Effect of an App-based Physiotherapeutic Exercise Regimen on Early Postoperative Compliance after Total Kneec Arthroplasty, Protocol of A Randomized Control Trial

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Abstract

Background: Early postoperative physiotherapy following total knee arthrosplasty (TKA) has been demonstrated to improve patient-related outcomes. However, some studies suggest 50% of TKA patients are not active enough to maintain their physical health. Mobile applications have been reported to be as effective as face to face rehabilitation in prior systematic reviews.

Objective: In the protocol at hand, a detailed description of the action plan regarding a randomized controlled trial (RCT) investigating the effect of a mobile reminder application on adherence to physical therapy and patient related outcome will be presented.

Methods: This monocentric RCT is carried out at the University Clinic of Brandenburg. Patients between the ages of 55 and 80 with an indication for TKA are recruited during the first outpatient visit. Patients are then randomized into two groups. The treatment group is supplemented with the app-based physical therapy program while the controllers receive a paper-based program in accordance to the standard of procedure. Objective adherence to physical therapy is recorded using accelometry-based sensors. Additionally, patient-reported outcome measures (PROMs) and relevant performance-based measures (PBMs) are noted. The hypothesis of the study is that app-based physical therapy leads to higher compliance than a paper-based approach. Finally, a previously developped non-compliance questionnaire helps uncover the reasons behind non-adherence to physical therapy.

Results: The primary outcome of this study is sensor-recorded compliance with physical therapy. Secondary outcomes includes the analysis of factors affecting compliance, patient-related outcome measures (PROMs), and patient-based measures (PBMs).

Conclusions: Compliance with a physical intervention is classically measured using questionnaires. The novelty of this study lies in the fact that adherence to the intervention is measured objectively using accelometers. As well, to our knowledge, no previous trial assessed a correlation between the degree of compliance to physical therapy on one hand and patient-related or performance-based measures. In the light of what was mentioned, this study might offer insights into regarding the extent to whch postoperative physical therapy has an effect on the postoperative outcome. Clinical Trial: The trial was registered at the Deutsches Register klinischer Studien. Registration number: DRKS00031414

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Abstract:
Background: Early postoperative physiotherapy following total knee arthrosplasty (TKA) has been demonstrated to improve patient-related outcomes. However, some studies suggest 50% of TKA patients are not active enough to maintain their physical health. Mobile applications have been reported to be as effective as face-to-face rehabilitation in prior systematic reviews.
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Trial Registration: The trial was registered at the Deutsches Register klinischer Studien. Registration number: DRKS00031414.

Keywords: Total Knee Arthroplasty; Total Knee Replacement; TKA; TKR, Physical Therapy; Compliance; Accelerometry; Sensors; App-Based Rehabilitation; eHealth

Introduction:
Osteoarthritis of the Knee is a degenerative joint disease that is typically due to wear and tear resulting in progressive deterioration of the cartilage (1) (2). It is a clinical syndrome that presents with varying degrees of functional debilitation and worsening of the quality of life (3). The degeneration of cartilage begins with a disruption affecting the synthetic activity of the matrix: the

balance between anabolic and catabolic processes shift to the side of the latter (4). Clinically this translates to increasing pain, a loss of function and an increased socioeconomic cost leading to the classification of TKA as a serious disease (5) (6). Additionally, the symptoms lead to a decreased level of activity and mental well-being which in turn aggravates the underlying pathology (7).

Since osteoarthritis is one of the most common age-related diseases, it is not surprising that total knee replacement (TKA) is one of the most performed surgeries in Germany (8). The procedure has been proven to be effective in restoring the patient´s quality of life, decreasing the amount of pain and regenerating the of the affected knee (8) (9) (10). In that context, it is important to mention that compliance with the postoperative physiotherapy might play an immense role in the improvement of the above-mentioned parameters (11). Since almost half of all patients do not comply with the prescribed postoperative physical therapy, new strategies must be explored. Previous trials revealed conflicting results when app-based physical rehabilitation was compared to the standard of care (12). One systematic review concluded that this discrepancy is due to the differing qualities of mobile applications. More research should be conducted to improve the delivery of physical therapy through electronic means (13).

