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

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

Summary

ID

NL-OMON51222

Source
ToetsingOnline

Brief title
Physiotherapy WORKs

Condition

- Joint disorders

Synonym
Ankylosing Spondylitis, Axial spondyloarthritis, m. Bechterew, Rheumatoid artritis

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ReumaNederland en het wetenschappelijk College Fysiotherapie (WCF) van het Koninklijk Nederlands Genootschap voor Fysiotherapie (KNGF).

Intervention

Keyword: Axial spondyloarthritis, Physiotherapy, Rheumatoid arthritis, Work ability

Outcome measures

Primary outcome

The primary outcome measure will be work ability, assessed by the Work Ability Index - Single Item Scale at 12 months follow-up.

Secondary outcome

Secondary outcome measures include: work presenteeism and absenteeism, job satisfaction, and self-efficacy (all work-related outcomes), physical function, pain, fatigue, anxiety, and depression (all clinical outcomes),
For the economic analysis, utilities, health care/informal care utilization, and costs will be measured. In addition, in the intervention group only, a process evaluation will be performed to identify barriers and facilitators of implementation of the intervention. All outcomes will be measured by questionnaires, obtained at baseline, 3 and 6 months (secondary time points) and 12 months follow-up (primary endpoint).
For the process evaluation, individual, semi structured interviews will be arranged with a selection of participants,
PTs and rheumatologists after 12 months follow-up. Apart from the primary,

secondary and economic outcome measures, personal and disease characteristics will be recorded. The personal characteristics consists of age, gender, weight, height, marital status, education level, current work adaptations and history (<=1 year) of work-oriented treatment or guidance. The disease parameters in this study include disease duration, current medication and comorbidities.

Study description

Background summary

Although work ability is considered a key element of quality of life, work is generally underexposed in current treatment in people with Rheumatoid Arthritis (RA) and axial SpondyloArthritis (axSpA). This is an undesirable situation, as work ability is reduced compared to the general populations, despite breakthroughs in the pharmacological treatment. Physical therapy could potentially play an important role in optimizing work ability in RA/axSpA, when focusing on and integrating work-oriented treatment modalities within their intervention. However, the effects of such an integrated physiotherapy intervention are not known yet.

Study objective

The present project aims to evaluate the effectiveness of a multi-modal, personalized, work-oriented physiotherapy intervention in optimizing work ability (primary outcome) and improving clinical outcomes (secondary outcomes), compared to usual care, in employees with RA/axSpA after 12 months of follow-up. Furthermore, this study aims to evaluate the cost-effectiveness of a multi-modal, personalized, work-oriented physiotherapy intervention in optimizing economic measures, compared to usual care, in employees with RA/axSpA after 12 months of follow-up.in employees with RA/axSpA after 12 months of follow-up.

Study design

A randomized, controlled trial (RCT) comparing a work-oriented physiotherapy intervention (experimental group) with usual care (control group) (1:1). During the trial of in total 12 months, the experimental and control group will

complete questionnaires on work-related, clinical and economic outcomes at baseline and follow-up measurements after 3, 6 and 12 months.

Intervention

Intervention and control conditions: The experimental intervention, in addition to usual care coordinated by the
patient*s rheumatologist, consists of the following modalities:
1. Personalized exercise therapy targeting aerobic capacity, muscle strength, stiffness and fatigue, and specifically focusing
on work-related activities that are limited due to the disease or relevant for the type of work;
2. Personalized education and self-management support focusing on RA/axSpA and adequate self-management strategies
(empowerment), with specific focus on work;
a. Optionally, an additional 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;
a. Optionally, an workplace intervention targeting essential adaptation at work and/or a workplace dialogue between employee and supervisor.
The control group will receive usual care, coordinated by the patient*s rheumatologist.

Study burden and risks

Patients randomized to the control arm will be treated as usual by their rheumatologist, whereas patients from the experimental arm will be additionally treated by a trained, specialized physical therapist, of which intervention clinical effects and minimal risks are expected. The burden of the patients will be minimized to the time necessary for completing the questionnaires and visiting the physiotherapist . All participants will complete 4 questionnaires during the study (20-30 minutes each) and the participants in the experimental arm will visit the physiotherapist for 10-21 times (30 minutes each).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

A patient should meet all of the following criteria to be eligible:
1. Clinical diagnosis of RA or axSpA, confirmed by a rheumatologist.
2. Having paid employment for >=12 hours/week (including self-employment).
3.Moderate to poor work ability (Work Ability Index-Single Item Scale (WAS) <=7/10), related to RA/axSpA and/or
self-reported history of sick-leave in the past 6 months related to RA/axSpA.
4. Self-reported limitations in physical functioning.

Exclusion criteria

Patients will be excluded if any of the following criteria are met:
1. Pensionable age within 2 years.
2. Comorbid disease or other (e.g. financial) situation influencing work ability.
3. Pregnancy.
4. Having a labor dispute.
5. Current sick leave period of more than 6 months.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-09-2021
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-04-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26117
Source: NTR
Title:

In other registers

Register	ID
Other	NL trial register, ID:NL9343
CCMO	NL75919.058.20