Telemonitoring with SpA-Net

Published: 23-07-2019
Last updated: 15-05-2024

We hypothesize that telemonitoring through SpA-Net, in combination with patient-initiated care, will lead to less outpatient visits, without compromising quality of care and health outcomes. Furthermore, we expect that telemonitoring through SpA-Net...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON25783

Source
NTR

Brief title
TeleSpA

Condition

- Autoimmune disorders

Synonym
Axial and/or peripheral spondyloarthritis, psoriatic arthritis, ankylosing spondylitis

Health condition

Spondyloarthritis

Research involving
Human

Sponsors and support

Primary sponsor: ReumaNederland
Source(s) of monetary or material Support: ReumaNederland (project no. 19-2-203)

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

At least 25% reduction in the number of scheduled and unscheduled outpatient visits to the rheumatology department in the telemonitoring group compared to the standard care group within a 1-year follow-up period.

Secondary outcome

• Non-inferiority of telemonitoring compared to standard care with respect to quality of care and health outcomes. • Non-inferiority with respect to experience with SpA-Net and general rheumatological care. • Association between patient-reported self-management skills and successful application of telemonitoring • Experience with telemonitoring through SpA-Net among care providers • Difference between the populations with regard to healthcare cost per quality adjusted life year (QALY) gained after 1 year • Difference between the populations with regard to societal cost per QALY gained after 1 year

Study description

Background summary

Spondyloarthritis (SpA) is a chronic inflammatory rheumatic disease with a heterogeneous presentation. Regular and personalised monitoring of disease activity, physical functioning, medication use and side effects is essential to improve and maintain patients' health-related quality of life (HRQoL) in SpA. Furthermore, care provided should be patient-centred, involving patients in treatment decisions and incorporating personal preferences, needs and values. Increasingly, transparency on outcomes of care delivered and efficiency of care are demanded. In daily practice, capacity issues, time constraints, lack of optimal tools for monitoring and providing transparency may hinder these important aspects of quality of care. Traditionally outpatient visits are pre-booked every 3-6 months, but these are frequently unnecessary in stable patients with low disease activity. Remote monitoring through a web application (telemonitoring) could be a solution for these patients. Telemonitoring has been shown to be possible, effective and safe in several chronic diseases, and clearly reduced health care utilization. To date, this has never been tested in SpA. In 2016, a web-based eHealth system for patients with SpA in the Netherlands ('SpA-Net') was developed as a personal monitoring system. SpA-Net includes clinical information on medication use, laboratory tests, several patient reported outcomes and a personal

treatment plan, providing a comprehensive view of the patient for the rheumatologists. An excerpt of this is available to patients. This serves as the basis for each outpatient consultation. Since 2016, SpA-Net has been increasingly used in daily practice. Focus interviews among patients and care providers showed high satisfaction and acceptance of SpA-Net. It is, however, unknown whether SpA-Net can also be used as a telemonitoring system, thereby replacing face-to-face consultations, and leading to a reduction in health care utilisation. In this study, remote care (telemonitoring) provided through SpA-Net, in combination with patient-initiated care, is compared with standard care, aiming at more efficient care. Concomitantly, a trial-based cost-utility analysis will be performed.

Study objective

We hypothesize that telemonitoring through SpA-Net, in combination with patient-initiated care, will lead to less outpatient visits, without compromising quality of care and health outcomes. Furthermore, we expect that telemonitoring through SpA-Net could reduce healthcare expenditures and/or societal costs.

Study design

Inclusion period December 2020 – July 2021 Follow up period December 2020 – July 2022 Data analysis, manuscript preparation July 2022 – January 2023 Cost-effectiveness analysis January 2023 – July 2023

Intervention

Combined asynchronous telemonitoring (through SpA-Net) and patient-initiated care

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 for participation in this study, subjects must meet all of the following criteria: • Adult patient (18+ years) • Diagnosis of SpA according to treating physician • At least 2 years of disease duration, to be familiar with signs, symptoms, and medication • Stable disease, defined as being in a patient acceptable symptom state according to patient AND treating physician (36) AND no treatment change expected in the next few months • Access to a computer, tablet and/or smartphone for the entire duration of the study

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: • Insufficient mastery of Dutch language • Incompetent to act for oneself • Limited life expectancy • Ongoing (or planned) pregnancy during the study period • Patients participating in other research project(s)

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	02-12-2020
Enrollment:	200
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	11-03-2020
Application type:	First submission
Review commission:	METC Academisch Ziekenhuis Maastricht / Universiteit Maastricht Postbus 5800 6202 AZ Maastricht 043 387 6009 secretariaat.metc@mumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 54628
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7883
CCMO	NL71041.068.19
ClinicalTrials.gov	NCT04673825

Register	ID
OMON	NL-OMON54628

Study results

Summary results
N/A