Publication bias is a systematic error that is due to selective outcome reporting leading to the over- or under-estimation of the effect of an intervention (14). The importance of protocols for randomized controlled trials helps in eliminating these errors by detailing elements regarding the planned intervention and the outcome as well as the sampled population and the comparators. They provide a clear “roadmap” to direct the clinical research (15). This is especially true in the field of orthopaedics and sports medicine research (16).

Objectives:

The aim of this protocol is to outline a RCT on the effect of mobile application-based physical therapy on the objectively measured compliance of patients in the early postoperative period following TKA. This will be compared to the standard face-to-face physical rehabilitation.

Trial Design:

For this purpose, a double-blinded, randomized, controlled trial is designed with two parallel patient groups. An equal number of participants is assigned to either group. Both groups receive an identical PT-regimen. Accelometry-based sensors is implied to objectively quantify knee motion. Questionnaires are implied to collect patient-related outcome measures, performance-based measures, and parameters affecting compliance.

Methods: Participants, Interventions and Outcomes

Study Settings:

Data is collected from patients at the center of Orthopaedics and Trauma Surgery at the University Clinic of Brandenburg, Germany.

Participants

Eligibility Criteria:

Patients between the ages of 55 and 80 receiving a total knee endoprosthesis for a primary osteoarthritis of the knee are eligible for inclusion. Patients should be able to read, understand and sign informed consent.

Exclusion Criteria:

Patients suffering from comorbidities that might significantly impact postoperative rehabilitation such as severe cardiac, neurologic, or psychiatric diseases are excluded from participation.

Informed Consent:

Informed consent is taken by surgeons at the monocenter on the first out-patient visit. Patients were informed regarding the possibility of withdrawal at any phase during trial conduction.

Interventions

Choice of Comparators:

As the scientific evidence clearly depicts a positive effect of physical therapy on the postoperative

outcome after total knee arthroplasty, comparators must receive the appropriate PT regimen to ensure the ethicality of the trial (17). The control group receives a paper version of the exact same regimen as the experimental group. Face-to-face rehabilitation is administered 20 minutes daily to all participants.

Intervention Description:

The main intervention of this trial is the delivery of physical therapy by the means of a mobile application. Details regarding the design of the mobile application to fit the needs of the target population are described in an earlier study. In summary, the application is explicitly made simple to fit the needs of the older population. Additionally, an alarm reminds patients to execute a given exercise. Videos, photos, and a descriptive text are added to guide the correct execution of the exercises. Figure 1 shows some aspects of the application.

<Insert Figure 1 here>

Figure 1: Physical therapy-based mobile application: A) Screenshot showing the rehabilitation plan. B) Screenshot showing the descriptive text. C) Screenshot showing corresponding video of the amended exercise.

The application previously underwent a round of conception based on a literature search. The first resulting beta version was tested by 2 senior orthopaedic surgeons, 2 physical therapists, 2 software engineers and 2 qualitative researchers specializing in public health. The suggested changes have been amended for a second beta version is ready to be tested. As one of the outcome measures is the system usability scale (SUS), patients will rate the application and present recommendations before the final version of the application is conceived (18).

Both groups receive a regimen based on the recommendation of a meta-analysis quantifying the effect of different PT interventions in moderate to high quality randomized controlled trials (19).

The exercises were described in the application as follows:

1. Body weight squats: the patient extends the arms and grabs a solid surface (A table for example). Then the body is lowered whilst engaging the knee joints. The patients then try to stand up focusing on the engagement of the quadriceps muscle. The exercise should be performed 10 times or until a discomforting pain threshold is reached.
2. Modified quadriceps setting: this exercise is performed whilst patients lie on a flat surface (hospital bed ideally). The knee is then adducted to an angle that still is comfortable. The knee is then maximally extended in a manner that produces a co-contraction of the quadriceps and hamstring muscles.
3. Drop and Dangle: This exercise mainly focuses on the quadriceps muscles. The exercise begins with patients sitting on a higher surface with the knee in 90 flexion. The knee is the extended and held at an 180 degrees until fatigue is achieved. The lower leg is then dropped and can dangle.
4. Walking: 50 meters walking distance is to be achieved by every patient. The patients should therefore walk out of their room, down the hallway and back to demarcated line. This ensures that patients walk a uniform distance starting at the door of the room on the ward.

Criteria for discontinuing the Intervention:

Patients suffering from adverse events of TKA such as wound infections and emboli discontinue the intervention. As the intervention is non-invasive, the authors of this paper assume that the risk of harm is negligible.

