Cost-effectiveness of a transmural integrated care program for knee arthroplasty patients in the working population

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In this study we will assess the (cost)effectiveness of a transmural integrated care programme supporting return to daily activities (including work)after knee arthroplasty compared to usual care. We hypothesize our transmural integrated care…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON52534

Source
ToetsingOnline

Brief title
Integrated care for knee arthroplasty patients

Condition

- Joint disorders

Synonym
Knee replacement surgery - arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Knee arthroplasty, Orthopedics, Randomized controlled trial, Work participation

Outcome measures

Primary outcome

The primary outcome measure will be quality of life.

Secondary outcome

Secondary outcome will be (work) participation.

Study description

Background summary

In 2030, there will be an estimated 57,900 knee arthroplasties in the Netherlands, with about half of these patients expected to be in working age. Three out of 10 Dutch knee arthroplasty patients do not return to work at all and only 50% of the patients return to work within 3 months, which has an major impact on patient*s quality of life.

Study objective

In this study we will assess the (cost)effectiveness of a transmural integrated care programme supporting return to daily activities (including work) after knee arthroplasty compared to usual care. We hypothesize our transmural integrated care intervention to increase (work) participation and quality of life, which will reduce healthcare and work absenteeism costs.

Study design

A randomized controlled trial with economic evaluation.

Intervention

The intervention under study will consist of a a transmural integrated care program, including: 1) active referral to a case-manager (e.g. an occupational/physical therapist), 2) a rehabilitation program based on patient specific participation goal attainment , and 3) a patient tailored m/eHealth

intervention (using the existing portal ikherstel.nl linked with activity trackers to provide feedback on achievement of activity goals). People receving this intervention will be compared with those receiving care as usual consisting of knee arthroplasty surgery and subsequent care, in accordance to the guidelines of the Dutch Orthopaedic Association (NOV).

Study burden and risks

We expect the risk of participation in this study to be negligible. The only burden that will be put on participation is that they will have spend their time (approximately 10 hours per patient) to participating in our study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients from the working age (18-67 jaar) with a paid job >8hrs a week who will undergo knee replacement surgery will be included.

Exclusion criteria

We will exclude participants who are not able to provide informed concent or who have insufficient understanding of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2020
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Patient Journey App
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-09-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-01-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-02-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL67692.029.18