ISRCTN09005050 https://doi.org/10.1186/ISRCTN09005050

# Feasibility of a therapeutic exercise before total hip replacement

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 02/09/2009 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 26/10/2009 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 26/10/2009 | Musculoskeletal Diseases | [ ] Record updated in last year |

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

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Nico van Meeteren

**Contact details**
Hospital Gelderse Vallei
Willy Brandtlaan 10
Ede
Netherlands
6716 RP
VeldmanA@zgv.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

## Study information

## Scientific Title
Feasibility and preliminary effectiveness of a short-term, preoperative therapeutic exercise programme for frail, elderly patients awaiting total hip replacement

## Acronym
Profyt2

## Study objectives
Is a short-term preoperative therapeutic intervention for frail elderly patients with osteoarthritis awaiting total hip replacement feasible?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Institutional Review Board of the University Medical Centre Utrecht (protocol number 07/051) and the Gelderse Vallei Hospital (protocol number Profyt 06/184-O) approved this study on the 5th June 2007.

## Study design
Randomised controlled single-blind pilot trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Hip osteoarthritis

## Interventions
Experimental group: Short-term (3-6 weeks), intensive, tailor-made therapeutic exercise (twice a week).
Usual care group: One information meeting and practicing the use of crutches.

## Intervention Type
Other

## Phase
Not Applicable

### Primary outcome measure
Feasibility towards patients satisfactory is assessed by the following main outcomes:
1. The occurrence of adverse effects during testing or training. Participants will have to register any discomforted, stiffness or other adverse events in their diary.
2. Adherence to the treatment. Both groups are asked to register their adherence to the home based training programme (i.e. time exercised, days exercised and perceived exertion). Pedometer adherence is defined as the number of steps recorded on the daily pedometer log that met or surpassed the weekly goal. Also adequate use of the diary will be assessed as part of the adherence to the intervention.
3. The patients' appreciation and motivation towards the therapeutic intervention will be determined by a patient evaluation form (satisfaction questionnaire) that patients complete at the end of the preoperative training.

### Secondary outcome measures
1. Preoperative effectiveness:
1.1. Aerobic capacity, assessed with the Physical Working Capacity 170
1.2. Strength and power of the lower limb muscles is assessed by the chair rise time
1.3. Functional mobility is assessed with the Timed Up and Go Test
1.4. Walking capacity is assessed with the six minutes walk test (6MWT)
1.5. Pain, functioning and quality of life is assessed with the Hip disability and Osteoarthritis Outcome Score (HOOS)
1.6. Patient specific complaint (Patient Specifieke Klacht [PSK]) questionnaire
1.7. Functional activities are assessed by the Longitudinal Aging Study Amsterdam (LASA) Physical Activity Questionnaire (LAPAQ)

2. Postoperative effectiveness:
2.1. Length of stay
2.2. Discharge destination (home, rehabilitation centre or nursing home)
2.3. The patient's functional mobility score using the Iowa Level of Assistance Scale

### Overall study start date
05/06/2007

### Completion date
09/11/2008

## Eligibility

### Key inclusion criteria
1. Both males and females, age ≥70 years
2. Scheduled for elective total hip arthroplasty (THA) (minimum waiting period of 3 weeks)
3. Osteoarthritis is the motive for the THA
4. First surgical intervention of this pathology
5. Scores ≥2 on the Clinical Frailty Scale (CFS)
6. Able to permit time for the intervention between enrolment and surgery

### Participant type(s)
Patient

### Age group
Senior

**Sex**
Both

**Target number of participants**
20

**Key exclusion criteria**
1. Unable to understand Dutch
2. Patients with severe heart disease

**Date of first enrolment**
05/06/2007

**Date of final enrolment**
09/11/2008

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Hospital Gelderse Vallei**
Ede
Netherlands
6716 RP

# Sponsor information

**Organisation**
Hospital Gelderse Vallei (Netherlands)

**Sponsor details**
Willy Brandtlaan 10
Ede
Netherlands
6716 RP

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.zgv.nl

**ROR**
https://ror.org/03862t386

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Hospital Gelderse Vallei (Netherlands)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

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