Outcomes:

Primary Outcome:

The primary outcome of this study is sensor-measured compliance of the patients with the prescribed regimen. A feasibility study demonstrating the efficacy of these sensors in monitoring postoperative knee activity following knee replacement was previously realized (20). Compliance was measured as reported by the patients in previous clinical trials. The novelty of this trial is the use of specially

designed sensors to objectively depict knee motion and the level of activity. Figure 2 depicts some measurements made by the used sensors.

Figure 2: (A) Application of the sensors on the distal end of the upper thigh and the proximal end of the lower leg. (B) Depiction of the sensors in that same position.

Secondary Outcomes

The OMERACT-OARSI statement dictates the core outcomes for knee osteoarthritis being pain, function, quality of life and adverse events including death (21).

1. Pain is a subjective measure and will be quantified using the different patient-related outcome measure (PROM) questionnaires.
2. Function will be assessed subjectively using the PROMs and objectively using a performance-based measure (PBM) by the means of a stair climb test.
3. Quality of life: Assessed using the PROM questionnaires (22) (23).
4. Adverse events related to the patients such as falls, injuries, anesthesia-related complications, and death as well as prothesis-associated problems such as infections will be reported.

As no clear association exists between the compliance to physical therapy in the early postoperative period, this study aims to investigate a correlation. In other words, this trial will try to establish whether an increased adherence to physiotherapeutic measures elevates the outcome in the postoperative period. Additionally factors affecting compliance to physiotherapy in the early postoperative period will be studies (24) (25).

Participant Timeline:

Table 1: Table representing the planned timeline of the trial:

	STUDY PERIOD									
	Enrolment		Allocation		Post-allocation					Close-out
TIMEPOINT**	-t1	-t2	0	t1	t2	t3	t4	t5	t6	tx
ENROLMENT:										
Eligibility screen	X									
Informed consent	X									
Allocation			X							
INTERVENTIONS:										
App based Exercise Regimen	X									
ASSESSMENTS:										
Sensor Monitoring										
Compliance Questionnaire						X				
PROMs	X					X		X		X
PBMs	X					X		X		X
	References: -t1 : 2 weeks preoperatively, -t2: 1 week preoperatively, 0: 1 day preoperatively, t1: 1 day postoperatively, t2: 3 days postoperatively, t3: 7 days postoperatively, t4: 14 days postoperatively, t5: 3 months postoperatively, t6: 3 months and 7 days postoperatively, PROMs: Patient Related Outcome Measures, PBMs: Patient Based Measures									

Sample Size:

After a consensus of clinicians at the University Clinic of Brandenburg and the statisticians at StatConsult GmbH it was assumed that 80% of patients in the experimental group will respond to the intervention in contrast to 40% of patients in the control group. A sampling size of 46 patients was determined.

Recruitment:

Patients are recruited in the interdisciplinary admission center of the University Clinic of Brandenburg, Brandenburg an der Havel, Germany. Patients with osteoarthritis of the knee scheduled to receive a total knee arthroplasty will be recruited during the initial presentation.

Assignment of Interventions: Allocation

Sequence Generation:

An allocation sequence is implied using computer generated random numbers. Stratification factors include age and BMI. Blocking is not planned for this trial.

Concealment Mechanism:

The allocation sequence is implemented using sequentially numbered, opaque, sealed envelopes. The envelopes will be opened after randomization.

Implementation:

The allocation sequence will be generated by StatConsult IT-Service GmbH. Patients are enrolled by the surgeon determining the indication for TKA. The intervention is assigned to a study nurse. The nurse is not further involved in the RCT.

Assignment of Interventions: Blinding

Who will be blinded:

1. Outcome assessors examining the PBMs, PROMs and compliance questionnaire.
2. The surgeon performing the operation.
3. The statistician analyzing the multiple outcomes.

Blinding patients to physical interventions is difficult. In the case of this trial, patients receive a mobile application and cannot be blinded as the standard of care is obvious.

Procedure for unblinding if needed:

Concealed patient-related information will be stored at the office of the head of research at the University Clinic. The data can be unblinded when adverse events occur. Patients are then assigned to a physician that is not involved in the RCT at hand. However, unblinding is very unlikely due to the negligeable side effects of out intervention.

