (11%).

Across all patients, Epidural analgesia was used more frequently in patients belonging to the experimental group (58% interventional group vs. 47% control group, $P = 0.047$). This still holds true when regarding the subgroup of patients who underwent open surgery (68% interventional group vs. 56% control group, $P = 0.049$). Other types of oral and parenteral analgesia and their durations were comparable between the 2 groups.

To quantify physiotherapy support, the cumulative physiotherapy minutes of the patients per treatment group on the respective POD were analyzed. Physiotherapeutic treatment was comparable between the control and experimental groups (Supplement 1, Supplemental Digital Content 1, http://links.lww.com/SLA/F14), with the exception of the laparoscopic cohort, in POD 5 onwards less physiotherapy was provided in the experimental group than in the control group (Supplement 1, Supplemental Digital Content 1, http://links.lww.com/SLA/F14).

Primary End Point

No Imputation had to be performed since no missing values in the variables were observed. In the intention-to-treat

TABLE 2. Surgical and Perioperative Data

	Control n = 173 (mean ± SD; median)	Experimental n = 174 (mean ± SD; median)	Total (mean ± SD; median)	*P*
Duration of surgery (min)	263 ± 110; 243	269 ± 111; 245	266 ± 110; 244	0.625
Estimated blood loss (mL)	628 ± 784; 400	631 ± 828; 400	630 ± 805; 400	0.979
Duration of epidural analgesia (d)	4.3 ± 3.9	4.3 ± 1.8	4.3 ± 2.9	0.976
Duration of PCA (d)	3.9 ± 2.7	3.3 ± 2.2	3.6 ± 2.5	0.308
	Control	Experimental	Total	P
Confirmed major abdominal surgery	172/173 (99)	174/174 (100)	346/347 (100)	0.315
Type of surgical access	—	—	—	0.764
Laparoscopic	58 (34)	61 (35)	119 (34)	—
Open	115 (66)	113 (65)	288 (66)	—
Intraabdom. drains	133 (77)	132 (76)	265 (76)	0.824[chi2]
Urinary catheter at the end of surgery	161 (93)	167 (96)	328 (95)	0.233[chi2]
Type of surgery	—	—	—	0.901
Colorectal surgery	47 (27)	44 (25)	91 (26)	—
Upper GI	19 (11)	20 (11)	39 (11)	—
HPB	75 (43)	77 (44)	152 (44)	—
Other surgery	8 (5)	6 (3)	14 (4)	—
Multivisceral	14 (8)	19 (11)	33 (10)	—
Gynecological	3 (2)	1 (1)	4 (1)	—
Urological surgery	7 (4)	7 (4)	14 (4)	—
Epidural analgesia	47	58	53	0.047
PCA	27	23	25	0.437
Additional oral analgesia	—	—	—	0.742
fixed and on-demand	67 (42)	63 (39)	130 (40)	—
fixed only	63 (39)	64 (40)	127 (40)	—
on-demand only	19 (12)	16 (10)	35 (11)	—
Additional intravenous analgesia	—	—	—	0.955
none	46 (29)	49 (31)	95 (30)	—
Fixed and on-demand	55 (34)	56 (35)	111 (35)	—
Fixed only	41 (25)	38 (34)	79 (25)	—
On-demand only	19 (12)	17 (11)	36 (11)	—

GI indicates gastrointestinal; HPB, hepatobiliary; PCA, patient-controlled intravenous analgesia.

analysis of the primary end point, no significant difference was found between the control and the experimental groups (CCI control, 22 ± 22 vs. CCI experimental, 23 ± 24; $P = 0.628$, 95% CI: [−6.1, 3.7]; Table 3). The same was true for the PP and mobile population analyses (Table 3).

In the ITT analysis, the comprehensive complication index for patients who underwent open surgery was 27 ± 23 in the control group versus 26 ± 26 in the experimental group ($P = 0.781$, 95% CI: [−7.3, 5.5]). Similarly, no difference was detected in patients undergoing laparoscopic surgery (CCI control: 13 ± 17 vs. CCI experimental: 18 ± 20; $P = 0.135$; 95% CI: [−12, 1.6]). Overall, patients in the laparoscopic subgroup experienced fewer complications than those in the open surgery group. Additional sensitivity analyses of the mobile (MP) and PP populations demonstrated no significant differences between the open and laparoscopic subgroups (Table 3).

