Dynamic disease activity monitoring in Psoriatic Arthritis by novel personalized digital biomarkers*

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To early identify changes in disease activity by changes in digital biomarkers. Smartphone screen time, keystroke dynamics, accelerometer & gyroscope data, emoticon use and incidental video recordings will be evaluated on occurring patterns in...

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53819

Source
ToetsingOnline

Brief title
PsAI

Condition

- Joint disorders

Synonym
arthritis psoriatica

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: farmaceut,Pfizer

Intervention

Keyword: Arthrits Psoriatica, Development, Digital biomarker, Disease Activity

Outcome measures

Primary outcome

Digital Measures

Raw smartphone data shall be translated into behavioural vectors for physical activity, sleep and mood. Like previously done for Parkinson in i.prognosis a feature extraction and classification pipeline will be set up to classify subjects with high and low disease activity.

- Keypad time-related data and metadata
- Accelerometer and gyroscope sensor data
- Video recordings of joint movements
- Screen time

Clinical Assessment:

Clinical evaluation of joints, tendons and skin, inflammatory bloodmarkers (usual care), VAS global and HAQ leading to the calculation of:

- Minimal disease Activity (MDA)
- Psoriatic Arthritis Disease Activity Score (PASDAS)
- Disease Activity Psoriatic Arthritis (DAPSA)

Daily Questions

Likert scale assessment within the smartphone app. will provide us with information to assess the disease symptoms over time outside the window of the

clinical assessment of disease activity.

- Pain. When in pain, follow-up question: *did you use painkillers or NSAIDs?*

- Stiffness

- Tiredness

Amendments: none

Secondary outcome

none

Study description

Background summary

The level of disease activity in Psoriatic Arthritis determines the actions the rheumatologist takes to optimise treatment outcome among patients with this disease. Currently disease activity is measured by a combination of clinical measures and patients selfreported symptoms and functional ability. This requires the patients to visit the outpatient clinic on regular intervals., which during Covid-19 pandemic was not always possible. The use of questionnaires to collect Patients Reported Outcome (PRO's) is a feasible option, the questionnaires fatigue is however a known limiting factor from a long term perspective. Currently there is no valid alternative for remote unobtrusive disease activity monitoring. The wide spread use of smart devices by the general population, such as smartphone or smartwatch, provides opportunities to develop and study possibilities for Unobtrusive Remote Disease activity monitoring (URD) using behavioural data captured by the sensors embedded within the smartphones/smartwatches. We hypothesize that high level of disease activity in Psoriatic Arthritis (PsA) will lead to lower degree of physical activity as registered by patients' smartphone as compared to a low disease activity state. Additionally, digital biomarkers are likely to provide information on other disease characteristics such as tiredness and sleep problems. Adding these will enhance discriminative ability of our approach. We also hypothesize that the information acquired by digital biomarkers will be comparable to the information received through usage of clinical measures and PROs. Last but not least, we hypothesize that patient will see the use of smartphone data as safe privacy-wise and a fair deal in return for lower amount

of follow-up appointments at the out-patient clinic.

Study objective

To early identify changes in disease activity by changes in digital biomarkers. Smartphone screen time, keystroke dynamics, accelerometer & gyroscope data, emoticon use and incidental video recordings will be evaluated on occurring patterns in relation to clinical disease activity. Parameters will be assessed in psoriatic arthritis patients and in healthy controls as well. Our working hypotheses are twofold: 1. Increase in disease activity is preceded by changes in the above parameters. 2. It is not the absolute value of these parameters but rather changes in the pattern belonging to an individual that will identify changes in disease activity. Amendment Index tests (intervention) > measuring hand function using keystroke dynamics using predefined texts, > evaluating range of motion using skeletal hand tracking on video using pre-specified hand gestures > evaluating hand function using a touch-based mobile game reference test /Comparator: clinical examination by the rheumatologist (swollen joints and hand function)

Study design

An exploratory prospective cohort will be set up.

Prototype Development
The technical prototype development is underway using the previous work by the AUTH* and FMH# in using artificial intelligence (AI)-based digital biomarkers in the monitoring of disease activity and progression in Parkinson*s Disease (www.i-prognosis.eu). A smartphone app is developed to capture accelerometer and gyroscope data, screen time and key stroke dynamics. In a separate application patients will be able to assess their joint flexibility capturing this on video following a prespecified protocol.
Short *test and adjust* cycles will assess the practicalities of the app-prototype. This will provide a feasible solution to be tested among a larger sample of patients.

Prototype Testing
The digital biomarker(s) will be tested in daily clinical practice over a 3-month period. Clinical disease activity will be captured by the treating physicians as part of usual care at start and finish of the 3-month study interval. As patients are already participating in DEPAR (DEPAR MEC-2012-549) we aim to use DEPAR data for the purpose of this study. Digital disease activity will be measured by a smartphone app as described. This will be accompanied by questions on pain, fatigue, and stiffness (Likert Scale) that will be generated in a random sequence of 1 to 3 times over a 24-hour period, taking a few seconds to be answered. The latter will provide us with information to assess the disease symptoms over time outside the window of the

clinical assessment of disease activity.

Amendment 1: Next to the unobtrusive data capture during daily living the patients will be asked to perform a few extra tests at the visit in the hospital
Amendment 2: patients with PsA will be asked to participate

Study burden and risks

Risks There are no health risks associated with participation in this study. Patients will receive usual care. Burden Patients will be requested to install an app on their phone that will collect the metadata of the keystrokes, emoticon use, screen time and the accelerometer & gyroscope data of the phone. In the app they have full control of the data they want to share. This means that they could stop data sharing at all times without asking our permission. To monitor the levels of pain, fatigue and stiffness during the day the app will also send requests to complete questions on these symptoms. This will be very short questions that are answerable within a few seconds. These questions will appear between 1 to 3 times a day. Clinical disease activity will be monitored each 3 months as described. For most patients this will be a regular visit to the physician. If they only visit their physician at 6 months or at longer intervals, they are asked to have an additional 3 month appoint for clinical disease activity assessment As participants already participate in DEPAR we will use their DEPAR self-reported measures. If they are diagnosed less than 12 month ago no additional work is required. If they participate longer than 12 months they may receive additional questions if we could not combine the current data collection with their regular DE PAR visit. This will take about 10 minutes extra per visit. Amendment 1: patients participating in the hand study will perform the tests on the study phone during the hospital visit. This will take about 20-30 minutes. Amendment 2: Also none_DEPAR patients like to participate in the study. They follow normal study procedures, being clinically examined twice and complete questionnaires twice.

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

active disease defined as not in MDA - 45 patients
inactive disease defined as in MDA - 45 patients
healthy controls - 30 subjects

Exclusion criteria

other disease that linfluence movement such CVA, prostethic limb etc in patients, and sport trauma in healthy controls

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2023
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	07-12-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-07-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-12-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL81628.078.22