Data collection and Management

Plans for assessment and collection of outcomes:

The primary outcome of this trial is the objective assessment of compliance with physical therapy. Data on knee motion is provided by two sensors placed proximally and distally to the knee joint. Each sensor is composed of 3 accelerometers measuring motion in a three-dimensional plane. Additionally, the recorded data can be transmitted to phones or tablets via Bluetooth. Both the calibration of sensors and extraction of measured data are realized using a mobile application. This app can only be accessed by outcome assessors and is a separate entity from the one provided for physical rehabilitation. All electronic devices including the rehabilitation app, the recorder app, and the sensors are provided by StatConsult IT-Service GmbH.

To obtain a baseline regarding knee activity in the preoperative period, sensors will be applied for 3 days after the initial outpatient visit, which corresponds to two weeks preoperatively. Monitoring continues for 3 days after TKA to assess the effect of the intervention as compared to the control. Sensor- based monitoring continues after discharge and 6 weeks after TKA. Data will be recorded for 3 consecutive days for both mentioned timelines.

Secondary outcomes including pain and quality of life as well as other aspects of function (besides the ones measured by sensors) are assessed using patient related outcome measures (PROMs). Furthermore, functionality is assessed by the means of the stair climb test, a performance-based measure (PBMs). PROMs are measured 2 weeks preoperatively as well as 6 days and 3 months after surgery. The stair climb test (PBM) will be measured after the initial outpatient visit at 2 weeks before surgery as well as 3 days and 6 weeks postoperatively. Assessors are trained to uniformly administrate the stair-climb test by the chair of research and physical therapy and the same flight of stairs will be implied in the process. This insures minimal discrepancy between measurements.

Two prior qualitative analysis studies have uncovered a plethora of variables that affect the patient's compliance with physical therapy in a hospital setting. Based on these analyses, two questionnaires have been developed. These surveys will be administered at the day of discharge to gain insights on the reasons of non-compliance with physical therapy.

Furthermore, patients will be continuously monitored for adverse events including bleeding, wound complications, thromboembolic diseases, neural deficits, vascular injuries, medial collateral ligament

injury, instability, malalignment, stiffness, deep periprosthetic joint infections, periprosthetic fractures, extensor mechanism disruption, patellofemoral dislocation tibiofemoral dislocation, implant loosening, implant fracture, or death as well as any reason for reoperation or revision will be reported. Table 2 below details how and when various outcomes are measured in this trial.

Table 2: This table details how and when the various outcomes are measured in the trial:

Outcome	Tool	Timeline
Primary Outcome		
Compliance with physical therapy	Sensors containing three accelerometers	3 days monitoring at: 2 weeks preoperatively, directly after surgery and at 6 weeks postoperatively.
Secondary Outcomes		
Parameters affecting compliance with physical therapy	Compliance questionnaires	3 days after TKA
Pain	PROMs: WOMAC, KSS, Oxford Score.	PROMs: 2 weeks before surgery, 3 days and 6 weeks after surgery. PBMs: 2 weeks before surgery, 3 days and 6 weeks after surgery.
Quality of Life		
Function	Subjectively assessed Function: WOMAC, KSS, Oxford Score. Objectively assessed Function: Stair climbing test (PBM)	
Adverse Events including death	Continuous monitoring in the hospital and the rehabilitation center	After the surgery for 6 weeks.

TKA: Total knee arthroplasty, WOMAC: Western Ontario and McMaster Universities Arthritis Index; PROM: Patient-Related Outcome Measure; KSS: Knee Society Score; PBM: Performance-Based Measure.

Plans to promote participant retention and complete follow-up:

Up until discharge from the university hospital, follow-up can be ensured. Afterwards, patients are given a routine follow-up appointment 6 weeks after TKA. At this point in time, sensors are reapplied to the patient´s knees. Patients will receive a pre-paid envelope with the address of the university clinic on it. Nurses working at the outpatient clinic are responsible to ensure that patients attend their follow-up visits 6 weeks after surgery. Study nurses will be responsible to call patients and ensure that sensors are sent back.

Data management:

Sensors have the capacity to identify and record changes in acceleration. The recorded data can be extracted using specially purposed tablets. After extraction using tablets, the data is sent to the engineer of the cooperation partner StatsConsult IT-Service GmbH. There data is decrypted by a specially engineered artificial intelligence to reconstruct the different motions of the knee. Hence, the level of activity and other details regarding how and when the knee was moved can be obtained. The mainframe of the cooperating partner ensures continuous circulation of data through different databases. Followingly, if any single database is decapacitated, data will not be lost.

Confidentiality:

PROMS, PBMs, Compliance Questionnaires (CQ) and sensor recorded data are all collected electronically and subsequently sent to the cooperating partner. After completion of PROMs, PBMs and CQs, the outcome assessor approves the transfer of information and locks the profile of participants. Followingly, no data can be obtained by a third party. As previously mentioned, sensor recorded data can only be interpreted using a specifically designed artificial intelligence. Hence, this

data is always protected. Due to the specialization of StatsConsult IT-Service-GmbH in the field of cybersecurity, the authors have no concern regarding the breach of confidentiality.

Statistical Methods

Statistical Methods and Secondary Outcomes:

Descriptive data is presented with a mean, median and standard deviation of the score- and sensor-based data. Confidence intervals are provided for all outcomes. Normal distribution will be analyzed with the Kolmogorov-Smirnoff test. If data is normally distributed, variance homogeneity will be tested with the Levene test. If variance homogeneity is absent, an independent t-test and ANOVA repeated measures will be used. Otherwise, non-parametric tests like U- or Wilcoxon test will be used for group comparison. Effect sizes will be reported. Pearson, Spearman and the exact Fisher´s test will be used for correlation analysis.

Interim analysis:

No interim analysis is planned as the authors hypothesize that the intervention is safe and a minimal number of 64 participants was determined to explore the efficacy of the intervention.

Methods for additional analyses (e.g. subgroup analyses):

No further subgroup analysis is planned.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data:

The primary outcome of this study is the adherence of patients to the prescribed physical therapy. Hence, no plans are made to promote adherence to the intervention as the primary outcome would be biased. Missing data will not be included provided that the drop-out rate remains below 20%. A further loss of data would lead to an intention to treat analysis. Outliers, if explainable will be included. Only if technical issues are responsible for outliers, these will be excluded.

Plans to give access to the full protocol, participant level data and statistical code:

The protocol of this study will be published in JMIR protocols. Registration was previously done at the Deutsches Register für klinische Studien. Anonymized data will be made available on request from the corresponding author.

Oversight and Monitoring

Composition of the coordinating center and trial steering committee

The coordinating center will be composed of the head of research at the university clinic, the chief of orthopaedic and trauma surgery, the statistician, the chief engineer of the cooperating partner StatsConsult IT-Service GmbH and two research fellows at the University Clinic. The coordinating center ensures the correct reporting of outcome parameters and the handling of missing data. The coordination center further ensures patient safety with respect to the applied intervention. Organizational support will be provided by the staff of the orthopaedic and trauma surgery department. This includes the nurses registrating and allocating patients as well as nurses delivering therapeutic measures and physiotherapists working on rehabilitative measures. Furthermore, the previously mentioned staff will be providing information on the patient´s availability during the period of the trial.

Composition of the data monitoring committee and its role:

The data monitoring committee is independent from the research team and the cooperating partner. Data will be monitored and subsequently analyzed by the Center of Clinical Studies at Brandenburg Medical School. Informing the steering committee if incorrect or unexpected data occurs will be the main responsibility of this entity.

Adverse events reporting and harms:

As physical therapy has been shown to improve multiple outcome variables such as pain, function, and the quality of life, authors hypothesize that the intervention will benefit patients undergoing TKA. Little to no complications are expected as a direct consequence of the intervention at hand.

Patients will be screened for the previously mentioned adverse events as well as falls and death. Exanthema and skin irritations due to the application of sensors will be treated and subsequently reported.

Frequency and plans for auditing trial conduct:

Auditions for the assessment of research conduct as well as the quality of measured data will be held every month to monitor the progression of the trial. Special attention is given to the correct application of the sensors, data reported by these sensors and the patient´s correct response the various scores and questionnaires. The head of research further evaluates the correct execution of the PBMs. This promotes data quality and integrity.

Plans for communicating important protocol amendments to relevant parties:

Any important modification regarding the methodology of the trial at hand is orally communicated to trial participants. Amendments regarding changes in the protocol is further communicated with the ethics committee, the appropriate registry, the trial steering committee, the cooperating partner and the journal publishing the protocol in writing.