Secondary End points

No differences were detected between the control and experimental groups regarding quality of recovery-15, length of hospital stay, and return of bowel function (Table 4). In the 6-minute walking test on POD 6, laparoscopic patients in the control group walked significantly more meters than those in the experimental group (control 422 ± 179 vs. experimental group 334 ± 140; $P = 0.025$, 95% CI: [11, 164]). However, no difference was observed

TABLE 3. Analysis of the Primary End Point

	Control (mean ± SD)	Experimental (mean ± SD)	Total (mean ± SD)	*P*	95% CI
CCI intention-to-treat population (ITT)					
All patients	22 ± 22	23 ± 24	23 ± 23	0.628	(−6.1, 3.7)
Open surgery	27 ± 23	26 ± 26	26 ± 24	0.781	(−7.3, 5.5)
Laparoscopic surgery	13 ± 17	18 ± 20	16 ± 19	0.135	(−12, 1.6)
CCI mobile population (MP)					
All patients	18 ± 19	18 ± 20	18 ± 19	0.976	(−4.9, 4.7)
Open surgery	22 ± 20	20 ± 19	21 ± 19	0.399	(−8.7, 3.5)
Laparoscopic surgery	10 ± 14	16 ± 20	13 ± 18	0.160	(−13, 2.1)
CCI per-protocol population (PP)					
All patients	18 ± 19	19 ± 23	18 ± 20	0.674	(−7.3, 4.7)
Open surgery	20 ± 19	22 ± 23	21 ± 21	0.67	(−6.5, 10)
Laparoscopic surgery	14 ± 17	15 ± 21	14 ± 19	0.796	(−9.7, 7.5)

CCI indicates comprehensive complication index; CI, 95% confidence interval.

TABLE 4. Analysis of Secondary End Points

	Control (mean ± SD)	Experimental (mean ± SD)	Total (mean ± SD)	*P*	95% CI
QoR-15					
Open surgery					
Visit 1	113 ± 27	117 ± 23	115 ± 25	0.226	(−12, 2.8)
Visit 4	96 ± 29	94 ± 27	95 ± 28	0.699	(−6.9, 10)
Difference V4−V1	−16 ± 27	−24 ± 27	−20 ± 27	0.078	(−0.85, 16)
Laparoscopic surgery					
Visit 1	113 ± 25	112 ± 27	113 ± 26	0.767	(−7.5, 10)
Visit 4	90 ± 24	93 ± 27	92 ± 25	0.513	(−12, 5.9)
Difference V4-V1	−23 ± 32	−18 ± 34	−20 ± 33	0.416	(−17, 6.9)
All patients					
Visit 1	113 ± 26	115 ± 25	114 ± 26	0.490	(−7.6, 3.6)
Visit 4	93 ± 27	94 ± 27	94 ± 27	0.937	(−6.4, 5.9)
Difference V4-V1	− 19 ± 29	− 21 ± 30	− 20 ± 30	0.515	(−4.6, 9.2)
6-minute walking test (in meter, mean ± SD)					
Open	329 ± 141	311 ± 137	320 ± 139	0.455	(−63, 28)
Laparoscopic	422 ± 179	334 ± 140	374 ± 164	0.025	(11, 164)
All	357 ± 159	319 ± 138	338 ± 150	0.06	(−1.6, 78)
Return of bowel function (in days, mean ± SD)					
Open	3.4 ± 2	3.9 ± 3.6	3.6 ± 2.9	0.234	(−0.32, 1.3)
Laparoscopic	3.2 ± 2.4	3.6 ± 1.7	3.4 ± 2.1	0.414	(−1.1, 0.47)
All	3.3 ± 2.1	3.8 ± 3.1	3.6 ± 2.6	0.15	(−1, 0.16)
Length of hospital stay					
Open	15 ± 9.7	16 ± 9.2	16 ± 9.3	0.666	(−1.9, 3)
Laparoscopic	9.3 ± 7.7	10 ± 8.1	9.8 ± 7.9	0.471	(−1.8, 3.9)
All	13 ± 9.5	14 ± 9.2	14 ± 9.3	0.491	(−1.3, 2.7)

CI indicates 95% confidence interval; QoR, quality of recovery questionnaire; V, visit.

in patients undergoing open surgery (control: 329 ± 141 vs. experimental: 311 ± 137, $P = 0.455$, 95% CI: [−63, 28]).

