ISRCTN51539448 https://doi.org/10.1186/ISRCTN51539448

A multi-centre randomised clinical trial to test the effectiveness of integrated symptom tracking in the management of rheumatoid arthritis

Submission date
16/05/2024

Recruitment status
No longer recruiting

Registration date
04/06/2024

Overall study status
Ongoing

Last Edited
17/10/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Currently doctors treating rheumatoid arthritis (RA) ask patients how they have been since the last appointment to plan treatment. In some cases, the last appointment may have been months before. Patients may not remember how their symptoms have been or they may forget to report important events, like flares. This study aims to address this issue by asking patients with RA to use an app to regularly record their symptoms. The information the patient records about their symptoms will be made available to their hospital doctor during the clinic appointment. The study involves hospitals in two different regions in England. The study will look at whether patients whose doctor can view information about their RA symptoms, captured via an app, do better than patients whose doctor does not have this information available to them.

Who can participate?
Patients who are over 18 years and have active RA and are under the care of a doctor who has agreed to take part in the study can participate. Patients need to own or have access to an Android or iOS smartphone or tablet with PIN code security and be able to access the internet regularly to complete the web surveys. Individuals will also need an email address so the researchers at the University of Manchester can offer support and email study information. The app is currently only available in English and so participants will also need to understand English or be supported by someone who can.

What does the study involve?
Following consent, participants will be allocated to either the normal care or integrated symptom-tracking group. Participants in the normal care group will be asked to attend usual routine clinics and they will be invited to complete a web-based survey when they join the study and then again at 3, 6, 9 and 12 months. The web survey is completed online and takes about 30 minutes to complete. This survey will ask about quality of life and use of healthcare. The researchers will also ask permission to obtain some information from the hospital medical records. The information collected includes age, gender, ethnicity, smoking status, body mass

index (BMI), diagnosis and duration of disease, recent disease activity assessments, medications, and any other illnesses. This information will be extracted by a member of the clinical team at the hospital at each doctor's visit for at least 12 months and no longer than 15 months.
Participants allocated to the integrated symptom tracking group will be asked to do the same as the normal care group (attend routine clinics, complete the web-based survey every 3 months and allow information to be obtained from the medical record). Participants in the integrated symptom-tracking group will also be asked to use the REMORA app. The welcome email will include guidance to help participants download, activate, login and use the app. Once participants have downloaded and logged in to the app, participants will be able to start recording information about their RA symptoms straight away. Participants will be asked to answer the same question set every day (daily questionnaire); this should take about 2 minutes to complete each day. Participants will also be asked to answer a different set of questions once a week (weekly questionnaire) and once a month (monthly questionnaire). The weekly and monthly questionnaires should take between 7-10 minutes to complete. The app will send reminders when the questionnaires are due for completion. Participants will be asked to record information about their RA symptoms for a period of at least 12 months and no longer than 15 months.
Participants will also be asked to consider being interviewed and/or observed during the clinic appointment. The interviews and clinic observations are optional and will not impact an individual's ability to take part if this option is declined. The researchers are interested in talking to people who are in both the normal care and the integrated symptom-tracking groups. This will help the research team to find out more about clinic consultations from a patient's perspective and how information is used during the appointment.

What are the possible benefits and risks of participating?
The benefits of participating are well balanced against any risk or burden. Potential benefits include improved quality of life and wellbeing and the opportunity to improve self-management of disease. Communication with the clinical team, level and quality of shared decision-making may also benefit leading to improved content and process of clinical consultations.

