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A feasibility study of remote monitoring of rheumatoid arthritis using a smartphone app

Submission date
18/10/2022

Recruitment status
No longer recruiting

Registration date
23/01/2023

Overall study status
Completed

Last Edited
12/08/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
REmote MOnitoring of Rheumatoid Arthritis (REMORA2) is an intervention designed to improve the care of people living with rheumatoid arthritis (RA) by enabling patients to track their symptoms using a smartphone app. This information will then be integrated into the electronic health record (EHR) to be viewed during consultations with their rheumatology team.
RA is a common chronic inflammatory disease which exemplifies challenges in the management of long-term conditions. Current best practice (6/12-monthly reviews) can lead to gaps in knowledge which prevent effective disease management. Symptom tracking via a mobile phone app has previously been demonstrated to improve shared decision-making and provide a clearer picture of fluctuations in a patient's condition.
The aim of this study is to inform the decision to proceed with a full trial to provide evidence on the effectiveness and impact of integrating daily patient-generated health data into the electronic health records (EHR) of patients with RA. The study will also investigate barriers to the use of this intervention and ways to enhance uptake for marginalised groups.

Who can participate?
1. Clinicians will be recruited across two NHS sites to be trained on the use of patient-generated data in the EHR.
2. Patients (adults aged 18 years and older) with RA or suspected RA seen by consenting clinicians will be recruited via the NHS site and allocated to the symptom-tracking group using the smartphone app. Patients who would be excluded from the use of the app, or decline to use the app, will be recruited to take part in interviews on barriers to digital inclusion, including Urdu-speaking patients and carers.
3. Local community group members who live with, or care for people with RA and who self-identify as being from a group at risk of digital exclusion, will be recruited to take part in focus groups to improve study processes and documents, to maximise participation.

What does the study involve?
The study will be open for a total of 6 months. There will be a 3-month recruitment period followed by a 3-month follow-up window. All participants will remain on trial until the close of the 3-month follow-up window. Patients recruited at the start of the recruitment window will therefore be on trial for up to 6 months; patients recruited at the end of the recruitment

window will be on trial for up to 3 months.
Eligible participants at each site will be allocated to symptom tracking using the smartphone app. Instructions for downloading and use of the app will be provided by the University of Manchester. Patients will track their symptoms on the app through a series of daily questions and via a weekly and monthly questionnaire. There are no extra study visits. Patients will return for clinic visits as normal standard of care. Follow-up data will be collected at any clinic visit that occurs (following consent) within the 6 month trial duration.
During the consultations, the data collected via the app will be available to view on the EHR by the consented clinician. Patients will also be asked by the University of Manchester research team to complete a web survey at baseline, 3 months and 6 months, if applicable.
Clinical consultations will be observed for a subset of consenting clinicians and patients.
Data will be collected on recruitment rates, use of the app and use of the data during consultations. Data on experiences of using the app and patient-generated data will also be gathered in interviews.
Patients who decline to take part in the symptom tracking or who consent to take part in the study but do not engage with the app will be invited to take part in interviews on barriers to digital inclusion. Urdu-speaking patients and carers will also be recruited through the Oldham site and via the community to take part in an interview to discuss barriers to digital inclusion.
Local community group members who live with, or care for people with RA and who self-identify as being from a group at risk of digital exclusion, will be recruited to take part in focus groups to improve study processes and documents, to maximise participation.

What are the possible benefits and risks of participating?
This study aims to recruit as broad a range of participants as possible, including those who are not able to take part in the feasibility study. Patients will be approached about the feasibility study in the first instance, and if they decline participation will then be asked if they are willing to receive information about interviews or EHR review.
There is a possibility that participants may feel pressured by getting a second request immediately after having refused to take part in the feasibility study. It will be made clear to participants that they can decline participation without giving a reason and without their care being affected. Further study information will not be sent to participants unless they have verbally consented to receive it. They will then have the chance to consider the information and ask questions before deciding whether to take part.

