Physiotherapeutic Treat-to-target Intervention after Orthopaedic surgery; a cost-effectiveness study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27356

Source
NTR

Brief title
PATIO

Health condition

Postoperative physiotherapy after total knee or hip arthroplasty for osteoarthritis (OA)

Sponsors and support

Primary sponsor: Prof.dr.J.A.N Verhaar, hoogleraar Orthopaedie, ErasmusMC
Source(s) of monetary or material Support: Leading the change

Intervention

Outcome measures

Primary outcome

The difference between both groups in change between baseline and 3 month postoperative KOOS-PS / HOOS-PS score will be used as primary outcome.

Besides, differences in medical consumption, adverse events, absence from work or decreased productivity, and patient costs, will be assessed

Secondary outcome

Difference in scores of OKS/OHS, NRS, EQ5D, performance tests, physical activity level, as well as anchor questions, and satisfaction question.

Study description

Background summary

To evaluate the cost-effectiveness of the optimized, treat-to-target PPT strategy in TKA and THA patients compared to usual PPT. The hypothesis is that with the optimized strategy superior functional outcome can be achieved to usual care, with lower costs (superiority study)

Study objective

Primary objective

1. To assess whether the functional outcome of an optimized, personalized treat-to-target PPT strategy after total knee arthroplasty (TKA) and total hip arthroplasty (THA) is superior to usual care PPT after 3 months follow-up.

2. To assess whether an optimized, personalized PPT strategy is cost-effective compared to usual care PPT.

Study design

baseline (preoperative)

6 weeks, 3,6,9 and 12 months after surgery

Intervention

Treat-to-target: optimized, personalized strategy implying that after receiving PT in the postoperative phase in the hospital will either or not be referred to primary care PT based on a standardized assessment of their health status, personal-, external factors and achievement of functional milestones. Those needing PPT in primary care receive a standardized, time contingent program, focused on evidence-based components muscle strengthening and functional exercises, with regular evaluations regarding achievement of functional milestones. After reaching the milestones, PPT is ended and patients will receive a

tailored advice with home-based exercises in combination with referral to exercise activities in the community. The treat-to-target PPT is based on scientific evidence and expert opinion and is presented in the form of a transmural care pathway. The final protocol has been registered.
Usual care: Current PPT delivery.

Contacts

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Eligibility criteria

Inclusion criteria

Patients eligible for this trial are patients with clinical and radiological knee or hip OA who are scheduled for a primary TKA or THA, and willing to comply with the study protocol

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: TKA or THA for a diagnosis other than OA, uncontrolled cardiovascular disease or hypertension, history of neuromuscular disorder that affects lower extremity function, terminal illness, plans to have another joint replacement during study follow-up, not able to attend follow-up measurements, not able to attend the PPT in primary setting, serious psychiatric disorders, or insufficient command of the Dutch language, spoken and/or written.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2018
Enrollment:	624
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	05-04-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55756
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6933
NTR-old	NTR7129
CCMO	NL61763.078.17
OMON	NL-OMON55756

Study results

Summary results
https://pubmed.ncbi.nlm.nih.gov/32795283/