Possible risks:
1. Participants find daily symptom tracking too onerous or difficult.
Previous REMORA studies demonstrated that patients find daily symptom tracking to be acceptable, with excellent longitudinal engagement. Participants provide informed consent prior to participating and may choose to stop tracking if they wish.
2. Daily symptom tracking may cause participants to over-focus on symptoms, which may negatively impact their mood and/or increase health-related anxiety.
Eligible participants who prefer not to track symptoms because of concerns about focussing on symptoms can choose not to participate. For those who would consider participating, contact details for the University of Manchester study team are provided to discuss any concerns. Experience from previous REMORA studies has shown this to be low risk.
3. Participants may not know how to use the technology or cannot solve problems themselves.
A user support network has been implemented. Participants can email the University of Manchester study team at any time or call and leave a message with questions or technical issues. The dedicated trial email inbox and voicemail will be monitored Monday to Friday, and the University of Manchester study team will respond within 3 working days to offer support. Our patient partners will also provide one-to-one support through the Patient Support Hub. Support will be offered by telephone and email.
4. Participants may believe their health (i.e., symptoms) is monitored in real-time by either the University of Manchester study team or their clinical team. As a result, patients may not seek healthcare when they need to or believe that a member of their healthcare team may be alerted to a sudden health need.

To address this there are explicit statements in the Participant Information Sheet and consent form, and daily reminders in the REMORA app. Participants are reminded that the symptom data is viewed only at their routine clinic visit, is not monitored throughout the study period, and that their data is only shared with their rheumatologist, and not the GP or other specialty providers. Participants will be regularly reminded via the app that they need to contact their clinical team through the normal avenues if they have any health concerns.
5. Participants may become upset during the interviewing process if:
a. talking about issues relating to accessing care and barriers to participation in the stepped wedge trial is distressing.
b. discussing participation in the REMORA2 study leads the participant to over-focus on symptoms, which may negatively impact mood.
To mitigate the risk of participant suffering, a distress protocol is in place. Participants will be given contact details of experienced members of the University of Manchester study team, with whom any concerns can be discussed. Information for withdrawal from the trial will be provided.
6. The health care professional does not read and/or use the REMORA dashboard as intended and described in the protocol.
To minimise any treatment risk, all healthcare professionals will undertake mandatory training which covers the access, functionality, and interpretation of the REMORA dashboard before the trial is open to patient recruitment. Due to the trial duration, regular refresher training will also be offered and the training slides will be available to all sites for review at any time. Support will also be offered by the University of Manchester study team. Physical reminders, including a Disease Activity Score for 28 joints (DAS28) desktop assessment tool, paper Case Report Forms (CRF) and REMORA2 logo merchandise, will also be made available for each site team. Where possible, tailored local reminders in the electronic health system at each site will also be incorporated.
7. Withdrawal of the consented health care professional from participation in the trial.
If a health care professional withdraws from trial due to relocation to a different Trust, the replacement health care professional/s who take on the patient list will be approached for trial if not already participating. This will allow consented patients to continue on-trial. If a healthcare professional withdraws consent to participate in the trial, any consented patients under their care will also need to be withdrawn. In such circumstances, the patient will be contacted by the University of Manchester study team and guidance provided. Based on previous experience, the likelihood of this occurring is extremely low and the healthcare professionals have been highly engaged with the programme and participation.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
October 2021 to March 2026

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

Who is the main contact?
Dr Deb Griffiths-Jones, deb.griffiths-jones@manchester.ac.uk

Contact information

Type(s)

Public

Contact name
Dr Deb Griffiths-Jones

Contact details
The University of Manchester
Centre for Epidemiology Versus Arthritis
Division of Informatics, Imaging & Data Sciences
Faculty of Biology, Medicine and Health
The University of Manchester
Third Floor, The Christabel Pankhurst Building
Dover Street
Manchester
United Kingdom
M13 9PS
+44 (0)161 275 1675
deb.griffiths-jones@manchester.ac.uk

Type(s)
Scientific

Contact name
Prof Will Dixon

ORCID ID
https://orcid.org/0000-0001-5881-4857

Contact details
Centre for Epidemiology Versus Arthritis
Division of Informatics, Imaging & Data Sciences
Faculty of Biology, Medicine and Health
The University of Manchester
Vaughan House
Portsmouth Street
Manchester
United Kingdom
M13 9GB
+44 (0)161 306 2000
will.dixon@manchester.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
322792

