ISRCTN25879022 https://doi.org/10.1186/ISRCTN25879022

Remote monitoring in rheumatoid arthritis

Submission date
04/05/2022

Recruitment status
No longer recruiting

Registration date
05/05/2022

Overall study status
Completed

Last Edited
14/06/2024

Condition category
Musculoskeletal Diseases

[X] 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 is a common disease affecting 1 in 100 UK adults, causing joint pain, stiffness and fatigue. Patients with rheumatoid arthritis need close monitoring of their arthritis activity to work out the most effective dose of their arthritis drugs. At the moment, this monitoring is done at clinic visits, meaning that patients have to regularly attend hospital. If it were possible for patients to be monitored remotely, this would avoid many trips to hospital and free up clinic appointments for those patients most in need. In this small study, we aim to assess the feasibility of remote monitoring in patients with active rheumatoid arthritis who are starting an arthritis drug.

Who can participate?
Patients with a diagnosis of rheumatoid arthritis, who are starting a new rheumatoid arthritis drug treatment.

What does the study involve?
We will invite 20 patients to take part and will be followed for three months. Patients will complete self-assessments of their arthritis activity using online questionnaires, and their physical activity and heart rate will be measured using small wearable monitors. Patients will also attend for monthly face-to-face visits with a nurse to assess their arthritis activity using standard measurements used in current clinical practice. We will compare remote measurements of arthritis activity with standard face-to-face assessments to assess their accuracy and reliability. Also, information from activity and heart rate monitors will be analysed to look for patterns that may identify when patients have active arthritis. Finally, patients will provide feedback on their experience of remote monitoring, and any aspects for future improvement.

What are the possible benefits and risks of participating?
There will be no direct benefit to participants for participating in this study. They will be making a valuable contribution to our understanding about the feasibility of remote monitoring in rheumatoid arthritis. In the future this may lead to new tools to check people's arthritis between hospital visits, improving the quality and safety of care that we can provide to our patients.
There are no obvious disadvantages or risks to taking part in the study. The monitors and smartphone that participants will be required to wear and use are non-invasive and have no associated risks. Sometimes blood tests can cause some minor bruising.

Where is the study run from?
Freeman Hospital, The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2021 to September 2023

Who is funding the study?
The National Institute for Health and Care Research Newcastle Biomedical Research Centre (UK)

Who is the main contact?
Dr Kenneth Baker, kenneth.baker@ncl.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Kenneth Baker

ORCID ID
http://orcid.org/0000-0002-6735-2911

Contact details
Translational and Clinical Research Institute,
3rd Floor, William Leech Building,
Medical School, Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 1912085337
kenneth.baker@ncl.ac.uk

Type(s)
Public

Contact name
Dr Kenneth Baker

Contact details
Translational and Clinical Research Institute,
3rd Floor, William Leech Building,
Medical School, Newcastle University
Newacstle upon Tyne
United Kingdom
NE2 4HH
+44 1912085337
kenneth.baker@ncl.ac.uk

Type(s)

Scientific

Contact name
Dr Kenneth Baker

Contact details
Translational and Clinical Research Institute,
3rd Floor, William Leech Building,
Medical School, Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 1912085337
kenneth.baker@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
313072

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 313072

Study information

Scientific Title
Remote monitoring of disease and physical activity in rheumatoid arthritis: a pilot study

Study objectives
To demonstrate the feasibility of remote disease activity monitoring in participants with rheumatoid arthritis, to support a future clinical efficacy trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2022, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224558458; gram.nosres@nhs.scot), ref: 22/NS/0072

Study design
Single centre observational longitudinal cohort study

Primary study design

Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
In this pilot study, we propose to recruit 20 participants with rheumatoid arthritis (RA) with active disease who are newly starting a disease modifying antirheumatic drug (DMARD). Participants will be followed for 3 months, with monthly face-to-face visits to measure the disease activity in 28 joints (DAS28) score. Throughout the study, participants will complete weekly patient-reported outcome measures (PROMs) in the form of the simple 5-question RA Disease Activity Index 5 (RADAI-5), captured electronically using the British Society for Rheumatology ePROMs online portal, with weekly email reminders to support participant uptake. In addition, at each monthly visit participants will be provided with activity trackers (lower back and wrist – Axivity AX6) and a combined activity and cardiorespiratory monitor (VitalPatch) to be worn for 7 days. Additional PROMs including FACIT-F and MFS (fatigue), HAQ-DI (physical function), PHQ-2 (anxiety/depression) and EQ-5D-5L (general health) will be captured at the monthly visits, in order to collect information necessary for interpretation of the activity monitor data.

Intervention Type
Not Specified

Primary outcome measure
1. Arthritis activity measured using the disease activity score in 28 joints (DAS28) score at baseline, week 4, week 8 and week 12.
2. Arthritis activity measured using the rheumatoid arthritis disease activity index 5 (RADAI-5) at baseline, week 4, week 8 and week 12

Secondary outcome measures
1. Physical activity measured by Axivity AX6 devices at baseline, week 4, week 8 and week 12
2. Cardiorespiratory activity measured by VitalPatch devices at baseline, week 4, week 8 and week 12
3. Fatigue measured by the FACIT-F questionnaire at baseline, week 4, week 8 and week 12
4. Fatigue measured by the MFS questionnaire at baseline, week 4, week 8 and week 12
5. Physical function measured by the HAQ-DI questionnaire at baseline, week 4, week 8 and week 12
6. Anxiety and depression measured by the PHQ-2 questionnaire at baseline, week 4, week 8 and

week 12
7. General health measured by the EQ-5D-5L questionnaire at baseline, week 4, week 8 and week 12

Overall study start date
17/12/2021

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Diagnosis of rheumatoid arthritis according to the 1987 American College of Rheumatology (ACR) or 2010 ACR/European Alliance of Associations for Rheumatology (EULAR) classification criteria applied at any time since diagnosis.
2. Participant about to commence (i.e. planned within next 4 weeks), or recently commenced (i.e. within past 8 weeks), a new disease-modifying anti-rheumatic drug (i.e. conventional synthetic DMARD, Janus-kinase inhibitor or biologic therapy)
3. Able to walk at least four metres independently without walking aids
4. Participant willing to commit to complete remote monitoring measurements and wear monitoring devices

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Total final enrolment
13

Key exclusion criteria
1. Unable to read or communicate in English
2. Current participation within an interventional clinical trial (participation in another observational trial is permitted)
3. Inability to provide informed consent
4. Age less than 18 years
5. Current diagnosis of a movement disorder
6. Current pregnancy

Date of first enrolment
01/06/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Newcastle Joint Research Office
Level 1, Regent Point
Regent Farm Road
Gosforth
Newcastle upon Tyne
England
United Kingdom
NE3 3HD
+44 191 233 6161
nuth.genericqueries@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
NIHR Newcastle Biomedical Research Centre

Alternative Name(s)
Newcastle Biomedical Research Centre, Newcastle NIHR Biomedical Research Centre

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made 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			28/06/2023	No	No