

# Feasibility of a therapeutic exercise before total hip replacement

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<b>Registration date</b> 26/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/10/2009	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

## 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

### **Study type(s)**

Treatment

### **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(s)**

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 discomfort, 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.

### **Key secondary outcome(s)**

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

**Completion date**

09/11/2008

## Eligibility

**Key inclusion criteria**

1. Both males and females, age  $\geq 70$  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  $\geq 2$  on the Clinical Frailty Scale (CFS)
6. Able to permit time for the intervention between enrolment and surgery

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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)

### **ROR**

<https://ror.org/03862t386>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Hospital Gelderse Vallei (Netherlands)

## **Results and Publications**

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

### **IPD sharing plan summary**

Not provided at time of registration