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
CPMS 56726, IRAS 322792

Study information

Scientific Title
Transforming outpatient consultations by integrating regular symptom tracking into clinical care: a stepped wedge randomised control trial of remote monitoring of rheumatoid arthritis, compared to usual care

Acronym
REMORA2 - SWT

Study objectives
This stepped wedge trial aims to identify if integrated symptom tracking:
1. Improves care and outcomes of long-term conditions, using rheumatoid arthritis (RA) as an exemplar, by integrating regular patient-reported symptom tracking into clinical pathways and systems;
2. Generates and disseminates knowledge on how to successfully implement patient-generated data into clinical pathways and systems in the NHS, including necessary change of behaviours and workflows.

Hypothesis: Patient-reported integrated symptom tracking will improve the disease activity score compared with usual standard of care in patients with RA attending rheumatology consultations in secondary care settings at 12 months' follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/08/2023, South Central – Berkshire B (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)2071048276; berkshireb.rec@hra.nhs.uk), ref: 23/SC/0266

Study design
Randomized; Both; Design type: Process of Care, Device, Management of Care, Active Monitoring, Cross-sectional

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions

This trial is a non-commercial, continuous recruitment, short exposure stepped wedge cluster randomized controlled trial to determine whether the use of integrated symptom tracking is superior compared with usual standard of care (SoC) in improving care and outcomes among patients with RA. The impact on other outcomes, such as quality of life, disability, shared decision-making, self-management and patient experience of consultations, will also be assessed.

Healthcare professionals will be recruited from 16 rheumatology services based in secondary care in the Greater Manchester and North West London geographical regions. Healthcare professionals who are responsible for assessing changing disease severity over time and are involved in treatment decision-making will be recruited during a recruitment window of 8 weeks prior to the start of patient recruitment. The patient population will be selected from individuals living with RA from the same 16 rheumatology services. Each centre, or 'cluster', will be randomly assigned to a 'set' (two centres/clusters per set) and will recruit patient participants continuously for 27 weeks. Each set will begin in the usual SoC (control) group, moving into the integrated symptom tracking (intervention) group within a randomly allocated transition sequence. Randomisation will be based on the cluster, not the individual. Sets will not be given notice that the intervention is being introduced. Patients will be recruited based on their eligibility and willingness to join the trial, but without yet knowing their allocation. Following recruitment, the UoM study team will notify participants of their group (usual SoC or integrated symptom tracking) depending on the status of the cluster at the time of recruitment. Sites will not be aware of the order that sets will change intervention type. If the set has not yet introduced the intervention, recruited patients will continue to receive usual care for their 12 months' follow-up. Once a set has introduced the intervention, recruited patients from this point forward will be asked to start using integrated symptom tracking via the REMORA app. As clinic visits are not scheduled to occur at exactly 12 months, all participants will be followed up for 12 months (+/- 3 months). Patients in both groups will complete web-based surveys at baseline, 3, 6, 9 and 12 months. The 12-month follow-up period (+/- 3 months) is determined by the date on which the participant is allocated to the intervention by the UoM study team. All participants will be exposed to either usual care or the intervention for the same duration, regardless of the cluster they belong to. Throughout the follow-up window, no extra trial visits will be required. Information will be collected from each consultation throughout the follow-up window, whenever they are seen according to clinical need. As all patients will have active definite or active probable RA, we expect all patients to have at least one follow-up clinic appointment within their 12-month follow-up window.

