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Study protocol for a pilot trial analysing the usability, validity and safety of an interventional health app programme for the structured prehabilitation of patients before major surgical interventions: the PROTEGO MAXIMA trial

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**ABSTRACT**

**Introduction** Major surgery is associated with a high risk for postoperative complications, leading to an increase in mortality and morbidity, particularly in frail patients with a reduced cardiopulmonary reserve. Prehabilitation, including aerobic exercise training, aims to improve patients’ physical fitness before major surgery and reduce postoperative complications, length of hospital stay and costs. The purpose of the study is to assess the usability, validity and safety of an app-based endurance exercise intervention in accordance with the Medical Device Regulation using wrist-worn wearables to measure heart rate (HR) and distance.

**Methods and analysis** The PROTEGO MAXIMA trial is a prospective, interventional study with patients undergoing major elective surgery, comprising three tasks. Tasks I and II aim to assess the usability of the app, using evaluation questionnaires and usability scenarios. In Task IIIb, healthy students and patients will perform a supervised 6 min walking test and a 37 min interval training on a treadmill based on HR reserve, wearing standard ECG limb leads and two smartwatches, which will be driven by the test software. The aim of this task is to assess the accuracy of HR measurement using wrist-worn wearables to measure distance.

**STRENGTHS AND LIMITATIONS OF THIS STUDY**

⇒ This is the first prospective, interventional study to examine an app-based prehabilitation programme, comprising an aerobic exercise training with real-time heart rate measurement using wrist-worn wearables in a remote setting.

⇒ The prehabilitation programme is based on a structured risk assessment of patients undergoing major elective surgery providing an individual exercise training.

⇒ The primary limitation of the non-randomised controlled design is that the effectiveness of the prehabilitation programme on postoperative outcomes cannot be assessed.

⇒ However, this will be tested in the upcoming LUMOS (A multicenter prospective randomized controlled trial to test a systematic app-based remote and home based prehabilitation program in comparison to no prehabilitation program before major surgeries) randomised controlled trial in a stepwise approach for a maximum of patient safety before it can be cleared by authorities as a medical device.

**INTRODUCTION**

Major surgery is associated with a high rate of postoperative complications, occurring in 15%–40% of patients. Almost half of all adverse events (AEs) in hospitalised patients are considered to be related to surgical procedures, having a deleterious impact on morbidity, mortality, length of hospital stay and healthcare costs. Moreover, patients after surgical interventions exhibit a marked reduction of physiological functioning, which is observed even in absence of complications. Several studies have determined predictors of high complication risk, which can be...
evaluated using validated assessment tools, including the American Society of Anesthesiologists Physical Status Classification, the Eastern Cooperative Oncology Group (ECOG) Performance Status, the Timed Up and Go-Test (TUG) and the Risk Analysis Index (RAI)-C score.\textsuperscript{2,4}

Particularly, frail, elderly and obese patients with a poor cardiopulmonary reserve are at high risk for adverse surgical outcomes and are especially vulnerable to failure to rescue due to their impaired physiological ability to recover from postsurgical AEs.\textsuperscript{9,10} Frailty is present in 10\%–20\% of people aged above 65 years, and even in 40\% of those older than 80 years, which will further increase in the next few years.\textsuperscript{11} Therefore, preoperative exercise interventions aiming at enhancing the patients’ individual aerobic capacity may have the potential to significantly improve surgical outcome.\textsuperscript{12} Such interventions can be performed safely 3–6 weeks prior to surgery, without increasing the risk of death due to treatment delay or progress of the underlying disease or using the window of neoadjuvant treatment to further optimise the patient.\textsuperscript{13}

