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Preparing to deliver a stepped wedge cluster-randomised trial to test the effectiveness of daily symptom tracking integrated into electronic health records for managing rheumatoid arthritis: a mixed-methods feasibility trial

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Abstract

Background We sought to assess the feasibility of a stepped-wedge cluster-randomised trial testing the effectiveness of a complex mHealth intervention called REMORA: a co-designed smartphone app enabling daily, weekly and monthly symptom tracking integrated into electronic health records for people with rheumatoid arthritis (RA).

Methods We conducted a mixed-methods feasibility trial using a convergent approach with some explanatory sequential elements. Patients were eligible to take part if they were older than ≥ 18 years of age, had (suspected) RA or undifferentiated inflammatory arthritis, and consented to take part from two outpatient departments. We analysed quantitative app and electronic health record data descriptively. We analysed qualitative data from interviews and clinic observations thematically. We assessed four feasibility domains: recruitment and consent (target: 15 patients per site), intervention uptake ($\geq 70\%$ of recruited participants completed on-boarding, i.e., registered with the app and submitted at least one symptom report), intervention adherence ($> 50\%$ daily symptom reports provided), and measuring disease activity as the primary outcome (scores available for $\geq 80\%$ of people with a follow-up clinic visit). Due to time constraints, we only recruited patients to the intervention group, leaving us unable to test the logistics of randomising sites in accordance with the trial's cluster stepped wedge design.

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Results Of 130 people screened, 52 consented. Of those, 32 (62%) completed on-boarding. On-boarded participants provided symptom data on 2384/3771 (63%) of possible days. Among the 48 people who had ≥ 1 follow-up appointment, at least one disease activity score was obtained for 46 (96%) of them. Factors related to intervention uptake formed the biggest threat to trial feasibility, including lack of clarity of communication and guidance, access to technology, and personal challenges (e.g., being busy or unwell).

Conclusion We found that delivering a trial to test the effectiveness of integrated symptom tracking in rheumatology outpatient settings was feasible. The future REMORA trial will contribute to the much-needed evidence base for the impact of integrated symptom tracking on care delivery and patient outcomes, including decision-making, patient experience, disease activity, and symptom burden.

Trial registration This feasibility trial was registered at <https://www.isrctn.com/> on 23-Jan-2023 (ISRCTN21226438).

Keywords Rheumatoid arthritis, Feasibility studies, Patient-generated health data, Smartphone applications, mHealth, Symptoms

Introduction

Rheumatoid arthritis (RA) is an exemplar for long-term conditions that may benefit from remote monitoring, with data integrated into health information systems and clinical workflows [1]. People living with RA, a common immune-mediated inflammatory disease, typically receive outpatient rheumatology care 1–4 times a year, with fluctuations in well-being and symptoms, such as pain and fatigue, between visits [2–4]. Recall and descriptions of these fluctuations are poor, hampering optimal clinical and self-management [2, 4, 5]. Developments in mobile technology and health apps have revolutionised possibilities for clinical- and self-management of long-term conditions, including rheumatic diseases (such as RA), by minimising the reliance on patient recall through frequent symptom tracking and therefore providing a clearer and more accurate picture of changing symptoms through time [2, 6].

Up to 86% of people with rheumatic diseases are willing to use symptom monitoring apps to improve their disease management [7, 8], and healthcare professionals responsible for treating RA perceive a benefit from gaining insight into the day-to-day lived experience of their patients [9]. Evidence from a range of long-term conditions has indicated that the collection of patient-generated health data and its integration into electronic health records (EHRs) could improve shared decision-making and patients' satisfaction and self-management, and decrease anxiety [4, 8, 10–12]. Further potential benefits may include more efficient utilisation of healthcare services, benefiting not just patients, but service providers and the wider economy [13].

Despite growing interest in integrating these complex remote monitoring interventions into clinical systems and processes, evidence of their impact on services and outcomes remains scarce [14]. Previous studies were not randomised, small (e.g., single centre studies), recruited a highly selected sample, collected symptoms infrequently (weekly/monthly), used low-tech interventions (e.g.,

SMS), and/or did not integrate the tracked symptom data in EHRs [14–18].