The primary outcome measure, that fulfils objective 1 (O1), is disease activity as assessed by the DAS28-C-Reactive Protein (DAS28-CRP) (28), which is assessed at baseline and 12 months (+/- 3 months). The DAS28 (28) is a composite outcome measure consisting of a tender and swollen joint count over 28 joints, a patient-reported global assessment of RA activity, and an inflammatory marker blood test: CRP, or erythrocyte sedimentation rate (ESR). Since follow-up appointments are scheduled according to clinical need, the 12-month assessment will be defined as the closest DAS28 score to 12 months between months 9 and 12 or, if no visit has happened in that interval, the closest DAS28 score to 12 months between months 12 and 15. All secondary outcome measures for objectives O2a and O2b will be assessed at baseline and 12 months. A total of 736 patient participants will be recruited over a period of 27 weeks (6.2 months).

In addition to evaluating the primary and secondary quantitative outcomes described above, a subset of up to 60 patients (30 patients receiving the intervention and 30 patients receiving SoC) and 16 healthcare professionals who consent to participate in the stepped wedge trial will be invited for a semi-structured interview and/or observation of clinic consultations to determine the use and effects of integrated symptom tracking on decision-making and interactions in

clinical consultations. Up to 10 healthcare professionals who decline participation in the REMORA2 trial will be invited for a semi-structured interview to explore the reasons for non-participation. Up to 5 other professionals or volunteers involved in the implementation of REMORA2, including implementation leads, service managers and supporting IT staff, where applicable, will be recruited per site. Up to a further 45 patients who are under the care of a consented health care professional and were approached to join the trial but declined or did not register for the app for any reason (including ill health), will be invited for interview to identify barriers to digital inclusion.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Disease activity is assessed using the DAS28-C-Reactive Protein (DAS28-CRP) at baseline and 12 months

Key secondary outcome(s))
1. Impact is measured using the difference in the proportion of participants meeting the EULAR response categories (Good, Moderate, Non-Responders) derived from disease activity score from the electronic health record at 12 months follow-up between the SoC and integrated symptom tracking conditions.
2. Patient-reported disease activity is measured using the:
2.1. Difference in RAPID-3 items total score at 12 months follow-up relative to initial (baseline) visit between SoC and integrated symptom tracking conditions.
2.2. Difference in patient global assessment from the REMORA2 web survey at 12 months follow-up relative to initial (baseline) visit between SoC and integrated symptom tracking conditions.
2.3. Difference in Rheumatoid Arthritis Impact of Disease (RAID) score from the REMORA2 web survey at 12 months follow-up relative to initial (baseline) visit between SoC and integrated symptom tracking conditions.
3. The difference in joint involvement and severity is measured via the Swollen Joint Count for 28 joints (SJC28) and the Tender Joint Count for 28 joints (TJC28) score taken from the electronic health record at 12 months follow-up relative to initial (baseline) visit between SoC and integrated symptom tracking conditions.
4. Medication use is extracted from the electronic health record at 12 months relative to initial level at first completion (baseline) between SoC and integrated symptom tracking conditions.
5. Work impairment is measured by the difference in Work Productivity and Activity Impairment Questionnaire (WPAI-RA) score as reported in the REMORA2 web survey at 12 months relative to initial level at first completion (baseline) between SoC and integrated symptom tracking conditions.
6. Quality of life is measured by the difference in the EuroQol five-dimension scale questionnaire (EQ-5D-5L) health profiles, index score and quality-adjusted life years gained as reported in the REMORA2 web survey at 12 months relative to initial level at first completion (baseline) between SoC and integrated symptom tracking conditions.
7. Disability is measured by the difference in the Health Assessment Questionnaire (HAQ) score as reported in the REMORA2 web survey at 12 months follow-up relative to initial (baseline) visit between SoC and symptom tracking conditions.
8. Patients' experience of shared decision-making during clinic visits will be assessed by the difference in CollaboRATE score as reported in the REMORA2 web survey at 12 months relative

