

Become Active in Beating osteoarthritis (BABS): A randomized controlled trial on the effectiveness of a promotional campaign in improving the management of osteoarthritis and quality of care

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An information campaign was developed targeting early-stage KHOA patients and healthcare professionals (HCPs) to optimise timing of referral to secondary care.

Ethical review	Positive opinion
Status	Completed
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON21469

Source

Nationaal Trial Register

Brief title

BABS

Condition

- Joint disorders

Health condition

Knee and Hip OsteoArthritis, KHOA

Research involving

Human

Sponsors and support

Primary sponsor: Radboudumc, Sint Maartenskliniek

Source(s) of monetary or material Support: Radboudumc, Sint Maartenskliniek

Intervention

- Life style intervention

Explanation

Outcome measures

Primary outcome

The primary endpoint will be the difference in health care use (Treatment for KHOA restricted to primary care (yes / no)) as reported by patients (standardized questionnaire on health care use) over a period of 18 months between the intervention and the control group.

Secondary outcome

- Quality of care (OA Quality Indicators (Østerås et al., 2013) and Consumer Quality Index (Nivel, 2019));
- Beliefs about physical activity, physical therapy, and pain medication for OA (subscales of Treatment beliefs in knee and hip OA questionnaire)(Selten, Vriesevink, Schers, et al., 2017);
- Self-management behavior (Patient Activation Measure)(Hibbard, Mahoney, Stockard, & Tusler, 2005);
- Physical activity (International Physical Activity Questionnaire Short Form)(van Poppel, Chin A Paw, & Mechelen, 2004);
- Pain coping by resting (subscale of PCI questionnaire)(Kraaijmaat & Evers, 2003);
- General health status (EQ5D)(Rabin, Gudex, Selai, & Herdman, 2014);
- Pain (at rest and during activity, standardized NRS);
- Daily functioning (LEFS)(Binkley, Stratford, Lott, & Riddle, 1999);
- Cost-effectiveness of promotional campaign compared to usual care (Dutch costing manual)(Kanters, Bouwmans, van der Linden, Tan, & Hakkaart-van Roijen, 2017);
- Barriers and facilitators for network collaboration as perceived by health care providers (semi-structured interview).
- Referral rates to OA health care services.

Study description

Background summary

Despite recommendations, non-surgical treatment modalities in knee and/or hip osteoarthritis (KHOA) are underused.

Study objective

An information campaign was developed targeting early-stage KHOA patients and healthcare professionals (HCPs) to optimise timing of referral to secondary care.

Study design

The Behaviour Change Wheel (BCW) was used as a theoretical framework for the campaign design. After an inventory of the literature, a selection was made of factors influencing healthcare use. Effectiveness will be evaluated with a cluster RCT. The study aims to recruit 300 patients in 24 general practices, randomly allocated to intervention or usual care (ratio 1:1). General practitioners (GPs) and affiliated HCPs are invited to participate in the trial and recruit patients. Patients are eligible to participate if they are Dutch speaking, aged 50 to 75, registered with KHOA at the general practice, without joint replacement nor having considerable walking impairment. The main endpoint is the difference in rate of referral to hospital care as reported by patients over a period of 18 months. Secondary parameters include quality of care, beliefs about KHOA treatment modalities, physical activity (PA), self-management behavior, and referral rates to secondary care. Patients receive online questionnaires at baseline, 6, 12, and 18 months. Online questionnaires are sent to HCPs at baseline and after 12 months to assess (changes in) beliefs about KHOA treatment modalities.

Intervention

n.a.

Study burden and risks

All methods are carried out in accordance with relevant guidelines and regulations and ethical approval was waived (file number 2020-7246).

Contacts

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Eligibility criteria

Age

Adults (18-64 years)

Adults (18-64 years)

Elderly (65 years and older)

Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, general practices must meet the following criteria: - Located in Nijmegen - ≥ 12 registered patients eligible to participate - Willing to provide access to health information system - Having connections with physical therapist(s)

In order to be eligible to participate in this study, health care professionals must be one of the following: - A GP working in one of the included practices - A practice assistant or practice nurse working in one of the included practices - A physical therapist to whom patients are regularly referred in an included practice In order to be eligible to participate in this study, patients must meet all of the following criteria: - known to the GP for having knee and/or hip complaints - Age > 50 years - having a painful knee and/or hip for at least the past three months - having a painful knee and/or hip > 15 days of the past month - morning stiffness < 30 minutes (knee) and/or < 60 minutes (hip) - having an e-mail address

Exclusion criteria

Patients meeting any of the following criteria will be excluded from participation in this study: - Age > 75 years; - unable to communicate and complete online questionnaires in Dutch. - wheelchair bound or a walking distance of less than 100 meters - either scheduled or having one or more replacements of hip and/or knee

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	01-08-2022
Enrollment:	300
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description

Deidentified individual data that supports the results will be shared after publication upon reasonable request, provided the investigator who proposes to use the data has approval from an Institutional Review Board (IRB), Independent Ethics Committee (IEC), or Research Ethics Board (REB), as applicable, and executes a data use/sharing agreement.

Ethics review

Positive opinion	
Date:	21-01-2021
Application type:	First submission
Review commission:	METC Oost-Nederland

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	NL9140
Other	METC Radboudumc : 2020-7246

Study results