Where is the study run from?
The study is being run by the University of Manchester and takes place in Pennine MSK Partnership Ltd, Oldham and Charing Cross Hospital, Imperial College Healthcare NHS Trust, London (UK)

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

Who is funding the study?
1. National Institute for Health and Care Research (NIHR) (UK)
2. Versus Arthritis (UK)

Who is the main contact:
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
310318

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 52473

Study information

Scientific Title
Transforming outpatient consultations by integrating regular symptom tracking into clinical care: the REmote MOnitoring of Rheumatoid Arthritis (REMORA2) feasibility study

Acronym
REMORA2

Study objectives
The aim of this study is to:
1. Provide the data to inform a stop-go decision, used to determine whether to proceed to the full-stepped wedge randomised control trial.
2. Understand how the intervention is experienced by both the patient and clinician participants, including the feasibility of use in the long-term, usability of study support materials and any identified problems or barriers which could impact the future success of the stepped wedge randomised control trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/04/2022, South Central - Berkshire B Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8253; berkshireb.rec@hra.nhs.uk), ref: 22/SC/0103

Study design
Multi-centre mixed methods feasibility study

Primary study design
Interventional

Study type(s)
Other

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

Interventions
All participants are asked to sign a consent form following a full explanation of the study. Eligible participants will be allocated to symptom tracking using the REMORA2 smartphone app. Patients will track their symptoms on the app through a series of daily questions and via a weekly and monthly questionnaire. There are no extra study visits. Patients will return for clinic visits as normal standard of care. Follow-up data will be collected at any clinic visit that occurs (following consent) within the 6-month trial duration. During the consultations, the data collected via the app will be available to view on the Electronic Health Record by the consented clinician.

Intervention Type
Other

Primary outcome(s)
The primary aim of this study is to assess the feasibility of conducting a stepped wedge RCT comparing usual care to integrated symptom tracking in patients with rheumatoid arthritis. The researchers will use the results to refine the design and processes of the main stepped wedge RCT and sample size calculations, as appropriate.
1. Recruitment rate, defined as the number of eligible participants who consent to participate in the study within the 3-month recruitment window
2. Retention rate, defined as the number of eligible participants who remain in the study until the end of the follow-up window
3. Intervention uptake rates among consented participants will be determined in reference to the number of:
3.1. Consented participants who successfully complete app download (in the period from recruitment opening to the close of trial)
3.2. Consented participants who successfully initiate symptom tracking (defined as completing at least one symptom report within the first 14 days of app download. Assessed in the period from recruitment opening to the close of trial)
3.3. Consented participants who complete the question sets on a daily, weekly and monthly basis (in the period from recruitment opening to the close of trial)
3.4. Clinical consultations in which available graphs of the REMORA data are reviewed at 3 months and 6 months, as applicable

This information will be used to evaluate the following continuation criteria, which will inform the decision to proceed to the full stepped wedge randomised controlled trial:
1. Recruitment of 15 or more consented participants per site and where symptom tracking is initiated in 70% or more of consented participants across both sites and where symptom data

has been received on over 50% of possible days of tracking. Possible days of tracking defined from the first day of receiving a symptom-tracking report.
2. Completion of 80% or more of the Disease Activity Score-28 (DAS28) in face-to-face consultations or the Clinical Disease Activity Index (CDAI) for remote consultations.

Key secondary outcome(s))

1. Perceptions related to user experiences of using the app, integration of the data in clinical settings and implementation of the symptom tracking in clinical care. This will involve patient and clinician data. Individuals from diverse backgrounds will be included to determine if experiences of the intervention differ and identify any barriers to engagement and their possible causes.
2. How the patient-generated symptom data are discussed, how it influences decision-making processes and the impact on consultation length. This will involve clinic observations.
3. Patients' and carers' perceptions of managing and regularly tracking RA symptoms and their views and experience of using technology to manage health. Personal care arrangements, experiences of and access to digital healthcare technology and their views and expectations regarding the use, and perspectives on using a mobile phone to collect health data to support clinical care, as well as barriers to remote monitoring of symptoms will be examined.

The secondary aim of this study is to explore patients' and rheumatology specialists' perspectives on the feasibility of delivering and using integrated symptom tracking and, via identification of barriers to digital inclusion among patients invited to the feasibility study and local community groups, to develop and refine supporting materials for a future trial accordingly.

