Physiotherapy WORKs: a randomized controlled trial on the (cost)effectiveness of a physiotherapist-led, multi-modal, personalized, work-oriented intervention in inflammatory arthritis.

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We hypothesize that a physical therapist-led, multi-modal, personalized, work-oriented intervention is more effective in optimizing work participation (primary outcome) and improving clinical outcomes (secondary outcomes) and is cost-effective,...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26117

Bron
NTR

Verkorte titel
PT WORKs

Aandoening

Rheumatoid Arthritis and Axial Spondyloarthritis

Ondersteuning

Primaire sponsor: Leiden University Medical Centre, LUMC
Overige ondersteuning: Dutch Arthritis Society (ReumaNederland) & the Scientific College of Physical Therapy (WCF) of the Royal Dutch Society for Physical Therapy (KNGF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure will be work ability, assessed by the Work Ability Index – Single Item Scale.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Although work participation is considered a key element of quality of life, work is generally underexposed in current treatment of people with Rheumatoid Arthritis (RA) and axial SpondyloArthritis (axSpA). This is an undesirable situation, as many patients are of working age and work participation is considerably reduced as compared to their healthy peers, despite breakthroughs in the pharmacological treatment. Physical therapy is a treatment modality that is used by a substantial proportion of patients and could potentially play an important role in optimizing work participation in people with RA/axSpA, when focusing on and integrating work-oriented treatment modalities within their intervention. However, the effects of such a physical therapist-led, integrated intervention are not known yet.

Objective:
The present project aims to evaluate the effectiveness and cost-effectiveness of a physical therapist-led, multi-modal, personalized, work-oriented intervention in optimizing work ability (primary outcome) and improving clinical outcomes (secondary outcomes), compared to usual care, in people with a paid job and RA/axSpA after 12 months of follow-up.

Study design:
A randomized, controlled trial (RCT) comparing a work-oriented intervention from a physical therapist (PT) (experimental group) with usual care (control group) (1:1). During the study of in total 12 months, the experimental and control groups will complete questionnaires on work-related, clinical and economic outcomes at baseline and follow-up measurements after 3, 6 and 12 months.

Study population:
One hundred forty (140) people with RA/axSpA will be randomized to the experimental or control group. People are eligible if they are diagnosed with RA/axSpA by a rheumatologist, have a paid job of at least 12 hours/week, have a self-perceived moderate to poor work ability and/or history of sick leave in the past 6 months because of RA/axSpA, are willing to use (and if needed pay for) physical therapy if allocated to the experimental group, can communicate in Dutch, and provide informed consent.

Intervention and control conditions:
The experimental intervention, which will be developed with strong involvement of end-users (e.g., patients), consists of the following modalities:
1. Personalized exercise therapy targeting aerobic capacity, muscle strength, joint mobility and fatigue, and specifically focusing on work-related activities that are limited due to the disease;
2. Personalized education and self-management support focusing on RA/axSpA and adequate self-management strategies (empowerment), with specific focus on work;
• Additionally (if opted by the participant), an online self-management training, to further optimize their self-management and empowerment skills (at work);
3. Personalized work-roadmap to guide the participant in when and how to receive the necessary support of which professional within the occupational domain;
• Additionally (if opted by the participant), an workplace intervention targeting essential adaptation at work and/or a workplace dialogue between employee and supervisor.

The content and frequency of supervised face-to-face contacts are personalized to the person's needs and preferences, during a shared-decision making process with participant and PT. The number of sessions will therefore vary, ranging between 6 to 12 sessions in the 3-month treatment period, supplemented by 4 to 9 'booster' sessions (online, phone or face to face) in the following 9-month follow-up period. All participants receive a personalized (endorsement) letter from the rheumatologist to underline their support for the intervention. This intervention will be provided by a PT specialized in rheumatic diseases and located nearby the participant. Participating PTs will be specifically trained to adequately apply the described intervention.

The control group will receive usual care, coordinated by the patient's rheumatologist, similar as they did before study inclusion.

Main study parameters/endpoints:
The primary outcome measure will be work ability, assessed by the Work Ability Index – Single Item Scale. Secondary outcome measures include work presenteeism and absenteeism, job satisfaction, and self-efficacy (all work-related outcomes), pain, fatigue, physical function, specific limitations at work, physical activity, anxiety, and depression (all clinical outcomes), and quality-adjusted life years, health care/informal care utilization, and costs (economic measures). In addition, a process evaluation will be performed to identify barriers and facilitators of implementation of our intervention.

All outcomes will be measured by questionnaires, obtained at baseline, 3 and 6 months (secondary time points) and 12 months follow-up (primary time point). For the process evaluation, individual, semi-structured interviews will be arranged with a random selection of participants, PTs and rheumatologists after 12 months follow-up.
Additionally, sociodemographic (age, gender, weight, height, marital status, education level, current work adaptations and recent history (≤1 year) of work-oriented treatment or guidance) and disease characteristics (symptom duration, comorbidities) will be collected by questionnaire (patient), whereas disease characteristics (diagnosis, year of diagnosis, disease activity, current medication) will be retrieved from the patient's rheumatologist.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Participants from the control arm will be treated as usual by their rheumatologist, whereas participants from the experimental arm will receive a multi-modal, personalized, work-oriented intervention by a trained PT, with no extra risks as compared to the regular delivery of primary care exercise therapy. The burden of the participants will be minimized to the time necessary for completing the questionnaires (1.5 – 2 hours in total), the visits with the PT (max. 21 visits of half an hour each). Furthermore, for participants with a sufficient supplementary health insurance, the costs of the treatments from the PT will be compensated. Patients without or with an insufficient supplementary health insurance shall pay for the treatments themselves (approximately 30 euros per treatment).

Doel van het onderzoek

We hypothesize that a physical therapist-led, multi-modal, personalized, work-oriented intervention is more effective in optimizing work participation (primary outcome) and improving clinical outcomes (secondary outcomes) and is cost-effective, compared to usual care, in people with a paid job and RA/axSpA after 12 months of follow-up.

Onderzoeksopzet

Assessments are done at baseline, after 3 and 6 months and at the end of the study (12 months).

Onderzoeksproduct en/of interventie

A physiotherapist-led, multi-modal, personalized, work-oriented intervention (intervention) or usual care (control)

Contactpersonen

Publiek

LUMC, Leiden
Thea Vliet Vlieland

071-5263616

Wetenschappelijk

LUMC, Leiden
Thea Vliet Vlieland

071-5263616

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A patient should meet all of the following criteria to be eligible, tested by the rheumatologist (during regular visit) and/or researcher (by phone):
• Diagnosed with RA or axSpA by a rheumatologist.
• Having (self-)payed employment for ≥12 hours/week.
• Moderate to poor work ability (Work Ability Index-Single Item Scale (WAS) ≤7/10 (13)) related to RA/axSpA and/or self-reported history of sick-leave in the past 6 months related to RA/axSpA.
• Self-reported limitations in physical functioning.
• Willingness to consult a participating PT located nearby.
• Willingness to pay for physical therapy (out-of-pocket or by supplementary health insurance).
• Command of Dutch language.
• Providing informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A patient will be excluded if any of the following criteria are met, tested by the rheumatologist (during regular visit) and/or researcher (by phone):
• Pension-eligible age within 2 years.
• Comorbid disease or other (e.g. financial) situation influencing work ability.
• Pregnancy.
• In labour dispute.
• Current sick leave period of more than 6 months.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-11-2020
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51222
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9343

Register	ID
CCMO	NL75919.058.20
OMON	NL-OMON51222

Resultaten

Samenvatting resultaten
N/A