to initial level at first completion (baseline) between SoC and integrated symptom tracking conditions.
9. Researcher-observed shared decision-making processes in clinic will be assessed by:
9.1. The difference in OPTION score as collected during clinic observations between SoC and integrated symptom tracking conditions.
9.2. Conversation analysis of recorded consultations compared between SoC and integrated symptom tracking conditions.
10. Patients' experience of consultation quality will be assessed by the difference in Patient Enablement Instrument (PEI) score as reported in the REMORA2 web survey at 12 months relative to initial level at first completion (baseline) between SoC and integrated symptom tracking conditions.
11. Patients' capabilities, opportunities, and motivations for self-management behaviour will be assessed by the difference in Capabilities-Opportunities-Motivations-Behaviour (COM-B) score as reported in the REMORA2 web survey at 12 months relative to initial level at first completion (baseline) between SoC and integrated symptom tracking conditions.
12. Patients' understanding of their RA will be assessed by the difference in the brief Illness Perception Questionnaire (Brief IPQ) score as reported in the REMORA2 web survey at 12 months relative to initial level at first completion (baseline) between SoC and integrated symptom tracking conditions.
13. Perceived differences, benefits and disadvantages regarding self-management and consultation and decision-making processes of using integrated symptom tracking compared with SoC will be assessed by a comparative analysis between SoC and integrated symptom tracking conditions based on interviews with health care professionals and patients, and observations and conversation analyses of clinic visits.
14. Patient and health care professional expectations, experiences and views regarding the acceptability and usefulness of (the support for) integrated symptom tracking and facilitators and barriers to patient and clinical behaviour change, and uptake and wider NHS implementation of integrated symptom tracking will be assessed by interviews with: patients and health care professionals taking part in the trial, health care professionals not taking part in the trial, patients declining to take part or who do not download the app, and other professionals and volunteers involved in the implementation of REMORA; observations of clinic visits; informal feedback from patient and professional participants and others (e.g., other staff, carers) via other routes, e.g., helpdesk queries.
15. Quality of life will be assessed by the difference in EuroQol five-dimension scale questionnaire (EQ-5D-5L) health profiles, index score and quality-adjusted life years gained as reported in the REMORA2 web survey at 12 months relative to initial level at first completion (baseline) between SoC and integrated symptom tracking.
16. Duration of consultations will be measured by the difference in cumulative consultation length at 12 months between SoC and integrated symptom tracking conditions.
17. Medication use will be assessed by the difference in medication use extracted from the electronic health record at 12 months between SoC and integrated symptom tracking conditions.
18. Resource use will be assessed by the:
18.1. Difference in cumulative resource use as extracted from the electronic health record at 12 months related to initial level at first completion (baseline) for SoC and integrated symptom tracking conditions.
18.2. Difference in cumulative resource use and travel time as reported in the REMORA2 web survey at 12 months between SoC and integrated symptom tracking conditions.
19. Healthcare professionals' engagement with integrated symptom tracking will be assessed by the number and duration of REMORA dashboard views in the electronic health record by healthcare professionals.
20. Patient engagement with integrated symptom tracking will be assessed by the number of completed daily, weekly and monthly questionnaires in the REMORA app in the integrated

symptom tracking group.
21. All quantitative and qualitative outcomes as listed above will be assessed by the relationships between primary and secondary indicators of disease activity (O1-2a) and other outcomes: shared decision-making, self-management and consultation experience (O2b); patients' and professionals' views and experience of integrated symptom tracking and factors influencing successful implementation (O3); and patient and health care professionals' engagement with integrated symptom tracking (O4).

Tertiary outcome measures:
1. Characteristics (demographics, comorbidities, etc) and medication/resource use of consented patient participants, linked to regional shared primary and secondary care health records of external reference RA populations will be assessed by the differences in REMORA2 participants' characteristics and medication/resource use compared to the wider RA population.
2. All quantitative outcomes as listed above that were collected at more than one timepoint, linked to regional shared primary and secondary care health records of external reference RA populations will be assessed for trajectories of outcomes through time for integrated symptom tracking and SoC groups, including associations with initiating a range of RA treatments.