The outcome measures that will be evaluated within this feasibility study are as follows:

1. Disease activity measured using DAS28 in a face-to-face consultation or the CDAI (obtained remotely) at baseline, 3 months and 6 months where applicable.
2. Symptom tracking data will be collected via the app on a daily, weekly and monthly frequency
3. Daily questions are completed from the date of registering the app until the trial exit. The question sets completed on a daily basis include:
3.1. Pain on a scale visual analogue scale (VAS) of 0-10
3.2. Function on a VAS of 0-10
3.3. Fatigue on a VAS of 0-10
3.4. Physical wellbeing on a VAS of 0-10
3.5. Emotional wellbeing on a VAS of 0/10
3.6. Coping on a VAS of 0-10
3.7. Morning stiffness on a 7-point Likert scale with a range of 0 to 180+ minutes
4. Weekly questions are completed from the date of registering the app until the trial exit. The question sets completed on a weekly basis include:
4.1. Tender joint count on a scale of 0-28
4.2. Swollen joint count on a scale of 0-28
4.3. Patient global assessment on a VAS of 1-10
4.4. Employment status (yes/no)
4.5. Hours missed due to health problems
4.6. Hours missed due to other reasons
4.7. Hours worked
4.8. Impact of health on work productivity on a VAS of 0-10
4.9. Impact of health on daily activities on a VAS of 0-10
4.10. Occurrence of flare (yes/no)
4.11. Flare description (free text)
5. Patient-reported outcomes measured using the Health Assessment Questionnaire (HAQ)

completed on a monthly basis from the date of registering the app until the trial exit
6. A web-based questionnaire survey will also be completed at time 0, 3 months and 6 months where applicable. Time 0 is defined as the date the app download instructions are sent to the consented participant. The web survey includes:
6.1. Ethnicity and smoking status (month 0 only)
6.2. Quality of life measured using the EQ-5D 5 level version (EQ-5D-5L)
6.3. Disability measured using the HAQ and four items from the Routine Assessment of Patient Index Data 3 (RAPID-3)
6.4. Patient global for pain using a VAS of 0-10
6.5. Disease activity using the CDAI and patient-reported components as determined by a patient-assessed swollen joint count, tender joint count and a patient global assessment of disease activity using a VAS of 1-10
6.6. Perceived involvement in decisions assessed using the 9-item Shared Decision Making Questionnaire (SDM-Q9)
6.7. Level of shared decision-making measured using the collaboRATE questionnaire
6.8. Performance of self-management behaviours using the Medication Adherence Report Scale
6.9. Assessment of capabilities, opportunities and motivations for behaviour change as determined by the COM-B questionnaire
6.10. Work productivity measured using the Work Productivity and Activity Impairment Questionnaire: Rheumatoid Arthritis (WPAI-RA).
6.11. Resource use assessed with questions to evaluate the number of recent outpatient visits, telephone consultations, GP visits and hospital admissions
7. Semi-structured interviews with potentially underserved or digitally excluded groups will be conducted with:
7.1. Consented participants who either do not start or stop symptom tracking or start and then stop symptom tracking. Interviews will take place for the duration of the trial.
7.2. Consented participants (and/or their carers) who decline trial participation. Interviews will take place from the start of the trial until approximately month 4, allowing any individuals who decline at the end of the recruitment window (month 3) to be approached and interviewed.
7.3. Urdu-only speaking participants who were excluded from the feasibility study but consented to be interviewed. Interviews will take place from the start of the trial until approximately month 4, allowing any individuals who were not eligible to participate in the feasibility at the end of the recruitment window (month 3) to be approached and interviewed.
Interviews will focus on people's experiences and beliefs about digital technology, an exploration of the barriers to digital inclusion and intervention uptake and, for those who consented to take part in the study but did not start or stopped symptom tracking or started and then stopped tracking, an exploration as to their reasons for not tracking. Guided by theoretical frameworks, the interviews will explore views and experiences of using digital technology such as symptom-tracking apps for managing rheumatoid arthritis and the perceived support system required to engage with a symptom-tracking app.
8. Health information will also be extracted from the patient medical record at baseline, 3 months and 6 months where applicable. Information includes:
8.1. Demographics: date of birth, gender, ethnicity, smoking status
8.2. Body mass index
8.3. Diagnosis including month and year of diagnosis
8.4. DAS28 score and score of the individual component parts:
8.1.1. CRP/ESR
8.1.2. Tender joint count on a scale of 0-28
8.1.3. Swollen joint count on a scale of 0-28
8.1.4. Patient global assessment on a VAS of 0-100
8.5. CDAI score and score of the individual component parts:
8.5.1. Tender joint count on a scale of 0-28

