Longstanding Exercise Therapy in Patients with axial Spondyloarthritis

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

Summary

ID

NL-OMON52399

Source
ToetsingOnline

Brief title
L-EXSPA

Condition

- Joint disorders

Synonym
Axial Spondyloatritis, Bechterews' disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW,Mogelijk wordt maximaal 10% van het onderzoek gefiniancierd door ReumaNederland en het KNGF

Intervention

Keyword: Axial Spondyloartritis, Exercise therapy, Longterm, Physical therapy

Outcome measures

Primary outcome

The primary outcome measure of effectiveness is the individual level of functioning (activities and participation), as measured with the Patient-Specific Complaints instrument (PSC) at 52 weeks.

Secondary outcome

Secondary outcome measures include the 10-item Patient Reported Outcomes Measurement Information System (PROMIS) and the BASFI (Bath Ankylosing Spondylitis Functional Index) for Physical Function and the and 6 minute walk test for functional ability; the SF-36 for health related Quality of life; and the EuroQol (EQ-5D-5L) for health valuation. In addition, in order to address the topic of cost-effectiveness, comprehensive measurements of costs and an economic analysis will be conducted as well.

Apart from the primary and secondary outcome measures, sociodemographic and disease characteristics, the presence of comorbidity will be recorded by means of the comorbidity questionnaire developed by the Dutch Central Bureau of Statistics.

In addition, an anchor question regarding the perceived effectiveness will be added in all cases (intervention and control) where longstanding exercise therapy was used (*has the exercise therapy changed your daily functioning*),

as well as a short questionnaire on patient satisfaction with treatment

Furthermore, we will retrospectively evaluate the content of provided care and the compliance of the patients in the intervention group by asking the patients to fill out a registration form on the frequency, duration, and content of treatment. At 52 weeks, the perception of any side effects of exercise therapy will be recorded. If treatment is discontinued, the reasons will be recorded.

Study description

Background summary

Axial Spondyloarthritis (axSpA) is a collective term for a group of chronic inflammatory diseases, mainly characterized by arthritis of the sacroiliac joints and spine, with back pain and stiffness as leading symptoms. In addition, arthritis of the peripheral joints may occur, and the condition may be associated with a variety of extraarticular manifestations involving the eye, bowel, lungs and heart. It affects about 0.1% of the population, with men being more often affected than women. During the course of their disease, some patients use short, intermittent physical therapy treatment (active exercise therapy) whereas others use longstanding weekly group exercise therapy, in order to prevent or diminish limitations in activities or participation. However, there is a substantial subgroup of patients with axSpA (<5 %) with persistent high disease activity, ossification of the spine, peripheral joint damage and/or complications of the disease or its treatment or comorbidity, resulting in complex limitations in activities and participation. Due to the individual nature of the problems and resulting disability, in this group the exercise therapy treatment is currently individual, highly personalized and usually longstanding (i.e. longer than 12 weeks and more than 20 sessions per year). Various systematic literature reviews have concluded that overall exercise in patients with axSpA is effective with respect to pain, aerobic capacity, spinal mobility, muscle strength, pulmonary function, physical functioning and quality of life (Regel 2017). Research on effectiveness of longstanding exercise therapy in the abovementioned patient group with complex limitations in activities and participation is however absent.

Study objective

This study aims to underpin the delivery of longstanding exercise therapy in the subgroup of patients with axSpA and complex disability.

There are 2 research questions to be addressed
1. Is longstanding, optimized active exercise therapy more effective with respect to functional ability than usual care in patients with axSpA with severe functional disability over a period of 52 weeks?
2. Which option (longstanding, optimized active exercise therapy or usual care) is more cost-effective?
3. What is the long-term course of functional ability, health status and health care consumption of patients using longstanding, optimized active exercise therapy?

Study design

Randomised, controlled trial comparing longstanding, active exercise therapy with usual care. After the experimental period of 52 weeks at which the primary end-point is assessed, the intervention will be continued in the intervention group and the effects will be monitored at follow-up measurements at 104, 156 and 208 weeks/end of study (variable follow-up duration, depending on the moment of inclusion). At 52 weeks, the intervention will also be offered to the patients randomized to the usual care group.

Intervention

The intervention concerns longstanding, intensive active exercise therapy (52 weeks), aimed at the improvement of specific individual limitations in daily activities and participation. It consists of a standardized program comprising active modalities (functional exercises, aerobic exercises, muscle strengthening and flexibility/joint range of motion exercises), with the type of exercises, their intensity, frequency, duration, site of delivery (practice or at home) and progression being tailored to the individual patients* functional disability and ensuing needs and goals. The control condition consists of care as usual, left to the discretion of the treating physicians and the patients.

Study burden and risks

The intervention concerns exercise therapy delivered by trained primary care physical therapists according to a standardized protocol, with no extra risks as compared to the regular delivery of primary care exercise l therapy. Regarding the burden, the maximum number of site visits is 4 (1 screening and 3 evaluation visits at baseline, 52 weeks (primary endpoint), and 104 weeks). The assessments mainly consist of the completion of sets of questionnaires at home (max. 1 hour at 7 timepoints: 0, 12, 26, 52, 104, 156 and 208 weeks) and maximum 4 site visits with one performance test (6-minute walk test) and the answering of a number of questions during the evaluation visits (max. total visit duration * hour).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, subjects must meet all of the following criteria:
a. they are diagnosed with axSpA by a rheumatologist; b. have severe functional deterioration despite medical treatment and their functional decline can or could not be stopped or improved by a short, intermittent physical therapy intervention; c. they need longstanding active physical therapy because of severe limitations in daily activities caused by axSpA such as limited walking distance, problems with making transfers and/or limitations in self-care; d. their limitations in daily activities are related to pain, stiffness, muscle function decline, limited cardiopulmonary condition and or limited motor control (danger of falling), caused by high disease activity despite optimal medical treatment and/or severe joint damage and/or deformities and/or sever

comorbidity (e.g. pulmonary or cardiovascular disease, depression, morbid obesity.

Exclusion criteria

Potential subjects who meet any of the following criteria will be excluded from participation in this study: Patients who were individually treated by a physical therapist and/or a multidisciplinary team in the setting of a rehabilitation center or rheumatology clinic or center in the last 3 months; patients in need of immediate admission to a hospital, rehabilitation center or rheumatology clinic or other forms of intensive, multidisciplinary care. Patients who are unable to give informed consent.

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:	Completed
Start date (anticipated):	11-07-2020
Enrollment:	215
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-12-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	29-09-2022
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: 22183
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70093.058.19