

# Knee rehabilitation: home visual feedback and video call follow up

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<b>Registration date</b> 27/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/06/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

After knee replacement surgery patients are discharged to their homes with walking aids and a standard exercise booklet. They are expected to carry out their home rehabilitation using these aids until their return to the hospital six weeks after surgery for a clinical assessment. During the time between leaving the hospital and the 6th-week clinic appointment patients also have access to a 24-hour phone support from the hospital. However, there is evidence showing that some patients may wish to have other forms of rehabilitation aids that provide real-time feedback. We have developed small wearable movement capture devices that can be worn by participants at home while they are doing their exercises. The participants can then see on their television screen or on a laptop computer exactly what they are doing during their exercises. The devices can also be used as a communication aid in that a hospital-based physiotherapist could see and talk to the patient about the captured movements via a video call so that if there were any concerns these could be looked into. We wish to see if this system would improve rehabilitation outcomes such as walking speed and quality of life of patients during the first 6 weeks of their rehabilitation.

### Who can participate?

Unilateral total knee replacement patients.

### What does the study involve?

All participants will be randomly placed into two groups. The control group will receive the usual care: exercise booklet/DVD and telephone follow-up. The intervention group will receive the usual care as well as a set of small wearable sensors/devices, a screen on which they will be able to see their movement and a videophone link. The participants will be required to wear the sensors and watch a real-time feedback of their movement each time they perform their rehabilitation exercises (training will be provided at the start of the study for the participants). After two weeks, the participant will receive a video call from the physiotherapist who carries out a remote supervision of an exercise session. After 6 weeks, we will assess the rehabilitation progress of both groups. The progress will be measured in terms of walking speed, timed up and go test, active knee range of motion, quality of life and adherence to exercise program. Furthermore, we will evaluate how the participant has used the system.

What are the possible benefits and risks of participating?

This study will include the use of novel rehabilitation tools that could help participants perform exercises better, get more involved in their rehabilitation and maximize the benefits of rehabilitation. Also, the devices could increase participants motivation to exercise in the home; however, this cannot be guaranteed. There are no identified risks of physical injury or harm. Possibly, participants may feel slight discomfort wearing the sensors, take longer time to setup for their rehabilitation exercises and feel less confidence with using this sort of technology. We have minimised these by providing adequate training at the start of the study, making the setup as simple as possible (comparable to using consumer electronic game controllers like the Nintendo Wii), and participants are advised to use the system only if they wish and are able to do so.

Where is the study run from?

Golden Jubilee National Hospital (UK)

When is the study starting and how long is it expected to run for?

November 2012 to May 2013

Who is funding the study?

Lifelong Health and Wellbeing Joint UK Research Council (UK)

Who is the main contact?

Mobolaji Ayoade

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**Study website**

<http://www.envisagerehab.co.uk/>

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

ClinicalTrials.gov number

Secondary identifying numbers

2.1

## Study information

### Scientific Title

Community- based visual feedback of motion during rehabilitation exercises and video call follow up with hospital based therapists following total knee joint replacement (TKR) surgery: a pilot randomised controlled trial

### Study objectives

Patients who receive visual feedback of motion and video conferencing with a remote physiotherapist during their home rehabilitation will show a statistically significant improvement in the early stage (up to 6 weeks post operatively) when compared to current standard care in walking speed, quality of life and adherence to rehabilitation programme.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

NHS West of Scotland Research Ethics Service, 26/06/2012, ref: 12/WS/0151

### Study design

Two-armed pilot randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Knee Replacement Rehabilitation

### Interventions

Control Group

This group will receive the usual care i.e. exercise booklet / DVD for the home exercises and a phone call from the hospital outcomes team 10-14 days after discharge.

## **Intervention Group**

This group will also have the usual care. In addition, wear motion sensors at least once a day during the home exercise sessions. During the session, participants will be able to view the feedback of their movement. In the 3rd week after discharge from the hospital, the participant will receive a video call from the hospital outcomes team.

After 6 weeks, we will assess the rehabilitation progress of both groups. The progress will be measured in terms of walking speed, timed up and go test, active knee range of motion, quality of life and adherence to exercise program. Furthermore, we will evaluate how the participant has used the system.

## **Intervention Type**

Procedure/Surgery

## **Phase**

Not Applicable

## **Primary outcome measure**

Difference in walking speed at baseline (1st week) and at 6th week.

## **Secondary outcome measures**

1. Timed up and go test
2. Oxford knee score
3. Quality of life i.e. SF-12 and EQ-5D
4. Active range of motion of the knee joint
5. Absence of knee extension lag
6. Adherence to rehabilitation exercises

## **Overall study start date**

19/11/2012

## **Completion date**

30/05/2013

# **Eligibility**

## **Key inclusion criteria**

Adult patients who would have consented to undergo a first unilateral primary total knee replacement at Golden Jubilee National hospital.

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

**Key exclusion criteria**

1. Patients listed for second or bilateral knee replacement or revision surgery
2. Patients unable to give informed written consent
3. Patients who are geographically located outside of 2 hours radius from Glasgow city centre. Transportation to patients homes for setups and training should not take too long for the researcher.
4. Patients who have severe visual, perceptual or cognitive problems as participants should be able to use and see the visualisation and video conferencing equipment after being trained.
5. Patients who are involved in any other intervention as these may influence the outcomes and be a source of additional stress for participants.
6. Patients who are referred for outpatient physiotherapy. This gives rise to the possibility of a patient being excluded after consent has already been provided. As a consequence the patient information sheet will contain a clause informing the patient of the likelihood of being excluded as a result of postoperative outcomes.

**Date of first enrolment**

19/11/2012

**Date of final enrolment**

30/05/2013

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**Golden Jubilee National Hospital**

Clydebank

United Kingdom

G81 4SA

**Sponsor information****Organisation**

Golden Jubilee National Hospital (UK)

**Sponsor details**

c/o Dr Catherine Sinclair

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.nhsgoldenjubilee.co.uk/home/research.php>

**ROR**

<https://ror.org/0103jbm17>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Lifelong Health and Wellbeing Joint UK Research Council (UK) ref: 91021

## **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