No differences were recorded between the 2 groups regarding postoperative pulmonary complications (control 3% vs. experimental group 2%, $P = 0.307$, 95% CI: [−0.016, 0.051]). The specific rates of pulmonary embolism (control group 1% vs. intervention group 2%, $P = 0.317$, 95% CI: [−0.034, 0.011]), deep vein thrombosis (control group 1% vs. intervention group 1%, $P = 0.565$, 95% CI: [−0.025, 0.014]), and pain at rest and during movement were comparable (Supplement 2, Supplemental Digital Content 1, http://links.lww.com/SLA/F14). Most patients in the control and intervention groups were discharged to their homes (93% and 92% in the control and experimental groups, respectively; $P = 0.207$).

Fitness Tracker Data

In the open surgery cohort, step counts were not significantly different between the 2 groups (Supplement 3, Supplemental Digital Content 1, http://links.lww.com/SLA/F14). In the laparoscopic surgery cohort, patients in the experimental group took significantly more steps starting on postoperative day 7 than those in the control group (intervention:5,664 ± 2,653 vs. control:3833 ± 2121, $P = 0.030$; CI [188, 3474]), but not between POD 1-6 (supplement 3, Supplemental Digital Content 1, http://links.lww.com/SLA/F14).

Sedentary bouts and light and moderate physical activities were comparable between the 2 groups (Supplement 4, Supplemental Digital Content 1, http://links.lww.com/SLA/F14). The latter 2 parameters increased significantly after surgery and reached a plateau on POD 3 (light activity) and POD 6 (moderate activity) (Supplement 4, Supplemental Digital Content 1, http://links.lww.com/SLA/F14). Similarly, there were no differences in the FT-recorded metabolic equivalents of task between the 2 groups (Supplement 5, Supplemental Digital Content 1, http://links.lww.com/SLA/F14), which remained similar over the inpatient course.

Health-related Quality of Life

Global health-related quality of life, measured using the EORTC QLQ-C30, was comparable in both treatment groups (Supplement 6, Supplemental Digital Content 1, http://links.lww.com/SLA/F14) and for the 2 subgroups (open and laparoscopic) at baseline and POD 6 and 8. The same was true for all subscales of the questionnaire (physical functioning, role functioning, emotional functioning, cognitive functioning, social functioning, and global health) (Supplement 6, Supplemental Digital Content 1, http://links.lww.com/SLA/F14). Similarly, all EORTC QLQ-C30 symptom scores were comparable between the 2 groups (fatigue, nausea/vomiting, pain, dyspnea, insomnia, appetite loss, constipation, and diarrhea).

Safety Analysis

The number of serious adverse events, defined as complications according to Dindo-Clavien grade III-V, was comparable in both groups. Overall, Serious adverse events occurred in 44 of 173 patients (25%) in the control group and in 35 of 174 (20%) patients in the experimental group ($P = 0.237$, 95% CI: [−0.035, 0.14]). The same rate of unintentional falls was observed in the experimental group as in the control groups (control: 3% vs. intervention: 3%, $P = 0.752$).

DISCUSSION

In this multicenter student-led clinical trial, 347 patients undergoing major abdominal surgery were randomly assigned to either postoperative step goals and feedback through fitness

trackers or standard of care (no step goals and fitness trackers with a blackened screen) in addition to local standards of perioperative care. No difference between the 2 groups was seen regarding the primary end point and postoperative complications assessed through the CCI, neither for the entire cohort nor for patients in the laparoscopic or open surgery subgroups. The intervention proved ineffective in increasing postoperative mobilization in the open surgery subgroup but not in the laparoscopic group, in which patients in the experimental arm took significantly more steps from day 7 onwards. All other aspects of postoperative recovery evaluated through numerous FT-based, patient-reported, and physical assessments were clinically comparable between the 2 arms.

Postoperative mobilization has been postulated to decrease postoperative complications in abdominal surgery, although evidence is lacking.[11,12] Multiple studies have shown a correlation between enhanced mobilization and favorable postoperative outcomes.[17,20,36,37] However, it remains unclear whether FT-assessed mobility is a mere predictor of recovery or whether enhanced mobilization plays a causal role in improving postoperative recovery. This is an important issue as enforcing mobilization requires substantial staff time, and lack of manpower is a main barrier to this practice.[13] In a recent systematic review, Fuchita et al identified 6 RCTs that evaluated FT-based interventions for mobilization after surgery.[38] In line with our results, none of the trials showed improvement in postoperative complications using fitness tracker-based interventions. However, in contrast to EXPELLIARMUS, none of these studies evaluated postoperative morbidity as a primary outcome parameter. Only 1 previous RCT used a patient-relevant primary outcome (6-minute walking test),[12] while all other trials focused on surrogate parameters, such as step count.[18,21,39–41] In addition, all but one of the previous studies exhibited a major risk of bias; most were single-center trials and significantly smaller (< 110 patients) than EXPELLIARMUS.[38] In addition, contrary to previous trials, EXPELLIARMUS evaluated a wide range of recovery parameters, patient-reported outcome measures, and FT data to cover the entire spectrum of postoperative recovery.[30] However, none of these outcomes showed clinically relevant improvement in the experimental group. Similar negative results have been reported for human resource-based interventions to improve postoperative mobilization. In a recent trial in patients undergoing colorectal surgery, facilitated mobilization (staff dedicated to assisting transfers and walking during hospital stay) failed to improve postoperative pulmonary complications and recovery.[42]

In the EXPELLIARMUS trial, step counts were significantly higher from POD 7 onwards only in the laparoscopic group but not in patients undergoing open surgery. Similar results were reported by Wolk et al, who showed an increase in steps only in the laparoscopic subgroup.[18] However, the results on step counts were not consistent across previous trials, with 1 RCT reporting no beneficial effect[39] while others recorded increased step counts.[12,21,40] In summary, FT-based feedback seems ineffective in increasing mobilization to the extent assumed by us and previous researchers. Postoperative mobilization seems to be a more complicated process that is influenced by many factors other than patient motivation, including physiotherapy support, adequate analgesia, and the ability to mobilize independently despite drains, epidural catheters, and intravenous lines. We aimed to control for these factors in the EXPELLIARMUS trial. For example, the duration of physiotherapy support, number of drains, and analgesic therapy were comparable between the 2 groups, except for epidural analgesia, which was applied significantly more often in the experimental group (Table 2). However, this did not lead to insufficient pain treatment, as pain scores were comparable between the 2 groups (Supplement 2, Supplemental Digital Content 1, http://links.lww.com/SLA/F14). Given our negative results, future studies on postoperative mobilization will have to consider all of these factors while simultaneously developing more sophisticated interventions to improve mobilization. Thus, FT may play a role in these complex interventions. Trials in other indications, such as chronic back pain, have shown that a combination of digital applications with human guidance can be effective while simultaneously saving manpower.[43]

Another important aspect of the EXPELLIARMUS trial is that it was planned, organized, conducted, and analyzed by more than 150 medical students of the SIGMA study group (www.sigma-studies.org) under the supervision of surgeons, biostatisticians, data managers, and trial personnel of the CHIR-Net (the Clinical Trial Network of the German Society of Surgery (www.chir-net.de). The organization and structure of the SIGMA network and its projects have been described.[24,25,44] To the best of our knowledge, this is the first randomized trial performed by medical students worldwide and is significantly more complex than previous student-led research projects.[45] This demonstrates the feasibility of student-led randomized trials in surgery and large-scale research-based learning projects. Research-based learning provides students with the opportunity to gain knowledge by conducting scientific inquiries or investigations of interest to the scientific or medical community.[46] Although we did not directly pursue educational goals in our trial, it is likely that participating students gained knowledge, skills, and competencies in clinical research, as shown in previous studies.[25,47,48] Feasibility was underlined by the excellent data completeness rate of 91.5% across participating centers and by the fact that, despite the COVID-19 pandemic, which led to a dramatic decline in recruitment, medical students were able to revitalize the project and finish recruitment over an extended period of time.

This study has several limitations. First, the fitness trackers (FT), as the central instrument of our intervention, showed various shortcomings in everyday use. Some patients in the experimental arm reported a variation between the step count recorded by our FT used in our trial and the commercially available FT and smartwatches worn by some patients. The problem with commercially available tools is that no raw data can be extracted from these devices, and algorithms for aggregated data may change with software updates, thus inhibiting comparability and scientific analyses of results. In addition, patients in the experimental group reported that not all steps were counted by the FT, limiting the acceptance of the intervention. The specificities of the postoperative setting (shuffling gait, small steps, drains, and catheters) present challenges for gait sensors. Similar challenges have been reported for other indications, such as Parkinson's disease, which has triggered the development of special tools.[49] Similar developments are required during the surgery. However, this problem might explain the higher number of patients in the experimental group that discontinuously used their trackers, putting them on and off (see PP analysis). Furthermore, fitting the FT to the wrist might have influenced the step count in cases where patients were using their hands to hold onto intravenous posts for walking. We aimed to circumvent this problem by allowing the tracker to fit on the other arm or any other part of the body.

Second, the participating hospitals were large tertiary university centers, which might have limited the external validity

of our results. Patient groups and surgeries performed (Tables 1 and 2) might not reflect surgical practice at other care levels, meaning that the results might not be transferrable to another clinical context. The step counts were measured until the day of discharge. Therefore, it is unclear whether the differences in steps seen in the laparoscopic subgroup are a persistent effect and how patients in the open surgery group mobilize after discharge.

In summary, the EXPELLIARMUS trial of the SIGMA Study Group failed to show any effect of step goals combined with FT-based feedback on complications in patients undergoing major abdominal surgery. However, the trial showed that high-quality multicenter randomized controlled trials can be carried out by medical students with the assistance of academic surgeons and experienced trial staff.

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REFERENCES

1. Weiser TG, Haynes AB, Molina G, et al. Estimate of the global volume of surgery in 2012: An assessment supporting improved health outcomes. *Lancet*. 2015;385(Suppl 2):S11.
2. Dencker EE, Bonde A, Troelsen A, et al. Postoperative complications: An observational study of trends in the United States from 2012 to 2018. *BMC Surg*. 2021;21:393.
3. Tevis SE, Cobian AG, Truong HP, et al. Implications of multiple complications on the postoperative recovery of general surgery patients. *Ann Surg*. 2016;263:1213–1218.
4. Mariette C, Markar SR, Dabakuyo-Yonli TS, et al. Hybrid minimally invasive esophagectomy for esophageal cancer. *N Engl J Med*. 2019;380:152–162.
5. Diener MK, Seiler CM, Rossion I, et al. Efficacy of stapler versus hand-sewn closure after distal pancreatectomy (DISPACT): A randomised, controlled multicentre trial. *Lancet*. 2011;377:1514–1522.
6. Mihaljevic AL, Schirren R, Özer M, et al. Multicenter double-blinded randomized controlled trial of standard abdominal wound edge protection with surgical dressings vs. coverage with a sterile circular polyethylene drape for prevention of surgical site infections: A CHIR-Net trial (BaFO; NCT01181206). *Ann Surg*. 2014;260:730–737; discussion 737-9.
7. Boden I, Skinner EH, Browning L, et al. Preoperative physiotherapy for the prevention of respiratory complications after upper abdominal surgery: Pragmatic, double blinded, multicentre randomised controlled trial. *BMJ*. 2018;360:j5916.
8. Anderson O, Davis R, Hanna GB, et al. Surgical adverse events: A systematic review. *Am J Surg*. 2013;206:253–262.
9. Ljungqvist O, Scott M, Fearon KC. Enhanced recovery after surgery: A review. *JAMA Surg*. 2017;152:292–298.
10. ERAS® Society. ERAS Guidelines. ERAS® Society. Accessed May 24, 2023. https://erassociety.org/guidelines/
11. Castelino T, Fiore JF, Niculiseanu P, et al. The effect of early mobilization protocols on postoperative outcomes following abdominal and thoracic surgery: A systematic review. *Surgery*. 2016;159:991–1003.
12. Fiore JF, Castelino T, Pecorelli N, et al. Ensuring early mobilization within an enhanced recovery program for colorectal surgery: A randomized controlled trial. *Ann Surg*. 2017;266:223–231.

