PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

PROMoting Quality - Intersectoral use of Patient Reported Outcome Measures to increase patient-relevant outcome quality

Trial Acronym

PROMoting Quality

URL of the trial

https://blogs.tu-berlin.de/mig_promotingquality/

Brief Summary in Lay Language

Purpose: In the research project PROMoting Quality, a survey instrument is used to evaluate the course of treatment after the use of hip or knee joint prostheses from the patient's perspective. The quality of treatment from the patient's point of view should be considered and improved.

Approach: Possible critical developments after surgery are detected early. In such a case, a study assistant at the participating hospital will contact the patient and, if desired, forward the information to the after-care doctor.

Benefits: The findings of this research project are designed to help improve post-clinical treatment for hip and knee joint replacement patients and thus, ensure the best quality of life and functionality following joint surgery.

Eligibility: All patients having a knee or hip replacement scheduled between October 2019 and October 2020 in one of the participating hospitals can participate.

Process: A survey tool is used to assess the course of treatment when using hip or knee replacement, also from a patient perspective. An intuitively usable web solution is used to continuously ask the person concerned about their state of health before and after their operation. Patients receive regular e-mails asking them to complete a questionnaire.
If the patient continues to consent, conspicuous results can be sent to his follow-up doctor - so that he can intervene early if necessary and improve the treatment success targeted. On the other hand, the patient also receives valuable information with which he can gain transparency about the course of treatment and can work towards an improvement in an interview with his postoperative doctor.

Brief Summary in Scientific Language

The overall aim of the study is to test the feasibility of an early identification and therefore timely treatment of post-surgical complications and/or the health related quality decreasing developments with help of PROMs.

The study is a German two-arm multi-center randomized controlled trial (RCT). Patient-centered questionnaires are employed to regularly measure PROMs of patients with TKR and THR from the time of hospital admission until 12 months after discharge. We have, together with doctors, defined PROM set values at 1,3, and 6 months to signal critical recovery paths of patients after TKR/THR – and by help of a software – alert patients and their after-care doctors to intervene in case of critical recovery paths.

By adding cost data on participant level, the study examines the effect of following up on patients up to 12 months post-surgery on treatment outcome and its corresponding outcome which is cost effectiveness.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00019916**
- Date of Registration in DRKS: **2019/11/26**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA4/169/19 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **M16 - Coxarthrosis [arthrosis of hip]**
- ICD10: **M17 - Gonarthrosis [arthrosis of knee]**

Interventions/Observational Groups

- Arm 1: **Participants in the intervention group have to complete (on top of the baseline questionnaire during hospital stay) four follow-up questionnaires, at month 1, 3 and 6, and a final follow-up 12 months post-discharge. All follow-up questionnaires are sent via e-mail and are filled in electronically by the participants, either on their computers, smartphones or tablets. In case the participants do not possess an e-mail account, e-mails are sent to relatives, if agreed upon. Results from the questionnaires will be automatically transferred to the study's software and are observable by the hospitals' study assistants and doctors. 1, 3, and 6 months results from aforementioned PROM sets will be screened for critical values or unfavorable developments.**
  When critical values or developments are detected, the software will consequently alert the study assistants of the corresponding hospitals and an intervention is initiated. Interventions are characterized by three steps: Firstly, the study assistant sends a standardized report to the participant, via post or vie encrypted e-mail, where critical values and developments are highlighted and a follow-up call is announced. Secondly, the study assistant calls the participant via phone informing him of the critical values, asking permission to forward the PROM results to his outpatient specialists or family doctors, and recommends a visit to his doctors to potentially adjust treatment. Finally, a report with the participant's results will be forwarded, via post or fax, to the outpatient doctor. In the following questionnaire the participants are asked to report changes in their treatment schedule in order to document modifications in the outpatient doctors' treatment, with respect to physiotherapy, medication or surgery.

- Arm 2: **Participants in the control group will only be surveyed during hospital stay (admission and discharge) as well as after 12 month. No intervention will be initiated.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver**
- Control: **Control group receives no treatment**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary outcome of the study is to investigate cost efficiency, thus the optimization of outcome quality compared to the resource utilization of the designed intervention. Outcome quality is defined as a composite measure of PROMs and clinical outcome measures. Utilized resources are direct and follow-up health care cost of the procedures and cost of implementing the designed intervention.

Secondary Outcome

Secondary outcomes include the improvement of functionality of the patient reflected by the KOOS-PS/HOOS-PS, of medium to long-term health-related quality of life evaluated by the EQ-5D-5L, of pain in knee, hip and lower back, of satisfaction with treatment outcome and of clinical outcome measures like post-operative revision and reoperation rates. Furthermore, these analyses will be repeated with subgroups, built by age, sex, baseline PROM scores, etc.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Helios ENDO-Klinik Hamburg GmbH, Holstenstraße 2, 22767 Hamburg, Hamburg**
- Medical Center **Schön Klinik Hamburg Eilbek, Dehnhaide 120, 22081 Hamburg, Hamburg**
- Medical Center **VAMED Ostseeklinik Damp GmbH, Seute-Deern-Ring 20, 24351 Ostseebad Damp, Damp**
- University Medical Center **Charité, CMSC, Campus Virchow Augustenburger Platz 1, 13353 Berlin, Berlin**
- Medical Center **DIAKOVERE Annastift, Anna-von-Borries-Straße 1-7, 30625 Hannover, Hannover**
- Medical Center **RoMed Kliniken, Postfach 100764, 83007 Rosenheim, Prien am Chiemsee**
- Medical Center **Schön Klinik Neustadt, Am Kiebitzberg 10, 23730 Neustadt i. H. , Neustadt**
- Medical Center **Sana Kliniken Sommerfeld, Waldhausstraße 44, 16766 Kremmen, Kremmen**
- Medical Center **Waldkliniken Eisenberg GmbH, Klosterlausnitzer Straße 81, 07607 Eisenberg, Eisenberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/10/01**
- Target Sample Size: **14000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**

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- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Eligible for this study are all patients with primary elective TKR/THR above the age of 18 having a scheduled surgery between October 2019 and October 2020 and having direct or indirect access to an e-mail account.

Exclusion criteria

Exclusion criteria for participation are emergencies (e.g., femoral fracture), patients with ASA classification 4-6 (4 - patient with life-threatening disease, 5 - moribund patient who is unlikely to survive without surgery, 6 - deceased patient with confirmed brain death, or organ donor), and patients younger than 18 years. Additionally, patients without direct or indirect access to an e-mail account are excluded from the study due to practical reasons. E-mail addresses from relatives are accepted. All patients who deny participation will not be included in the study.

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

■ Approval of ethics comm. (mandatory for transfer to Studybox) **Ethical vote of the Charité**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*