Digital Cohort of Rheumatic Disease

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21144

Source
NTR

Brief title
DICODE

Health condition

Ankylosing Spondylithis, Psoriatic Arthritis, Rheumatoid Arthritis

Sponsors and support

Primary sponsor: Pfizer, Sanofi-aventis, Novartis, Eli Lilly
Source(s) of monetary or material Support: Pfizer, Sanofi-aventis, Novartis, Eli Lilly

Intervention

Outcome measures

Primary outcome

Adherence at 3 months

Secondary outcome

Adherence at 6 months, patient empowerment as measured by the Effective Consumer scale (EC-17), patient-physician interaction as measured by the Perceived Efficacy in Patient-Physician Interaction Questionnaire (PEPPI-5)

Study description

Background summary

The DICODE is a prospective observational cohort study in patients with inflammatory rheumatic diseases. The objective is identifying patient demographics influencing adherence to the MijnReuma Reade smartphone application. The app is developed as a tool for self-monitoring and consists of a weekly questionnaire to measure the disease activity. Primary outcome is adherence at 3 months, secondary outcomes are adherence at 6 months, patient empowerment and patient satisfaction. Patient recruitment will start in March 2020 at Reade Centre for Rheumatology located in Amsterdam, Netherlands. Estimated inclusion time will be 18 months with a target of 186 patients. Eligible patients are diagnosed with Ankylosing Spondylithis, Psoriatic Arthritis or Rheumatoid Arthritis, speak and write Dutch and own a smartphone with IOs or Android. Exclusion criteria is participating in other interventional study. The study is on December 18th 2019 approved by the METc of the VUmc.

Study objective

Patients demographics (age, sex, health literacy etc.) influence adherence rates of mobile self-monitoring

Study design

baseline, 3 months and 6 months

Intervention

At inclusion patients are asked to use the MijnReuma Reade smartphone application. The app provides the possibility to complete a weekly questionnaire. This questionnaire has been derived from the MDHAQ/RAPID3© questionnaire. It contains the RAPID3 and additional questions regarding fatigue, sleep, morning stiffness, anxiety, stress, social participation and self-reported flare. The app was designed to function on both the iOS and Android and met all guidelines for submission to the Dutch Apple App and Google Play stores. The app will send users a notification every week, prompting them to login using their username and password or touch-ID using fingerprint identification to answer questions related to inflammatory arthritis. If users have not answered their weekly questions in 24 hours, they will receive another notifications at 24 hours and 1 week to remind them to complete the questions. The app is integrated within the Reade Electronical Medical Record. Results of the questionnaire are therefore viewable by the rheumatologist. All patients are able to follow their disease activity over time in the dashboard function of the app.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with Ankylosing Spondylithis/Psoriatic Arthritis/ Rheumatoid Arthritis 2. Able to speak and write Dutch 3. Owning a Andriod or IOs smartphone

Exclusion criteria

Taking part in an other digital self-monitoring trial

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-02-2020
Enrollment:	186
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
n/a

Ethics review

Positive opinion Date:	28-02-2020
Application type:	First submission

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
NTR-new	NL8414
Other	METC VUmc : 2019.641

Study results