Integrated Care Program for Working-Age Knee Arthroplasty Patients

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24012

Source
NTR

Brief title
ACTIVE trial

Health condition

Knee osteoarthritis

Sponsors and support

Primary sponsor: Amsterdam UMC – location VUmc
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Quality of life, based on patient-reported health of physical functioning (PROMIS-PF).

Secondary outcome

- Return to work: the time between the surgery and the first day back at work, as well as the

time until full resumption of work activities (4 weeks without absence due to pain and complications resulting from KA surgery).
- Difficulty experienced at work before and after the knee replacement (Work, Osteoarthritis or joint-Replacement Questionnaire, WORQ)
- Functional knee status (Knee Injury and Osteoarthritis Outcome Score questionnaire, KOOS)
- Pain intensity (von Korff questionnaire visual analog scale, VAS)
- Fatigue (measured with the multidimensional fatigue inventory, MFI-20)
- Physical activity (measured with an activity tracker)
- Direct and indirect costs from a healthcare- and societal perspective
- Evaluating the implementation by performing a process evaluation in which reach, dose delivered, dose received, fidelity and patient attitudes will be analyzed according to the Linann and Steckler method

Study description

Background summary

Knee osteoarthritis is the most prevalent joint disease in the Netherlands with 571,600 patients in 2016 suffering from it. This burden is particularly high for those undergoing knee arthroplasty (KA). Due to the ageing population and the obesity epidemic, it is expected that there will be about 57,900 knee arthroplasties in the Netherlands in 2030 [1]. Half of these patients are expected to be in the working population. Currently, the post-surgery care as usual is not aimed at (work) participation. Three out of ten Dutch knee arthroplasty patients do not return to work (RTW) and only 50% of the patients accomplish RTW within three months [2]. This is accompanied by a significant impact on patients' quality of life as periods of being off work not only lead to a high risk of work disability, but also contribute to poor general and mental health of the patient and increasing health care and work productivity loss costs for society. Hence, improving perioperative care for KA patients, with a primary focus on societal participation, could contribute to more (cost) effective care.
In a previous systematic review, we investigated the effect of integrated care programs on perioperative care in orthopaedic surgery [3]. We searched for effective elements of interventions (e.g. integrated care programs) aiming to increase societal participation. Although limited evidence was available, our findings showed that integrated care programs consisting of one or a combination of: an active referral to a case-manager, a patient tailored rehabilitation program using goal setting and/or eHealth, showed small effects on work- and/or sports participation post-surgery. Moreover, previous studies by our research group showed positive effects on societal participation of integrated care programs with similar intervention elements among other patient populations such as low back pain patients [4, 5] and gynaecological or abdominal surgery patients [6-8].
In this transmural integrated care intervention, we will combine the identified effective elements (e.g. referral to a case-manager, rehabilitation with personalized goals and eHealth) aiming to increase (work) participation and thereby quality of life of KA patients. In a multi-center randomized controlled trial, we will examine whether this integrated care program will be (cost) effective as compared to the care as usual on resumption of (working) activities and

improving quality of life in KA patients.

1. Otten, R., P.M. van Roermund, and H.S. Picavet, [Trends in the number of knee and hip arthroplasties: considerably more knee and hip prostheses due to osteoarthritis in 2030]. Ned Tijdschr Geneeskd, 2010. 154: p. A1534.
2. Kievit, A.J., et al., Total knee arthroplasty and the unforeseen impact on return to work: a cross-sectional multicenter survey. J Arthroplasty, 2014. 29(6): p. 1163-8.
3. Coenen, P., et al., Integrated care programmes for sport and work participation, performance of physical activities and quality of life among orthopaedic surgery patients: a systematic review with meta-analysis. BMJ Open Sport & Exercise Medicine, 2020. 6.
4. Lambeek, L.C., et al., Effect of integrated care for sick listed patients with chronic low back pain: economic evaluation alongside a randomised controlled trial. BMJ, 2010. 341: p. c6414.
5. Lambeek, L.C., et al., Randomised controlled trial of integrated care to reduce disability from chronic low back pain in working and private life. BMJ, 2010. 340: p. c1035.
6. van der Meij, E., et al., Personalised perioperative care by e-health after intermediate-grade abdominal surgery: a multicentre, single-blind, randomised, placebo-controlled trial. Lancet, 2018. 392(10141): p. 51-59.
7. Bouwsma, E.V.A., et al., Effectiveness of an internet-based perioperative care programme to enhance postoperative recovery in gynaecological patients: cluster controlled trial with randomised stepped-wedge implementation. BMJ Open, 2018. 8(1): p. e017781.
8. Vonk Noordegraaf, A., et al., A personalised eHealth programme reduces the duration until return to work after gynaecological surgery: results of a multicentre randomised trial. International Journal of Obstetrics and Gynaecology, 2014. 121(9): p. 1127-1135.

Study objective

We hypothesize that our integrated care intervention, as compared to usual care and a placebo version of the m/eHealth intervention, will increase quality of life of KA patients by improving societal participation including work, indirectly reducing health care and work absenteeism costs.

Study design

Our primary outcome will be measured at baseline (i.e. 2 weeks before surgery), 4 and 6 weeks after surgery, and 2,3,4,5,6,9 and 12 months after surgery.

Our secondary outcomes will be measured at baseline (i.e. 2 weeks before surgery), 6 weeks after surgery and 3, 6, 9 and 12 months after surgery.

Intervention

On top of care as usual, patients in the intervention group will receive an intervention consisting of three components: 1) an active referral of the orthopaedic surgeon to a case-manager, 2) a rehabilitation program based on goal attainment scaling and 3) an m/eHealth intervention including an activity tracker and using the existing web-portal ikherstel.nl. The control group will receive usual care and a placebo version of the m/eHealth intervention.

Contacts

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Eligibility criteria

Inclusion criteria

- Scheduled for primary TKA or UKA surgery
- 18-67 years of age
- Paid job ≥ 8 hours a week
- Have the intention to get back to work after knee arthroplasty

Exclusion criteria

- Pregnancy
- Patients receiving a combination of several surgical procedures
- Patients having a knee replacement due to another cause than severe osteoarthritis
- Patients having a neuromuscular disease influencing the lower extremities
- Patients having another planned joint replacement during study period
- Patients having a serious psychiatric disorder
- Patients having severe comorbidity that could influence post-operative recovery
- Being unable to understand informed consent and patient information
- Having insufficient understanding of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	368
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Criteria are to be decided on

Ethics review

Positive opinion

Date:	14-04-2020
Application type:	First submission

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
NTR-new	NL8525
Other	METC VUmc : METC 2019.429

Study results

Summary results

We plan to publish the results of this study in peer-reviewed scientific journals.