Prehabilitation is an emerging field in perioperative medicine, and is defined by the implementation of proactive generally exercise-based interventions to increase patient preparedness in the lead-up to surgery.\textsuperscript{1,15} Interventions may comprise aerobic exercise, resistance or functional training, nutritional supplementation and psychological interventions with the aim of optimising patient’s functional capacity before surgery, reducing surgery-related morbidity and facilitating recovery after surgery.\textsuperscript{16} Several extensive systematic reviews focusing on prehabilitation programmes have shown positive effects on patients’ physical fitness.\textsuperscript{17–19} Thomas et al demonstrated a significant increase in aerobic capacity, heart rate (HR) (13±15\%) and oxygen uptake (7±6\%, p<0.05).\textsuperscript{20} Waterland et al found a significant improvement in 6min walking distance (mean difference 33.09 m, p=0.01), which is consistent with the findings of a meta-analysis from Lau (mean difference 32.5 m, p=0.003).\textsuperscript{17,19} Further, emerging randomised controlled trials (RCTs) and meta-analysis provide evidence for the effectiveness of prehabilitation to reduce postoperative complications, length of hospital stay and total hospital charges.\textsuperscript{14–17,18,21–26} Barberan-Garcia et al revealed a significant reduction of postoperative complications (31\% vs 62\%) after major abdominal surgery in a cohort of 144 high-risk patients, similar to the findings of Moran et al, describing a decrease in all types of postoperative complications (OR 0.59, p=0.03).\textsuperscript{26} A meta-analysis of Heger et al involving eight studies showed a significant reduction of pulmonary complications (OR 0.37, p=0.001) and overall morbidity (OR 0.52, p=0.001).\textsuperscript{22} Further, preliminary economic evaluations suggest that the resulting reduction of short-term and long-term outcomes will substantially decrease total hospital charges and improve the use of health resources.\textsuperscript{23}

Despite the overall positive effects of prehabilitation programmes, conclusions about the impact on postoperative clinical outcomes, including complications, length of hospital stay, and overall morbidity remain inconsistent and the quality of evidence is low.\textsuperscript{20,27} Moreover, a huge heterogeneity was observed regarding study design and the content of the prehabilitation programmes applied in the studies, showing differences in terms of training type, frequency, intensity, duration and the number of modalities included resulting in limited comparability.\textsuperscript{20}

\textbf{Patronus Prehab App}

In the present study, we aim to assess a novel, app-based approach, providing an individual, risk-based aerobic endurance exercise programme to patients before surgery. The Patronus Prehab App will be a medical device class IIa, and is currently developed by the Patronus Health GmbH, a spin-off company of the Goethe-University Frankfurt/Main. The app encompasses a structured risk assessment, which is performed by the physician with patients scheduled for elective major surgery, as depicted in figure 1. Based on the assessment of a structured set of risk factors, the patient will be stratified into a specific risk group. A individual endurance interval training will be calculated based on the Karvonen method to determine the target HR based on the maximum and resting HR including the presence or absence of specific risk factors with the desired training intensity.\textsuperscript{26,29}

In the final intended use, the patient will undergo a 3 to 6-week aerobic training programme, comprising a 6min walking test (6MWT) at the beginning and end of the training period to measure the progress of the moderate to vigorous aerobic interval training. The exercises will consist of 3–4 interval training per week (37min interval training (2min of high endurance and 3min of relaxation) plus 5min warm-up and 5min cool down, in a home-based patient empowering environment, which can be any type of training (including hiking, cycling, walking and running) during any time of the day. Importantly, most previous studies suggested a hospital-based prehabilitation programme with a supervised setting in an outpatient clinic, which might be a barrier for patients with travel-time, geographical and/or mobility constraints.\textsuperscript{30,31} Home-based programmes using a digitalised approach in a remote setting are a convenient alternative, enabling patients to easily decide on the training setting, time and location, still ensuring a strict safety profile.\textsuperscript{32} Doing the exercise, the patient will wear a smartwatch on the hand wrist, which will be connected to the software and measures the HR, distance and steps. Specific alarm settings of the app will assist the patient to keep the optimal HR through moderate to vigorous intensity training. At the end, a symptom checklist will be completed within the app. The treating physicians will be connected to their patients’ app, enabling them to supervise the training, and will immediately be informed about the occurrence of potential alarms or symptoms.