Completion date
15/03/2026

Eligibility

Key inclusion criteria
TRIAL PARTICIPANTS
Healthcare professionals:
1. Has responsibility for the assessment and care of patients with RA
2. Has responsibility for treatment decision-making
3. Has access to the medical record at site as part of routine care
4. Is willing to review the REMORA dashboard during clinical interactions for consented patients
5. Is willing to provide full written informed consent

Patient trial participants:
1. Adult patients >=18 years of age (no upper age limit) with active definite or active probable RA, who are under the care of a consented health care professional. Active disease is defined by meeting at least one of the criteria below:
1.1. A DAS28 score of 3.2 or above recorded within 6 months of the baseline visit or as assessed at the baseline visit.
1.2. A change in Disease-Modifying Antirheumatic Drug (DMARD) or steroids administered in the last 6 months for RA.
1.3. Follow-up visits more frequently than annually i.e., anticipated to have at least one follow-up visit in the next 12 months from the baseline visit.
2. Own or have daily access to an Android or iOS smartphone or tablet with PIN code security, software version that supports the app, and the ability to access the internet daily to support data upload.
3. Regular access to a valid email address.
4. Have an NHS login account or is willing to create an NHS login account.
5. Have a medical record that can be viewed either by direct access or web-based access to the Greater Manchester Care Record (GMCR) (for patients in the Greater Manchester region) or the Whole Systems and Integrated Care (WSIC) tableau server (for patients in the North West London region).

6. Individuals who speak and understand English or can be supported by someone who can (if individuals have limited ability to read, speak, write or understand English they must have support from someone who can speak, read and understand English).
7. Can follow the requirements of the study independently or with support, including downloading the REMORA app onto a smartphone or tablet device.
8. Have capacity and are capable of providing full written informed consent.

INTERVIEWS
Patient interviews:
Recruitment target across clusters: up to 30 patients in usual SoC and 30 patients in the integrated symptom-tracking group
1. Patients eligible and consented to take part in the stepped wedge trial who are able and willing to be interviewed
2. Provide full informed consent either in writing or verbally before or at time of interview

Interviews with healthcare professionals, volunteers or professionals involved in the implementation of REMORA2

Healthcare professional interviews
1. Healthcare professionals working in a trial site who have indicated willingness to be interviewed
2. Provides full informed consent either in writing or verbally before or at time of interview

Non-REMORA2 healthcare professional interviews
1. Healthcare professionals working in a trial site who have declined to take part in the stepped wedge trial but have indicated willingness to be interviewed
2. Provides full informed consent either in writing or verbally before or at time of interview

Interviews of any professionals or volunteers involved in the implementation of integrated symptom tracking, including NHS staff
1. Any professionals or volunteers, including NHS staff, involved in the implementation of REMORA2 at a trial site, in collaborating organisations or within the community
2. Individual indicates willingness to be interviewed
3. Provides full informed consent either in writing or verbally before or at time of interview

Participants in interviews to identify barriers to digital inclusion:
1. Patients who were approached and eligible to join the trial but declined
2. Patients who consented to trial but did not register the app for any reason (including ill health)
3. Patient able and willing to be interviewed
4. Capable of providing full informed consent either in writing or verbally before or at time of interview

OBSERVATIONS
Patient observed clinics:
1. Patients eligible and consented to take part in the stepped wedge trial who are willing to be observed during a clinic consultation either in person or remotely
2. Patient able to understand the project information and reason for participation
3. Capable of providing full written informed consent

Healthcare professional observations:
1. HCP has consented to be involved in the REMORA2 trial
2. HCP indicates willingness to have clinic consultations observed either in-person or remotely
3. Provides full written informed consent

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
TRIAL PARTICIPANTS
Healthcare professionals who:
1. Do not have responsibility for the assessment and care of patients with RA
2. Do not have responsibility for treatment decision-making
3. Do not have access to the medical record at site as part of routine care
4. Healthcare professionals who are not willing to participate in the stepped wedge trial and review the REMORA dashboard during clinical interactions
5. Do not provide full written informed consent

