Development of Artificial inTelligence based digitaL monitoring of rheumAtoid arthritis patientS (ATLAS)

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Primary Objective: To evaluate the *Triple Aim* performance of Care Pathway Technology for RA: - Evaluate and compare predefined RA health outcomes; Disease activity measured by DAS 28 joint score at baseline, month 12; RAPID3, HAQ-DI at baseline...

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

Summary

ID

NL-OMON54394

Source
ToetsingOnline

Brief title
ATLAS

Condition

- Autoimmune disorders

Synonym
Rheuma, rheumatoid Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reumatology Research Center Northern Netherlands-MCL
Source(s) of monetary or material Support: de onderzoeksgroep (RRCNN) faciliteert het onderzoek

Intervention

Keyword: artificial intelligence, digital monitoring, eHealth, Rheumatoid Arthritis

Outcome measures

Primary outcome

Primary endpoint: proportion of patients in clinical disease remission: DAS28 joint score < 2.6 at clinic visits at baseline and month 12; RAPID3 score <3, HAQ-DI < 0.5 at baseline, months 12.

Secondary outcome

- Evaluate differences in use of clinical services by comparing the number of
- Clinic visits,
- Hospitalizations,
- Laboratory procedures,
- Medication alteration (both intensification and tapering) and
- Intra-articular joint injections
- Patient & Provider Experiences: proportion of patients and providers who would recommend this platform to others (Net Promotor score: > 0: good, > 30: great, > 50: excellent); plus the System Usability Scale (SUS).
- Proportion of patients with >= 20% increase in Quality of Life (VAS) at 12 months compared to baseline. (Visual Analogue Scale (VAS): Quality of Life >= 2 points increase on a scale of 1-100)
- Proportion of patients with >= 20% increase in Productivity (VAS) at 12 months compared to baseline. (Visual Analogue Scale (VAS): Productivity >= 2 points increase on a scale of 1-100)

Study description

Background summary

Regular clinical monitoring of disease activity is a vital part of current treatment strategies for Rheumatoid Arthritis (RA), such as Treat to Target (T2T) and Tight Control. The management of RA by Care Pathway Technology can, by providing personalized medicine, optimize treatment outcome, improve patient satisfaction and potentially lessen the burden on RA clinical care by reducing the number of clinical visits.

Study objective

Primary Objective: To evaluate the *Triple Aim* performance of Care Pathway Technology for RA:
- Evaluate and compare predefined RA health outcomes; Disease activity measured by DAS 28 joint score at baseline, month 12; RAPID3, HAQ-DI at baseline and month 12, DEARhealth Quality of life questionnaire and Productivity and Activity (WPAI) indices at baseline, month 4, 8, 12.
- Evaluate the user experience of patients, their caregivers and provider teams.
- Evaluate differences in use of clinical services (number of clinic visits, hospitalizations, lab procedures, medication alterations and joint injections)

Study design

: A prospective randomized-controlled study in Rheumatoid Arthritis patients, who will be included during their regular outpatient visits to the rheumatology department of the Medical Center Leeuwarden (MCL).

Study burden and risks

There will be no additional risk for patients: all treatment is conform regular care. Use of the DEARhealth app should in the future provide a time saving alternative to clinical RA care.

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

- Age >= 18 years
- A diagnosis of RA existing for at least five years and meeting the 2010 American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) criteria. (17)
- Willing and able to independently provide written informed consent
- Owns and is able to use a mobile device (Android or iOS)

Exclusion criteria

- Insufficient knowledge of the Dutch language to engage with the eHealth tool

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-02-2023
Enrollment:	164
Type:	Actual

Medical products/devices used

Generic name:	DEARhealth app
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-12-2021
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	06-03-2023
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	10-09-2024
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
CCMO	NL79073.099.21