13. Pearsall EA, Meghji Z, Pitzul KB, et al. A qualitative study to understand the barriers and enablers in implementing an enhanced recovery after surgery program. *Ann Surg*. 2015;261:92–96.
14. Wolk S, Distler M, Müssle B, et al. Adherence to ERAS elements in major visceral surgery-an observational pilot study. *Langenbecks Arch Surg*. 2016;401:349–356.
15. Schwab M, Brindl N, Studier-Fischer A, et al. Postoperative complications and mobilisation following major abdominal surgery with vs. without fitness tracker-based feedback (EXPELLIARMUS): Study protocol for a student-led multicentre randomised controlled trial (CHIR-Net SIGMA study group). *Trials*. 2020;21:293.
16. de Leeuwerk ME, Bor P, van der Ploeg HP, et al. The effectiveness of physical activity interventions using activity trackers during or after inpatient care: A systematic review and meta-analysis of randomized controlled trials. *Int J Behav Nutr Phys Act*. 2022;19:59.
17. Nevo Y, Shaltiel T, Constantini N, et al. Activity tracking after surgery: Does it correlate with postoperative complications? *Am Surg*. 2022;88: 226–232.
18. Wolk S, Linke S, Bogner A, et al. Use of activity tracking in major visceral surgery-the enhanced perioperative mobilization trial: A randomized controlled trial. *J Gastrointest Surg*. 2018;23:1218–1226; Published online October 8.
19. Ghomrawi HM, Baumann LM, Kwon S, et al. Using accelerometers to characterize recovery after surgery in children. *J Pediatr Surg*. 2018;53: 1600–1605.
20. Low CA, Bovbjerg DH, Ahrendt S, et al. Fitbit step counts during inpatient recovery from cancer surgery as a predictor of readmission. *Ann Behav Med*. 2018;52:88–92.
21. Ni CY, Wang ZH, Huang ZP, et al. Early enforced mobilization after liver resection: A prospective randomized controlled trial. *Int J Surg*. 2018;54(Pt A):254–258.
22. Wells CI, Xu W, Penfold JA, et al. Wearable devices to monitor recovery after abdominal surgery: scoping review. *BJS Open*. 2022;6:zrac031.
23. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomized trials. *Ann Intern Med*. 2010;152:726–732.
24. Frey PE, Friedrich M, Rädeker L, et al. Encouraging student-driven clinical research in Germany: The CHIR-Net SIGMA network. *Innov Surg Sci*. 2017;2:255–260.
25. Rädeker L, Schwab M, Frey PE, et al. Design and evaluation of a clinical investigator training for student-lead prospective multicentre clinical trials: A CHIR-Net SIGMA Research-based Learning Project. *Zentralbl Chir*. 2020;145:521–530.
26. Slankamenac K, Nederlof N, Pessaux P, et al. The comprehensive complication index: A novel and more sensitive endpoint for assessing outcome and reducing sample size in randomized controlled trials. *Ann Surg*. 2014;260:757–762; discussion 762-763.
27. Slankamenac K, Graf R, Barkun J, et al. The comprehensive complication index: A novel continuous scale to measure surgical morbidity. *Ann Surg*. 2013;258:1–7.
28. Stark PA, Myles PS, Burke JA. Development and psychometric evaluation of a postoperative Quality of Recovery Score: The QoR-15. *Anesthes*. 2013;118:1332–1340.
29. Kleif J, Waage J, Christensen KB, et al. Systematic review of the QoR-15 score, a patient- reported outcome measure measuring quality of recovery after surgery and anaesthesia. *Br J Anaesth*. 2018;120:28–36.
30. Lee L, Dumitra T, Fiore JF, et al. How well are we measuring postoperative "recovery" after abdominal surgery? *Qual Life Res*. 2015; 24:2583–2590.
31. van Bree SHW, Bemelman WA, Hollmann MW, et al. Identification of clinical outcome measures for recovery of gastrointestinal motility in postoperative ileus. *Ann Surg*. 2014;259:708–714.
32. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: A new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg*. 2004;240:205–213.
33. Kahan BC, Harhay MO. Many multicenter trials had few events per center, requiring analysis via random-effects models or GEEs. *J Clin Epidemiol*. 2015;68:1504–1511.
34. Buuren S. *Flexible Imputation of Missing Data*. Chapman and Hall; 2012. Accessed November 15, 2014. http://www.crcpress.com/product/isbn/9781439868249
35. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)–A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42:377–381.
36. Turan A, Khanna AK, Brooker J, et al. Association between mobilization and composite postoperative complications following major elective surgery. *JAMA Surg*. 2023;158:e231122.
37. Kane WJ, Hassinger TE, Myers EL, et al. Wearable technology and the association of perioperative activity level with 30-day readmission among patients undergoing major colorectal surgery. *Surg Endosc*. 2022;36: 1584–1592.
38. Fuchita M, Ridgeway KJ, Kimzey C, et al. Accelerometer-measured inpatient physical activity and associated outcomes after major abdominal surgery: Systematic review. *Interact J Med Res*. 2023;12: e46629.
39. Waller GC, Kim TG, Perez S, et al. Comparing activity trackers with vs. without alarms to increase postoperative ambulation: A randomized control trial. *Am Surg*. 2021;87:1093–1098.
40. No JH, Kim K, Kim YB, et al. Effects of an activity tracker with feedback on physical activity in women after midline laparotomy: A randomized controlled trial. *J Obstet Gynaecol Res*. 2021;47: 2544–2550.
41. Steffens D, Solomon MJ, Beckenkamp PR, et al. Individualised, targeted step count intervention following gastrointestinal cancer surgery: The Fit-4-Home randomised clinical trial. *ANZ J Surg*. 2022; 92:703–711.
42. Balvardi S, Pecorelli N, Castelino T, et al. Impact of facilitation of early mobilization on postoperative pulmonary outcomes after colorectal surgery: A randomized controlled trial. *Ann Surg*. 2021;273:868–875.
43. Sander LB, Paganini S, Terhorst Y, et al. Effectiveness of a guided web-based self-help intervention to prevent depression in patients with persistent back pain: The PROD-BP randomized clinical trial. *JAMA Psychiatry*. 2020;77:1001–1011.
44. CHIR-Net SIGMA Study Group*Mihaljevic AL. Multicenter prospective cohort study of the patient-reported outcome measures PRO-CTCAE and CAT EORTC QLQ-C30 in major abdominal cancer surgery (PATRONUS): A Student-Initiated German Medical Audit (SIGMA) Study. *Ann Surg Oncol*. 2021;28:3075–3089.
45. STARSurg Collaborative. Multicentre prospective cohort study of body mass index and postoperative complications following gastrointestinal surgery. *Br J Surg*. 2016;103:1157–1172.
46. Huber L, Hellmer J, Schneider F. *Forschendes Lernen im Studium Aktuelle Konzepte und Erfahrungen*. 2nd ed. UVW Universitäts Verlag; 2009.
47. Amgad M, Man Kin Tsui M, Liptrott SJ, et al. Medical student research: An integrated mixed-methods systematic review and meta-analysis. *PLoS ONE*. 2015;10:e0127470.
48. Hren D, Lukić IK, Marusić A, et al. Teaching research methodology in medical schools: Students' attitudes towards and knowledge about science. *Med Educ*. 2004;38:81–86.
49. Antonini A, Reichmann H, Gentile G, et al. Toward objective monitoring of Parkinson's disease motor symptoms using a wearable device: wearability and performance evaluation of PDMonitor®. *Front Neurol*. 2023;14:1080752.

