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# Kneehab® pre and post total knee replacement surgery

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 23/03/2010 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 25/03/2010 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 13/04/2017 | Surgery | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
BMR-09-1007

## Study information

**Scientific Title**
The effect of augmenting a standard therapy protocol with a 12-week peri-operative programme of Kneehab® neuromuscular electrical stimulation in patients undergoing total knee replacement: a randomised controlled trial

## Acronym
Kneehab

## Study objectives
Neuromuscular electrical stimulation (NMES) can help prepare the quadriceps muscle for the rehabilitation phase by building exercise capacity before the operation. The immediate deficit, which normally follows knee surgery, would therefore be compensated to some extent and the post-operative NMES treatment would be expected to counteract the activation inhibition that is thought to occur in the early weeks following surgery. Overall, the patient would be in a better position to benefit from conventional rehabilitation exercises aimed at improved co-ordination and functional performance.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The Ethics Committee of the Royal Liverpool & Broadgreen University Hospital NHS Trust, 30/06/2009

## Study design
Randomised controlled blinded parallel group trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Patients undergoing total knee replacement surgery

## Interventions
Kneehab® group: 6 weeks before and 6 weeks after total knee replacement surgery (30 minutes of NMES twice per day for 12 weeks), plus standard physiotherapy.
Control group: 12 weeks (6 weeks pre and post) standard physiotherapy.

## Intervention Type
Procedure/Surgery

## Phase
Not Applicable

## Primary outcome(s)
Determine the efficacy of Kneehab® in promoting early recovery of quadriceps performance in patients recovering from total knee arthoplasty as determined by:
1. Clinically significant increase in isometric extensor strength compared to controls
2. Clinically significant reduction in Timed Up-and-Go (TUG) and Stair Climbing Test (SCT) score compared to controls

## Key secondary outcome(s))

1. Quality of life measures
2. Health economic outcomes

### Completion date
01/03/2014

## Eligibility

### Key inclusion criteria
1. Individuals who are scheduled for Total Knee Replacement surgery
2. Individuals who are at least 18 years of age
3. Individuals with a body mass index (BMI) <35
4. Individuals who are walking independently with or without assistive devices
5. Must be able and willing to complete all study assessments and to be followed for the full course of the study
6. Must be able to read, write and follow instructions in English
7. Must be able and willing to provide informed consent
8. Must be willing and able to attend the additional pre-op assessment

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Individuals who have failed the pre-Total Knee Arthroplasty (TKA) operative assessment
2. Individuals with a history of foot and/or ankle pathology
3. Individuals with a history of tibial or femoral fractures
4. Individuals with a history of any underlying neurological conditions
5. Individuals with physical conditions which would make them unable to perform study procedures
6. Individuals with a total hip replacement
7. Individuals undergoing revision TKA of the same operated leg
8. Pregnant women or inadequate precautions to prevent pregnancy
9. Diagnosis of a medical condition that would contraindicate treatment with the product, e.g. skin lesions at electrode site
10. Individuals with an active implanted medical device (i.e. pacemaker, pump)
11. Individuals with a history of stroke
12. Individuals with a history of neurological disorder that affects lower extremity function (stroke, peripheral neuropathy, Parkinsons disease, multiple sclerosis, etc.)

13. Individuals with a diagnosis of inflammatory arthritis (rheumatoid arthritis, gout or psoriatic arthritis)
14. Individuals with muscle diseases (i.e. muscular dystrophy)
15. Visible skin injury or disease on their legs
16. Principal investigator for this study, or member of study staff

### Date of first enrolment
12/04/2010

### Date of final enrolment
01/03/2014

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**The Royal Liverpool & Broadgreen University Hospital**
Liverpool
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L14 3LB

## Sponsor information

### Organisation
The Royal Liverpool & Broadgreen University Hospital (UK)

### ROR
https://ror.org/009sa0g06

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Royal Liverpool & Broadgreen University Hospital (UK)

**Funder Name**
Bio-Medical Research, Ltd., (Ireland) - provide Kneehab (NMES) devices

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |