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Knee rehabilitation: home visual feedback and video call follow up

Submission date	Recruitment status	[ ] Prospectively registered
09/11/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/11/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/06/2017	Surgery	[ ] 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

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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 being 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
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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