8.5.2. Swollen joint count on a scale of 0-28
8.5.3. Patient global assessment on a VAS of 0-10
8.5.4. Physician global assessment on a VAS of 0-10
8.6. Health care usage:
8.6.1. Number of rheumatology clinic visits in the last 6 months
8.6.2. Dates of rheumatology clinic visits in the last 6 months
8.6.3. Number of rheumatology telephone consultations in the last 6 months
8.6.4. Dates of rheumatology telephone consultations in the last 6 months
8.7. Comorbidities
8.8. Treatment history:
8.8.1. Past and current use of disease-modifying antirheumatic drugs (DMARD)
8.8.2. Rituximab use in the last 6 months
8.8.3. Steroid use

Completion date
18/12/2023

Eligibility

Key inclusion criteria
Across all participant groups, recruited individuals must have mental capacity to understand the study information provided and to give informed consent. Additional specific criteria for each participant group is provided below:

Clinical Team members:
Clinicians and nurses, at either of the participating centres, who have primary responsibility for the care of patients with RA or suspected RA.

Patients:
Participants in the feasibility study:
1. Adult patients (i.e. ≥18 years of age) with RA or suspected RA, who are under the care of a consented clinician
2. Own an Android or iOS smartphone, with the ability to access the internet daily to support data upload
3. Can speak and understand English or are supported by someone who can

Participants in the interviews to identify barriers to digital inclusion:
1. Adult patients (i.e. ≥18 years of age) with RA or suspected RA, who are under the care of a consented clinician, and were approached to join the feasibility study but declined for any reason (including ill health), and/or their carers.

Urdu-speaking participants in the interviews to identify barriers to digital inclusion:
1. Adult patients (i.e. ≥18 years of age) with RA or suspected RA, who are under the care of a consented clinician, who are Urdu-speaking only, and/or their carers.

Participants in Electronic Health Record review-only:
1. Adult patients (i.e. ≥18 years of age) with RA or suspected RA
2. Under the care of a consented clinician
3. Has the mental capacity to consent

Community group members:
1. Adult patients (i.e. ≥18 years of age) with RA or other rheumatic and musculoskeletal diseases (RMDs), who also self-identify as having experience of one or more of the following: more severe (or multiple) disabilities, are older people (aged over 75 years), people living in an area of high deprivation, people from Black And Minority Ethnic communities, or their carers.

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
75

Key exclusion criteria
Clinical Team members:
1. Individuals who do not have primary responsibility for the care of eligible patients, such as physiotherapists, occupational therapists, pharmacists or podiatrists will not be recruited to the study, as we do not depend on them for recruitment or data completion.

Patients:
1. Recruited patients must feel well enough to take part and be able to understand the relevant project information (with support if needed, e.g. a translator for Urdu-speaking participants). Patients who do not meet these criteria will not be recruited.
2. No patients under 18 years. There is no upper age limit.
3. Patients and clinicians will be eligible whether their consultations are being conducted in-person or remotely.

Community group members:
1. Participants must feel well enough to take part and be able to understand the relevant project information (with support if needed).

Date of first enrolment
09/01/2023

Date of final enrolment
08/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Pennine MSK Partnership Ltd
Integrated Care Centre
New Radcliffe Street
Oldham
United Kingdom
OL1 1NL

Study participating centre
Stepping Hill Hospital
Stockport NHS Foundation Trust
Poplar Grove
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SK2 7JE

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Versus Arthritis

Alternative Name(s)
Arthritis UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data and necessary metadata will be made available to other researchers via the University of Manchester institutional repository (Research Data Management Service). Intended future re-use of research data will be clearly captured in the participant information sheet and consent forms to ensure data sharing during and beyond the programme is consistent with the participant's preferences and expectations. Specific data-sharing procedures are to be confirmed, however, the researchers do reserve the right to not publish data until they have published/gained the required impact.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/02/2025	12/08/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes