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Remote monitoring in rheumatoid arthritis for early detection of flare, does remote patient-reported flare assessment agree with clinician flare assessment?

Submission date
30/07/2019

Recruitment status
No longer recruiting

Registration date
28/10/2019

Overall study status
Completed

Last Edited
28/10/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Rheumatoid arthritis (where joints become swollen because the body's defence systems attack them) affects 1% of the UK population. Rheumatoid arthritis is a life-long incurable disease and symptoms change over time.

Current medical treatment of rheumatoid arthritis is based on pre-arranged hospital appointments, sometimes many months apart. Currently, the only way for patients to tell their rheumatology doctor how their arthritis is, is at routine hospital appointments or by requesting an additional emergency appointment.

Flare-ups in inflammatory activity occur in many patients with rheumatoid arthritis and are unpredictable. Flares can last for days or weeks and cause significant disability and impact on activities of daily living. Identifying flares quickly and starting appropriate treatment is recommended within standard care and can improve symptoms and reduce a flare's duration. However, it is often difficult for patients to be reviewed by a rheumatology specialist doctor quickly because rheumatology clinics are often fully booked. This means that the rheumatoid arthritis disease activity may worsen further before the patient can be seen by a rheumatology specialist.

This research project will use patient reported symptom severity scores, grip strength and image-recognition data (gathered from photos of hands taken by patients on their smartphones), collected through a secure smartphone app, to see if patient reported flares relate to clinician assessed flares in clinic.

Who can participate?
Patients with a diagnosis of rheumatoid arthritis, a smartphone and an email address will be eligible to take part.

What does the study involve?
This research project will last 16 months and be conducted within the rheumatology outpatient clinics at the Royal National Hospital for Rheumatic Diseases (RNHRD)/Royal United Hospital Bath (RUH). Patients will be asked to complete regular questionnaires about their rheumatoid arthritis disease activity via their smartphone, to record which joints they feel are tender and/or swollen, and measuring grip strength using a specialist grip-strength monitor. A subset of patients will also be required to take regular photos of their hands. If they experience a flare, patients will be asked to repeat these measures. They will then be reviewed within three working days by a rheumatologist who will examine their joints and make any treatment changes required.

What are the possible benefits and risks of participating?
Benefits: participants will receive additional contact time with clinicians as part of the 3 monthly data collection appointments and have a fast-track appointment should a flare occur. Participants may receive closer clinical monitoring and management of their rheumatoid arthritis, providing timely care which may not ordinarily have occurred. Furthermore, participants will benefit from being able to view a record of their condition's variability as they populate the information fields across the study duration.
Risks: participants may need to visit the hospital for more appointments than they would normally and these will be during normal working hours. Additional blood sample at each visit may occur more often if your appointments were previously less than every 3 months. Participants will be required to spend time each week for a duration of 12 months answering questionnaires on a smartphone application, checking which joints are swollen and sore, and using the dynamometer to measure grip strength in each hand each.

The smartphone application is already used in the NHS and data is encrypted before being transferred to the company and then again before being made available to clinicians. The app is compliant with GDPR and meets the NHS Information Governance Toolkit regulations.
The use of the technologies involved is low risk. Both the dynamometer and smartphone data collection presents no danger to patients, beyond the potential physical hazard risk posed by these devices.

Where is the study run from?
Royal National Hospital for Rheumatic Diseases, UK

When is the study starting and how long is it expected to run for?
July 2019 to September 2020

Who is funding the study?
Innovate UK

Who is the main contact?
Dr Saion Chatterjee
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Contact information

Type(s)
Scientific

Contact name

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Additional identifiers

Central Portfolio Management System (CPMS)
42212

Protocol serial number
260182

Study information

Scientific Title
Remote Early Flare Detection for Rheumatoid Arthritis (REFDRA)

Acronym
REFDRA

Study objectives
Does remote patient-reported flare assessment of rheumatoid arthritis agree with clinician flare assessment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/07/2019, South West-Frenchay Research Ethics Committee (Bristol HRA Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; 0207 104 8041; nrescommittee.southwest-frenchay@nhs.net), ref: 19/SW/0092

Primary study design
Observational

Study design
Prospective, single centre cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Remote data will be collected over a 12 month period using the Living With Rheumatoid Arthritis smartphone application, dynamometer and thermal camera (in a subset of patients). In addition to routine clinical assessment with validated measures, participants will have a musculoskeletal ultrasound examination of their hands and feet undertaken when they experience flare.

Intervention Type
Mixed

Primary outcome(s)
Agreement between patient assessment of flare (binary yes/no, reported in-app or in clinic) and a DAS28-CRP flare (yes/no) measured using Receiver Operator Curve (ROC) analysis. DAS28 flare is defined as an increase in DAS28 score of ≥1.2 from the most recent previous non-flare DAS28 score if it was <3.2, or an increase of ≥0.6 if the previous recorded non-flare DAS28 was ≥3.2. Agreement is defined as ≥0.7.

Key secondary outcome(s)
1. Agreement between patient and clinician reporting of objective and patient-reported flare components. These components align with the Core Domain's identified by the OMERACT group and encompass pain, physical function, fatigue, stiffness and participation. See omeract.org.
1.1 Clinician reported measures include: DAS 28-CRP and its constituent elements (28 tender joint count (TJC), 28 swollen joint count (SJC), physician global health assessment), and ultrasound assessment for joint synovitis (greyscale and Doppler).
1.2 Patient-reported measures include: patient-reported TJC and SJC, patient global health assessment, Routine Assessment of Patient Index Data 3 (RAPID3), the Health Assessment Questionnaire Disability Index (HAQ-DI), and grip strength (measured using a dynamometer in kg).
2. C-Reactive Protein (CRP) will be measured from blood drawn at time of clinical assessment, and a subset of patient will undergo thermal and photographic imaging of hands.

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Can access and operate an Android or iOS operating system smartphone or tablet device
2. Access to the internet
3. An active email account
4. Capacity to consent to participate in the study
5. Able to attend face-to-face appointments 3-monthly and within three days of onset of a flare
6. Able to complete the remote monitoring according to the documented schedule
7. English language proficiency to use the smartphone application and complete remote data entry

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
All

Sex
All

Key exclusion criteria
1. Fibromyalgia syndrome (FMS). The symptomatology of this condition can be a source of confounding of patient-reported outcome measures (PROMs) in rheumatoid arthritis.

Date of first enrolment
15/07/2019

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal National Hospital for Rheumatic Diseases
Upper Borough Walls
Bath
United Kingdom
BA1 1RL

Sponsor information

Organisation
Royal United Hospitals Bath NHS Foundation Trust

ROR
https://ror.org/058x7dy48

Funder(s)

Funder type

Charity

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No