

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

Submission date 01/12/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/12/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/12/2023	Condition category Surgery	<input type="checkbox"/> 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

Contact name

Dr Andrea De meco

ORCID ID

<https://orcid.org/0000-0001-5419-4275>

Contact details

Via Siris 11
Kroton
Italy
88900
+39 (0)962 23973
a.demeco@isakr.it

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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-podal 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 muscles (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(s)

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).

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

55 years

Upper age limit

80 years

Sex

All

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

Via Siris 11

Crotone

Italy

88900

Sponsor information

Organisation

Institute S'Anna

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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

[Results article](#)

Details

Date created

11/12/2022

Date added

29/12/2023

Peer reviewed?

Yes

Patient-facing?

No