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Visual feedback training for movement recovery in patients who have had a knee replacement

Submission date
01/12/2022

Recruitment status
No longer recruiting

Registration date
06/12/2022

Overall study status
Completed

Last Edited
29/12/2023

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
For patients with severe knee osteoarthritis (OA), which affects about one in ten people over the age of 50 years, total knee replacement (TKR) surgery is an effective treatment. TKR is one of the most common replacement surgeries with about 650 thousand surgeries done in the USA every year. Patients usually complain of persistent pain and subsequent mobility reduction, either at night or at weight bearing, not relieved after 6 months of conservative treatments. Indeed, the main outcome of TKR is to relieve pain and improve knee function in people with severe symptoms and end-stage radiographic disease. The aim of this study is to evaluate the effects of visual feedback training on motor recovery in patients after TKR.

Who can participate?
Patients with severe OA who underwent motor rehabilitation after TKR

What does the study involve?
Participants are randomly allocated to one of two groups. The intervention group undergo advanced motor rehabilitation with an innovative and user-friendly visual feedback system through a detailed and objective kinematic gait analysis. There are 20-min sessions, 2 per day for 5 days a week, for 6 consecutive weeks. This treatment is combined with an additional 40 min of conventional therapy on the same days. The control group receive only conventional treatment (1-h session, 2 per day for 5 days a week, for 6 consecutive weeks)

What are the possible benefits and risks of participating?
This kind of intervention is without risk and could improve motor functions as well as pain.

Where is the study run from?
Institute S'Anna (Italy)

When is the study starting and how long is it expected to run for?
February 2019 to June 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Andre De Meco, andreademeco@hotmail.it

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Efficacy of visual feedback training for motor recovery in post-operative subjects with knee replacement: a randomized controlled trial

Study objectives
This randomized controlled study is aimed at evaluating the effects of visual feedback training protocol on motor recovery in postoperative patients with total knee replacement (TKR)

compared with a standard rehabilitation. To the best of the researchers' knowledge, this is the first study applying this kind of rehabilitation approach (integrating VFB) on patients after TKR, using gait analysis as an objective measurement of clinical recovery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/07/2019, Ethical Committee of the Regione Calabria (Viale Europa - 88100 Catanzaro, Italy; +39 (0)961 3694097; protocollo@cert.unicz.it), ref: 169

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Pain and knee function after total knee replacement (TKR) surgery

Interventions
Participants were randomly assigned to two groups using a computer-generated randomization code.

The experimental group underwent a visual feedback (VFB) rehabilitation plan of 20-min sessions, 2 per day for 5 days a week, for 6 consecutive weeks. This treatment was combined with an additional 40 min of conventional therapy on the same days. The VBF plan was made using Walker View 3.0 SCX and ProKin 252 (Tecnobody, Bergamo, Italy), respectively, for gait training and balance training. Walker View 3.0 SCX is a sensorized treadmill with a 3D camera that provides an immediate and objective dynamic image of the patient's posture during training, the load of the lower limbs, the range of movement (ROM) of the requested joint, and the bending of the front, back, and side. ProKin 252 is an electro-pneumatic platform that, after an initial assessment phase, proposes a series of exercises that can be performed in mono or bi-podalic mode with biofeedback of joint ROM and the center of pressure. These tools include a series of rehabilitation games to keep up the patient's concentration and improve compliance with the therapy.

The control group received only the conventional treatment (1-h session, 2/day for 5 days a week, for 6 consecutive weeks). The standard care rehabilitation for TKR included exercises for:

a) ice/compression therapy; b) isometric contraction of operated leg mus-cles (especially in the first phase of the rehabilitation plan); c) moderate muscular resistance training with a progressive load placed at the calf; d) active/passive knee joint mobilization with a physiotherapist's assistance to enhance knee range of motion. When the patients were able to bear weight, they began gait and balance training in order to gradually become independent of the crutches.

Intervention Type
Behavioural

Primary outcome measure
Walking performance assessed using the well-validated G-WALK wearable system (BTS S.p.A. - Italy) measured at baseline and after treatment (lasting 6 weeks).

Secondary outcome measures
Measured at baseline and after treatment (lasting 6 weeks):
1. Pain measured using the Numeric Rating Scale (NRS-11)
2. Activities of daily living following surgery assessed using the Barthel Index (BI)

Overall study start date
01/02/2019

Completion date
01/06/2022

Eligibility

Key inclusion criteria
1. 55-80 years old
2. Unilateral TKR
3. Maximum time from surgery 40 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
55 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
96

Total final enrolment
40

Key exclusion criteria
1. Inflammatory disease after TKR
2. Any neurological, musculoskeletal, or other conditions affecting movement

Date of first enrolment
01/09/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Italy

Study participating centre
S'Anna Institute
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Sponsor information

Organisation
Institute S'Anna

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Sponsor type
Hospital/treatment centre

Website
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (FigShare) at https://www.istitutosantanna.it/
The type of data stored: demographic data, clinical assessments and kinematic analysis.
The process for requesting access (if non-publicly available): Direct e-mail to our administrative office (info@istitutosantanna.it)
Dates of availability: After scientific publication.
Whether consent from participants was required and obtained: Yes
Comments on data anonymization: Following GDPR criteria and national guidelines (https://www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/1671330) , all clinical information stored at S'Anna Institute underwent health data anonymization processing by using validated and implemented archiving systems.
Any ethical or legal restrictions: No
Any additional comments: No

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/12/2022	29/12/2023	Yes	No