Dissemination plans:

The results of the trial will be published in an open-access professional peer-reviewed journal and on national and international conferences. No restrictions are made regarding the accessibility of data. Primary data will be available by the corresponding author upon request. Materials and methods will be made available in a subsequent publication to ensure the reproducibility of the results.

Discussion

The main objective of the upcoming trial is to measure the effect of application-based physical therapy following total knee arthroplasty on compliance with a given rehabilitative regimen. An extensive literature search revealed that compliance was previously measured using questionnaires. This has been a main limitation in these studies as it introduces error in assessing the objective adherence to rehabilitative programs. The main novelty of this study will lay in the application of two knee sensors. Hence, an accurate reconstruction of knee activity in a three-dimensional plane is reconstructed. Followingly, the correlation between adherence to physical therapy in the early postoperative period and its effect on short- and long-term outcomes can be objectively quantified.

Previous pilot studies reported positive effects regarding the use of Ehealth rehabilitative applications following total knee arthroplasty. The main findings of these studies underline the effectiveness of these applications in personalizing health care delivery and increasing the engagement of the target population (26). Additionally, results “comparable to those of face-to face rehabilitation” regarding patient satisfaction were observed in one study (27). Furthermore, pharmacologic studies assessing the effectiveness of mobile reminder applications report a positive outcome on compliance with medication regimens (). In the light of this research, measuring the effect of mobile application-based physical therapy on rehabilitation following TKR is a promising method of treatment delivery.

The application at hand was developed on the basis of a thorough literature search and underwent multiple rounds of expert review. Main issues regarding the usability of smart phone-based technologies by the target population were identified (28) (29). Older age was therefore equated for by a simple design of the mobile application at hand. A second challenge consisted of the lack of evidence regarding the superiority of a single exercise regimen. Sattler et al. (2019) identified four randomized controlled trials with higher levels of evidence analyzing the effects of physical therapy regimens on patients following TKR (19). Based on this systematic review, an exercise regimen integrating different components of these programs was conceived. Afterwards, the application underwent expert review and final modifications were introduced. The details regarding the conceptions of the mobile application are the subject of a soon-to-be published paper.

Finally, some limitations were encountered whilst pilot-testing the sensor-based monitoring. Sensors

stop recording between 10 PM and 6 AM as the half-life of the battery did not allow for continuous recording. Additionally, the authors of this study hypothesize that patients will have minimal knee-related activity during the night. Furthermore, securing sensors to the anterior aspect of the knee will prove challenging. Participants will, however, be advised to wear loose clothing around the knee joint to minimize the effect of friction on the motion of sensors. Other limitations of the study will be included in the final publication.

Trial status

This is the first version of the protocol dated 14.06.2024. Recruitment has not begun but is soon to start and the medical center. The authors hypothesize that recruitment will be completed 6 months after starting the trial.

Abbreviations

PROM: Patient-related outcome measure
PBM: Performance-based measure
WOMAC: Western-Ontario McMaster Universities Arthritis Index
KSS: Knee Society Score
CQ: Compliance Questionnaire
TKA: Total knee arthroplasty
DRKS: Deutsches Register klinischer Studien

Declarations

Acknowledgements:
We acknowledge the organizational planning of the Center of Orthopaedic Surgery and Trauma Surgery at the University Clinic of Brandenburg.

Author´s Contribution:
HTH is the main author of this manuscript who contributed to the design of the study. NR and MS oversaw the development of the assessment plan. RP is the chief methodologist who conceived the trial and its design. RB is the chief investigator who oversaw the conception of the trial and contributed to the fine-tuning of the protocol. HTH and RB investigated the clinical applicability of the protocol. All authors read and approved the final version of the protocol.

Funding:
No funding is provided for this protocol. The Library of the Brandenburg Medical School - Theodor Fontane provided funding for the publication of this protocol.

Availability of data and material:
The statistician analyzing outcome measures, all involved research fellows, the head of research and the head of the orthopaedics and trauma surgery at the University Clinic will always have full access to the trial dataset.

Ethics approval:
The trial at hand is approved by the ethics committee of the Medical School Brandenburg – Theodor Fontane. Ethics number:

Consent for publication:
All authors consented the publication of the protocol.

Competing interests:
The authors declare that they have no competing interests.

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Supplementary Files