Trial Description

Title

Pabee – “Patientenbegleiter für endoprothetische Eingriffe” – Patient Companion for Joint Replacement Surgery

Trial Acronym

pabee

URL of the trial

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Brief Summary in Lay Language

The implantation of a joint replacement is a conventional therapy for the treatment of osteoarthritis. The aim of the surgery is to provide/restore maximum functionality, reduce pain, and thus, improve the quality of life of the patient. Patient-related factors, such as the handling of the prosthesis, influence the outcome of the surgery and durability. For this patient group, there is a great need for efficient pain therapy and an increase in patient competencies. The smartphone application "RECOVER-E" accompanies the patient throughout the entire course of the treatment and enables optimal education of the patient as well as the recording and evaluation of treatment-relevant parameters by the patient him-/herself and upon his/her request, also by the medical team.

Brief Summary in Scientific Language

Background:
In Germany, about 28% of women and 20% of men are affected by osteoarthritis of the hip and knee joints. The implantation of endoprostheses (joint replacement) due to these joint diseases has become routine. The aim of the joint replacement initial implantation is to enable best possible functionality, reduce (knee- or hip-related) pain and achieve rapid mobilization. A number of factors influence the success of the therapy and durability. These include patient-related factors, such as interference with activity and participation, environmental factors, such as aids, social interactions as well as factors, such as age, mechanical stress and comorbidities. An efficient pain therapy contributes to convalescence, rapid mobilization and a reduced complication rate. For this patient group, there is a great need for efficient pain management and competence development within the framework of self-care for handling the prostheses and the management of pain situations. This is crucial for the optimal rehabilitation of patients.

Research questions:
Primary outcome: Can patients undergoing hip or knee replacement surgery and using the application RECOVER-E attain better mobility/function in activities of daily living three months post-surgery when compared to patients undergoing surgery without using the app?

Secondary outcome: Can patients undergoing hip or knee replacement surgery and using the application RECOVER-E attain less symptoms, less pain, better

function in sport and recreation as well as a better knee/hip related quality of life three months post-surgery when compared to patients undergoing surgery without using the app?
Can patients using the RECOVER-E application attain less preoperative anxiety and postoperative pain when compared to patients undergoing surgery without using the app?

The qualitative approach focuses on the usability of the app RECOVER-E and its benefit for patients undergoing joint replacement. Structured telephone interviews with patients will be carried out after completing the quantitative data collection. Furthermore the perceived benefit concerning the efficiency of the treatment and the hospital-patient-communication by the involved coordinators in the hosptials will be analyzed by structured telephone interviews. The interviews will be digitally recorded and subsequently transcribed. The content analysis (Mayring 2015) will be carried out computer-assisted, with MAXQDA.

Intervention:
Standardized application of the pabee App, which provides information to the patient during the course of treatment and facilitates assessment and evaluation of pain, mobility and other relevant factors. In addition, treatment-related information is provided to the hospital by the patient. The app comprises an interface with a clinical web portal for the clinical care teams that can be used to customize information on the individual clinic. Additionally patient data collected in the app can – with the patients' permission – be transferred to the web portal for clinicians to monitor the recovery process.

Data collection and evaluation:
- Standardized data collection of the outcome: mobility/function in daily living, pain intensity, quality of life, symptoms, function in sport and recreation, preoperative anxiety (collected by the Pain Nurse, evaluated by the project team)
- Qualitative survey of patients and medical groups (collection and evaluation by the project team)
- Structural data (collection and evaluation by the project team)
- The data on the app usage pattern are collected pseudonymized on a server and evaluated by the project team.
To collect the data on the outcome measures, a collection tool is installed on the tablet PCs. The data collected via the tablet PCs are pseudonymized and analyzed using IBM©SPSS. The group interviews are digitally recorded, transcribed and content analyzed with MAXQDA.

Relevance:
The App is designed to improve the care of patients with a scheduled hip or knee replacement surgery through structured information and training as well as data exchange with the participating medical groups.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00012744**
- Date of Registration in DRKS: **2019/01/25**
- 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.: **2017-329-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Patients allocated to the intervention group will receive the smart phone application “RecoverE” in addition to standard care four to six weeks before surgery until 3 months post surgery. Recruitment of patients for the intervention group takes place from August 2019 until March 2020.**
- Arm 2: **The control group receives standard care and will be recruited before the intervention group. All patients of the control grouo, that fulfill the inclusion criteria will be recruited from February 2019 until July 2019.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Other**
- Assignment: **Other**
- Phase: **N/A**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Non-randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control (effective treament of control group)**

Purpose: **Other**

Assignment: **Other**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary outcome mobility/function in activities of daily living will be measured by the activities of daily living (ADL) subscale of the Knee injury and Osteoarthritis Outcome Score (KOOS) and the Hip disability and Osteoarthritis Outcome Score (HOOS) at t0 (baseline, 4-6 weeks before surgery) and t4 (3 months post-surgery).

Secondary Outcome

Secondary outcomes pain, symptoms, function in sport and recreation and knee/hip related quality of life will be measured by the subscales for pain, symptoms, function in sport and recreation and knee/hip related quality of life of the Knee injury and Osteoarthritis Outcome Score (KOOS) and the Hip disability and Osteoarthritis Outcome Score (HOOS) at t0 (baseline, 4-6 weeks before surgery) and t4 (3 months post-surgery); preoperative anxiety will be measured by the Hospital Anxiety and Depression Scale (HADS-D) at t0 (baseline, 4-6 weeks before surgery) and t1 (the day of admission to the hospital); postoperative pain will be measured by rating pain at rest and pain under activity via an eleven point numerical rating scale (NRS 0 - 10) at t0 (baseline, 4-6 weeks before surgery), t1 (the day of admission to the hospital), t2 (the 1st postoperative day), t3 (the 7th postoperative day) and t4 (3 months post-surgery).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **St. Josef-Stift Sendenhorst, Sendenhorst**
- Medical Center **Berufsgenossenschaftliche Unfallklinik Murnau, Murnau**
- Medical Center **Sana Kliniken Sommerfeld, Kremmen**
- University Medical Center **Universitätsklinikum Bonn , Bonn**
- Medical Center **Orthopädische Klinik Markgröningen, Markgröningen**
- Medical Center **Asklepios Orthopädische Klinik Lindenlohe, Lindenlohe**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/02/26**
- Target Sample Size: **160**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Inclusion criteria for patients:
- Patients, who are scheduled to receive an elective total hip or total knee replacement
- Patients at or above 18 years of age
- Signed informed consent (on paper)
- Patients, who have a smartphone and an e-mail account

Inclusion criteria for the medical team:
Coordinator in included hospitals

Exclusion criteria

Exclusion criteria for patients:
• Patients, who receive an emergency hip or knee replacement surgery, such as after a fall
• Patients with revisions or exchange surgery
• Patients, who already received a replacement of another joint
• Patients under the age of 18
• Patients with cognitive impairments of all types (as assessed by the admitting physician)
• Patients with mental illnesses of all types (as assessed by the admitting physician)
• Patients, who failed to download the App or didn’t use it when they were admitted to the hospital
• Patients, who have post-surgery complications, such as infections, allergies, instability, delirium, or other
• Patients, who can´t use the App or complete the questionnaire due to limited language skills

Addresses

- **Primary Sponsor**

  Paracelsus Medizinische Privatuniversität, Institut für Pflegewissenschaft und -praxis
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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  Grünenthal GmbH
  Steinfeldstraße 2
  52222 Stolberg
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **2020/12/31**
- Number of Participants in Germany after Recruiting complete: **99**
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **99**

Trial Publications, Results and other documents

- Paper **Publication Study Protocoll**

** 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.*