Patient trial participants:
1. Do not have definite or probable RA
2. Do not have active definite or active probable RA at the time of recruitment
3. Do not own or have daily access to a compatible smartphone device or tablet
4. Do not have or unwilling to add PIN code security on the device
5. Do not have access to an email address
6. Do not have or is unwilling to create an NHS login account
7. Do not have a medical record in the GMCR or WSIC platforms
8. Patients who do not understand relevant project information (despite support, if needed)
9. Patients who are unwilling or do not have the capacity to provide full written informed consent

INTERVIEWS
Patient interviews:
1. Patients have not consented to take part in the stepped wedge trial
2. Patients who are not willing to participate in an interview
3. Patients who are not able to understand the project information and reasons for participation (despite support, if needed and available)

4. Patients who have taken part in the REMORA2 feasibility study between January and July 2023
5. Patients who are unwilling or unable to provide full informed consent for interview

Healthcare professional interviews:
1. HCP who is taking part in the stepped wedge trial but is not willing to participate in an interview
2. Do not provide full informed consent

Non-REMORA2 health care professional interviews:
1. HCP declined to take part in the stepped wedge trial and is not willing to participate in an interview
2. Do not provide full informed consent

Interviews of any professionals or volunteers involved in the implementation of integrated symptom tracking, including NHS staff
1. Professionals or volunteers, including NHS staff, not involved in the implementation of REMORA2 at a trial site, in collaborating organisations or within the community.
2. Individual is not willing to participate in an interview
3. Does not provide full written informed consent

Participants in the interviews to identify barriers to digital inclusion:
1. Patients who are participating in the trial and have registered with the app
2. Patients who are not willing to participate in an interview
3. Patients who are not able to understand the project information and reasons for participation (despite support, if needed and available)
4. Patients who cannot speak and understand English and are unable to attend an interview without an individual for support who can speak and understand English
5. Patients who are unwilling or unable to provide full informed consent for interview

OBSERVATIONS
Patient observed clinics:
1. Patients who are not participating in the stepped wedge trial
2. Patients who are consented to take part in the stepped wedge trial but are not willing to be observed during a clinic consultation either in-person or remotely
3. Patients who are not able to understand the project information and reasons for participation (despite support, if needed and available)
4. Patients who are unwilling or unable to provide full written informed consent for observation of their clinic consultation

Healthcare professional observed clinics:
1. HCPS who are not participating in the stepped wedge trial
2. HCPS who are not willing to have their clinic consultations observed
3. Do not provide full written informed consent

Date of first enrolment
10/06/2024

Date of final enrolment
15/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Royal Royal Infirmary
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Trafford General Hospital
Moorside Road
Urmston
Manchester
United Kingdom
M41 5SL

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre

Fairfield General Hospital
Fairfield General Hospital
Rochdale Old Road
Bury
United Kingdom
BL9 7TD

Study participating centre
Rochdale Infirmary
Whitehall Street
Rochdale
United Kingdom
OL12 0NB

Study participating centre
Pennine MSK Partnership
Oldham Intergrated Cc
New Radcliffe Street
Oldham
United Kingdom
OL1 1NL

Study participating centre
Stepping Hill Hospital
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Bolton Royal Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Wrightington Hospital
Hall Lane

Appley Bridge
Wigan
United Kingdom
WN6 9EP

Study participating centre
Tameside General Hospital
Fountain Street
Ashton-under-lyne
United Kingdom
OL6 9RW

Study participating centre
St Mary's Hospital
Praed Street, London,
London
United Kingdom
W2 1NY

Study participating centre
Hammersmith Hospital
Du Cane Road
Hammersmith
London
United Kingdom
W12 0HS

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Central Middlesex Hospital
Acton Lane
London
United Kingdom
NW10 7NS

Study participating centre
Chelsea and Westminster Hospital
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
Versus Arthritis

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202030

Results and Publications

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?
Protocol article		15/10/2024	17/10/2024	Yes	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