We hypothesise, in line with the above-mentioned studies, that aerobic interval training before major
surgical procedures will remarkably reduce complications and healthcare costs. However, to date, there are no app-based, risk-adjusted exercise programmes performed in a remote setting. As the software used in this trial is currently being developed and is not yet certified, the primary aim of this study is to assess the usability, validity and safety of the software in healthy probands and patients under medical supervision, in accordance with the DIN ISO 14155, the Medical Device Regulation (MDR) and the Medizinproduktedurchführungsverordnung (MPDG).

METHODS AND ANALYSIS

Study design
The PROTEGO MAXIMA trial is an investigator-initiated, prospective, interventional pilot study to assess the feasibility and safety of the Patronus Prehab App in patients undergoing elective major surgery at the University Hospital in Frankfurt, Germany. The study protocol complies with the DIN ISO 14155, the MDR, the MPDG and is written in accordance with the current Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT 2013). The SPIRIT checklist is given in (online supplementary file 1). Ethical approval for this study was granted by Institutional Review Board (IRB) of the University Hospital of Frankfurt and by the Federal Institute for Pharmaceuticals and Medical Products (BfArM, reference number 94.1.04-5660-13655) on 7 February 2022. All protocol amendments must be by law reported to and approved by the IRB and BfArM. The clinical trial is funded by the Else Kröner Fresenius Stiftung in the translational research programme under number (2021_EKTP10).

The trial comprises three tasks with the first and second tasks aiming to evaluate the usability of the app using paper-based (Task I) and live app-based (Task II) mockup evaluations with standardised questionnaires and usability scenarios. The third task assessing the validity and safety, comprises a non-interventional app-based structured risk assessment in patients undergoing major surgery to correlate risk factors with 90-day outcome (Task IIIa), and an interventional 1-day endurance exercise programme to analyse the validity of HR measurement and distance assessment in comparison to a medical ECG on a treadmill, which will be performed by healthy volunteers and patients at the Institute of Sports Science of the Goethe-University Frankfurt (Task IIIb).

Study population
Tasks I and II will involve eight experts having experience in the treatment of patients and app-based risk assessment and eight potential patients, respectively. Task IIIa will be conducted in 300 patients undergoing elective major surgery in different surgical departments (Thoracic, Visceral, Vascular Surgery, Urology and Gynaecology), representing the heterogeneity of
patients that may benefit from prehabilitation. Task IIIb includes 10 healthy students, and 65 patients divided into subgroups with patients having a treated cardiovascular disease, and/or chronic obstructive pulmonary disease (≤ grade II).

Eligibility criteria include: (1) adults aged ≥18 years, (2) participants able to understand the respective task and provide written informed consent, and only affecting Task III, (3) patients undergoing one of the following elective major surgeries: gastrointestinal resection, resection of the hepatobiliary pancreatic system, endocrine glands, lung or bronchus, splenectomy, abdominal wall hernia, urological or gynaecological resections, or vascular surgery without cardiovascular procedures. Corresponding Operation and Procedure Classification System (OPS)-codes are given in figure 2B. Main exclusion criteria for Task III include (1) pregnancy or breast feeding, (2) unable to understand or participate in the task, (3) acute cardiovascular or pulmonary disease or (4) acute non-cardiopulmonary disorder that might affect or

Figure 2  Flow diagram of the PROTEGO MAXIMA trial usability. (A) Task I: expert and patient mockup evaluation with standardised evaluation tools, Task II: live app expert and patient usability scenario. Evaluation in Tasks I and II will be performed by eight experts and eight potential patients, respectively. (B) Task III: live app validity and safety patient usability scenarios. Exercise programme includes a 6 min walking test and a 37 min interval training on a treadmill. *OPS-codes of major surgery: 5-070-5-073, 5-077 to 5-079, 5-32 to 5-43, 5-434 to 5-438, 5-44, 5-454, 5-455, 5-456, 5-484 to 5-485, 5-502, 5-503, 5-512, 5-514.30, 5-515, 5-518.4 and .5, 5-523, 5-524, 5-525, 5-527 and 5-529, 5-413, 5-419, 5-536, 5-538 to 5-539, 5-553, 5-554, 5-575 to 5-579, 5-604, 5-652, 5-653, 5-661, 5-683 to 5-687, 5-87, 5-88. ABACUS, App Behavior Change Scale; AE, adverse event; APS, Aktionsbündnis Patientensicherheit eV.; CD, Clavien-Dindo; HR, heart rate; SAE, serious adverse event; uMARS, Mobile Application Rating Scale.
be aggravated by exercise performance (eg, infection, renal failure).

**Study procedure and measurement methods**

**Recruitment procedure**

The overall flow diagram for all tasks and assessment schedules are outlined in figure 2A,B and table 1. For Tasks I and II, experts and potential patients will be asked to participate in the study, requiring no additional screening procedures. In Task III, patients scheduled for elective major surgery will be screened for eligibility by the study team either in the outpatient departments or on the day before surgery. Additionally, all physicians will be trained and briefed on the recruitment procedure to optimise the recruitment rate. Eligible patients will be invited to participate in the study and written informed consent will be obtained.

**Task I: expert and patient mockup evaluation with standardised evaluation tools**

In the first task, aiming to assess the usability, functionality and trustworthiness of the Patronus Prehab App, participants will receive detailed information documents (including the app description and the user manual) and mockups of the app for review. A structured evaluation using standardised paper-based questionnaires with the Mobile Application Rating Scale, elements of the App Behavior Change Scale, the Trustworthiness Checklist and the App-checklist of the ‘Aktionsbündnis Patientensicherheit eV.’ will be performed to identify possible errors and design flaws in the app. The findings will be amended in the live app version and reevaluated in Task II.33–36

**Task II: live app expert and patient evaluation and usability scenarios**

In the second task, comprising the assessment of the usability, safety and intuitive walkthrough of the app, the structured evaluation tool of Task I will be repeated with the live app to evaluate possible amendments from Task I. Additionally, participants will be guided and supervised through a set of usability scenarios focusing on the critical functions of the app (including intended troubleshooting, warnings and alerts). Subsequently, they will be evaluated by a supervisor.

**Task III: live app validity and safety patient usability scenarios**

Task III will assess the validity and safety of the app. In Task IIIa, the study team will screen patients undergoing elective major surgery and perform a structured risk assessment using the live app, which will be correlated with their 90-day outcome. Therefore, a follow-up will be performed as a structured telephone interview to assess complications according to Clavien-Dindo classification (CD) and overall survival.37 Moreover, the psoas density of participants will be measured based on CT, which will serve as a validated parameter for sarcopenia and frailty and additionally be correlated with the outcome of patients.38

In Task IIIb, participants will perform a 1-day training session comprising of a 6MWT and a 37 min interval
training on a treadmill, based on the structured risk assessment and the Karvonen method of the Patronus App. During the exercise, patients will be connected to an ECG and will wear two smartwatches each linked to a smartphone encompassing the tested software. Four device combinations will be assessed: iPhone 13+Apple Watch 7 (Apple 13), iPhone SE+Apple Watch 3 (Apple SE), Samsung A52 (Samsung) or Google Pixel 6 (Pixel 6)+Samsung Watch 4. Based on the monitoring of the HR, heart rhythm, blood pressure and distance, an ergometry-based analysis will be performed, enabling correlations of the smartwatch measurements (HR and distance) with the standard ECG and the distance measurements of the treadmill. Perceived exertion and pain of participants will be assessed during the exercise using the Borg scale and the Visual and Numerical Analogue Scale (VAS, NAS). At the end, occurrence of symptoms, cardiac or AEs will be assessed, and safety and misuse scenarios testing the alarm settings of the app will be implemented in the exercise. Blood samples will be taken before and after the interval training to further assess the safety of the app-based exercise training. Moreover, the validity of the Karvonen method including the risk adjustments by risk factors as defined will be assessed and correlated with the occurrence of clinical symptoms. Participants will be followed up on days 7 and 30 to assess the occurrence of (serious) AEs or (serious) device failures.

Outcome measurements

Primary outcomes
The primary outcome of this study is to evaluate the usability, safety and validity of the Patronus Prehab App.

Secondary outcomes

► Tasks I and II: a structured evaluation tool and a set of usability scenarios are used to improve the usability, design and safety of the app in accordance with the regulatory requirements of the MDR and the DIN ISO 13485 for certification.

► Task IIIa: the risk assessment of the app is validated by correlating its data with complications according to CD including overall survival, indication and diagnosis. The risk assessment comprises the following baseline data: year of birth, sex, height, weight, smoking, resting pulse, ECOG, TUG, haemoglobin (g/dL), RAI-C score. Additionally, psoas density will be assessed and diagnosis and surgery are determined using the International Classification of Diseases 10th Revision (ICD-10) and the OPS for surgical procedures.

► Task IIIb: the safety and validity of the app and smartwatch measurements is assessed by comparing ECG and distance data with the data assessed by the app. Further parameters include blood pressure, heart rhythm, VAS, NAS, Borg scale, cardiorespiratory fitness (VO2 max), symptom checklist, cardiac and AEs, baseline EORTC QLQ 30 data, wrist circumference, skin appendices and skin humidity. Parameters of the blood test comprise creatine kinase, creatine-kinase-MB, lactate dehydrogenase, glucose, sodium, potassium, chloride, C reactive protein, bicarbonate, lactate and circulating free DNA. Moreover, data on structured misuse scenarios will be obtained.

Adverse events

All AEs, adverse device effects (ADE), serious adverse events (SAE) and serious adverse device effects (SADE) occurring during Task IIIb or the follow-ups will be recorded in the electronic case report form (eCRF). An AE is defined as an undesirable sign, symptom or disease temporally being associated with the application of the device, without necessarily requiring a causal relationship. If a causal relationship with the device seems possible, the AE is defined as an ADE. For all AEs and ADEs, duration, consequences, and assessment of the relationship to the device will be registered. AEs or ADEs leading to a life-threatening illness, injury, prolonged hospitalisation, permanent disability, medical or surgical intervention, or death, will be categorised as SAE or SADE and will be immediately reported to the sponsor, legal representative and manufacturer in accordance with the regulatory requirements of the MDR and the MPDG. Corresponding follow-ups will be provided as necessary.

Statistical analysis

Tasks I and II

Evaluation questionnaires used in Tasks I and II to identify critical features of the app encompass items with dichotomous questions (yes/no) and 5-point Likert scale. Each item will be analysed by descriptive analyses and using the Kappa coefficient, respectively. Two separate analyses will be conducted for the expert group and the group of potential patients. Items with a Kappa coefficient ≤0.8, a median score ≤3 for a 5-point Likert scale item and ≥4/8 negative answers for a dichotomous item will be documented as critical findings and considered for amendment of the app.

Task IIIa

In Task IIIa, the pp-based risk scores (I, II, III) will be correlated with the 90-day outcome of patients according to the CD scoring. Therefore, two areas under the curve (AUC) will be calculated, with AUC 1 comparing the risk score 1 versus 2 and 3 and AUC 2 comparing risk scores 1 and 2 versus 3. In addition, Kaplan-Meier analysis and log-rank tests will be performed for the risk assessment.

Task IIIb

In Task IIIb, Bland-Altman analysis will be used to compare HR measurements of the smartwatch with the standard ECG. Regression analysis will be used to assess the impact of different variables (including wrist circumference, skin humidity, skin appendices, age and HR) on the measurement accuracy. The safety of the Patronus Prehab App will be assessed with regards to the measurement of the HR and the warnings defined for the individual exercises,
including misuse scenarios. Safety data will be assessed descriptively.

**Sample size and power calculation**

The study provides a power of 80%, assuming a p value of \(\leq0.005\) as statistically significant. The power calculations for all tasks were conducted using PASS 2008 (V.08.0.15, NCSS, LLC, Kaysville, Utah, USA) and BiAS (V.11.0, epsilon 2015).

Power calculations of Task I were made assuming two separate analyses for each group, a Kappa coefficient of 0.8 and a one-sided alpha of 0.05, providing a power of more than 80% for both types of items (dichotomous and 5-point Likert scale). In Task II, the following calculations for the AUC were made: an AUC of 0.75 will provide a 95% CI of approximately \(\pm 0.15\) if the sample size of the smaller group is not less than \(N=82\). For larger values of the AUC, the corresponding 95% CI will be smaller. Assuming a power of 0.8 and a two-sided alpha of 0.05 for Task IIIb, a sample size of \(N=56\) would be sufficient, if a maximal difference of \(\leq 50\) bpm and a maximal irrelevant mean difference of \(\leq 10\) bpm are provided, which are based on Nelson et al and Wang et al.

**Data management and data safety**

All clinical data will be stored securely in the eCIF using the SecuTrial System (https://www.secutrial.com/), a web-based data management application. Data entered into the app and data obtained from the ergometer will be stored on DIN ISO 27001 compliant server systems located in Germany. Only authorised and trained members of the study team will be able to enter data and will systematically check for accuracy and completeness. Clinical data will be documented pseudonymously using a specific identification number. Participants will not be identifiable by name or other personal information in any report of this study. All study data obtained will be integrated into a statistical software and analysed by the Institute of Biostatistics and Mathematical Modelling Frankfurt.

**Data monitoring**

Regular monitoring will be performed by the data monitoring committee according to Good Clinical Practice guidelines and DIN ISO 14155. Monitors will review data for compliance with the study protocol and accuracy concerning the source data documents, including patients’ electronic health records, the Patronus App and the ergometer. Monitoring will ensure completeness of data entry, accuracy of study management and safety documentation.

**Ethics and dissemination**

The study will be performed in accordance with the Declaration of Helsinki and the Good Clinical Practice for medical devices as outlined in DIN ISO 14155. Participants will be informed about the aim, outline and potential risk of the study and written informed consent will be given. After a sufficient period, the patient can sign the written informed consent and will receive a signed copy. If a patient sustains any trial-related harm, they are covered by a study specific insurance. Predictable risks are addressed by safety protocols in the Patronus Prehab App and safety issues will be carefully monitored, documented and reported, if necessary.

The results of this study will be submitted for publication in peer-reviewed journals in a summarised anonymised manner and shared with the medical community.

**Trial status**

Recruitment of participants of Task I, II and III started on 14 March 2022, and is still ongoing. The trial is anticipated to be completed until February 2023.

**Patient and public involvement**

Patients were not involved in the development of the research question or study design. They will however be involved in all three tasks. In Tasks I and II, participants will be interviewed by the study team using standardised questionnaires. In Task IIIa, a structured, app-based risk assessment will be performed with patients scheduled for major surgery. In Task IIIb, participants will perform an exercise training on a treadmill. Further, follow-ups will be performed as a telephone interview or in person with the patients for data assessment (on days 7, 30 or 90).

**DISCUSSION**

Patients before major surgeries face an increased risk for experiencing complications. Today, the awareness and potential of optimising a patient’s risk profile before such a surgical trauma, becomes increasingly acknowledged by researchers and professional associations. Prehabilitation, based on a preoperative risk assessment, is a preventive intervention, to enhance patients’ functional capacity before surgery and substantially reduce postoperative complications. Current studies across a variety of elective surgical procedures, including abdominal, pulmonary and cardiac surgery have acknowledged significant effects of prehabilitation on patients’ functional fitness, as described above. However, despite the beneficial effect of prehabilitation, the significant heterogeneity in study design entails limited comparability, making the implementation of prehabilitation programmes into the clinic still challenging. Moreover, the impact of prehabilitation on postoperative outcomes including mortality remains controversial with several studies showing no significant effect.

Digital healthcare applications facilitate the use of home-based interventions, increasing empowerment and self-management of patients, and overcoming barriers to participate (ie, costs, transportation and time required for use). Particularly, mobile health apps have shown to markedly enhance patient adherence to the programme, achieving promising satisfaction and usability, and making them accessible for a larger population. So far, only few prehabilitation apps are currently available (ie, ‘Craetus’, ‘Eurecat’, ‘PeerWell’, ‘Exphy Surgery’), which...
are not yet validated or provide limited access to patients, emphasising the urgent need for further development and validation of digital prehabilitation applications and enforcing their large-scale implementation.

The Patronus Prehab App provides a novel approach for an individual endurance exercise programme, which is based on a structured risk assessment, incorporating a set of validated measures (including the RAI-C score, ECOG, TUG and haemoglobin (g/dL)) and stratifying patients into specific risk groups. A variety of risk assessment tools have the potential to efficiently assess patients’ risk factors before surgery and predict postoperative outcomes.41-46 The RAI-C score has been validated prospectively in a cohort of 6856 patients, representing an effective tool to measure frailty-associated risk in patients before surgery with a high predictive value for 180-day mortality (C-statistics 0.772).41 Another prospective study including 984,550 patients, who were stratified into five different RAI-C-based risk groups, revealed a dose–response association between frailty and postoperative complications.11 Similarly, the ECOG performance status demonstrated a high predictive value in two studies of patients with ovarian cancer undergoing cytoreductive surgery, exhibiting that ECOG >0 or 1 significantly correlated with severe postoperative complications (OR 13.3, p<0.01).44,46 The ECOG score also independently correlated with 30-day mortality in patients undergoing high-risk emergency laparotomy (OR 5.9, p<0.01).45 The validity of those risk tools that do not require any additional tools to assess them, which is a potential showstopper for clinical penetration and scalability has been analysed by the prehabilitation group at the Goethe University Frankfurt in a quality project and revealed a high correlation with 90-day outcomes (currently unpublished data).

The Patronus App further integrates data of the structured risk assessment with the HR reserve of patients using the Karvonen method to calculate an individual target HR to perform an endurance training with low and high-intensity intervals. Accurate HR measurement using wrist-worn devices is crucial to ensure an optimal training, aiming to improve patients’ aerobic capacity. Specific alarm settings displayed on the devices either by colour or haptic vibration will assist the patient to keep the optimal HR, and particularly, warn if the suggested HR range is exceeded. Preliminary studies have already examined HR accuracy by comparing device measurements (ie, Apple Watch, Fitbit, Samsung Watch) with gold standard ECG electrodes, indicating that these devices provide an acceptable accuracy for HR measurement.41,42,47,48

The primary aim of our study is to measure the HR accuracy of four different devices, which are driven by the software, and evaluate the suggested HR ranges and the change between low and high-intensity intervals of the training. Safety assessment includes the testing of alarm awareness during exercising and the response of participants to warning signals as well as lab testing. Further, data obtained from the risk assessment will be correlated to postoperative outcome of patients to assess the predictive value of this assessment tool. The results of this study will be used for potential adjustments to the software and to comply with the requirements and regulations of the MDR for certification. Subsequent studies, including an RCT, will be required to assess the effectiveness of the app-based prehabilitation programme and its impact on postoperative complications, mortality, morbidity and hospital costs of patients undergoing major surgery.

REFERENCES


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