We previously demonstrated proof-of-concept of the REmote MONitoring of Rheumatoid Arthritis (REMORA) system, a complex mHealth intervention that enables people living with RA to track their symptoms daily, integrate REMORA data into the EHR and share these with their rheumatology team [6]. Having shown that both patients and clinicians were positive about the intervention, we wished to scale up its use and study its impact on clinical outcomes using a multi-centre stepped wedge cluster randomised trial; in the remainder of the manuscript, we refer to this trial as the “REMORA trial” [19]. The trial aims to evaluate the effectiveness of the integrated symptom tracking intervention on care delivery and patient outcomes, such as disease activity, decision-making, patient experience, and other patient priorities, such as pain and fatigue.

Prior to undertaking the REMORA trial, we needed to gain a comprehensive understanding of the likely feasibility of, and potential barriers to, conducting such a trial, to understand whether it would be feasible to proceed, and to optimise recruitment and participation. Therefore, the current study aimed to better understand the feasibility of our proposed trial by assessing rates of recruitment and consent, intervention uptake, intervention adherence and primary outcome completion, and exploring the factors that influenced these rates.

Methods

Context: a planned cluster-randomised stepped wedge trial to evaluate the effectiveness of integrated symptom tracking (the REMORA trial)

The REMORA trial formed the context for the current feasibility trial and guided its design. The REMORA trial will be conducted within 16 rheumatology outpatient departments (i.e., sites) in England, United Kingdom (UK), using randomisation at site-level (i.e., cluster randomisation). Randomisation will follow a stepped wedge

design, i.e., randomisation determines the time at which sites switch over from recruiting participants to standard-of-care to integrated symptom tracking. This means that patients who are recruited after a site's switch-over will be allocated to using the integrated symptom tracking intervention (see Figure S1 for a visualisation of the trial design). Follow-up will last 12 months from date of recruitment for each participant, with clinical evaluation based on routine visits requested by clinical care teams, rather than additional research visits. The primary outcome measure will be disease activity as recorded by clinical care teams; disease activity score for 28 joints (DAS-28) for in person appointments and clinical disease activity index (CDAI) for remote appointments [20]. Secondary outcomes, collected via web surveys, include patient reported symptoms (e.g. pain, fatigue), work productivity and disease activity (e.g. joint counts, patient global). A mixed-methods process evaluation will determine the effectiveness, and underlying mechanisms, of the intervention. We refer to the REMORA trial protocol for further details [19].

Feasibility setting, participants, intervention, and procedures

Design and setting

We reported the current feasibility trial in accordance with the CONSORT 2010 statement extended for pilot and feasibility trials [21] and the consolidated criteria for reporting qualitative research (COREQ) [22] (Tables S1 and S2 in the supplementary material).

We conducted an integrated mixed-method feasibility trial [23, 24] that complemented assessment of traditional quantitative feasibility performance measures (such as rates of recruitment and intervention uptake) with qualitative data on participants' experiences and suggestions for overcoming barriers to successful trial delivery. We used a convergent approach (i.e., concurrent data collection and analysis) with some explanatory sequential elements (i.e., quantitative data analysis guided some of the qualitative data collection and analysis) [25]. The study took place in two rheumatology outpatient departments in Greater Manchester, United Kingdom. Although we had originally planned to test the logistics of sites switching over from recruiting patients to standard-of-care to recruiting them to the intervention group, time constraints meant we were unable to assess this aspect as part of the feasibility trial.

Participants

We first recruited and consented rheumatology healthcare professionals responsible for patient care to take part in the study. This included consent for reviewing the symptom tracking data in consultations for consented patients with an optional interview and/or clinic

observations. Site recruitment teams then identified potential patient participants under the care of consented healthcare professionals. Eligible patients were adults (i.e. ≥ 18 years of age) with confirmed or suspected RA or undifferentiated inflammatory arthritis, and an Android or iOS smartphone with daily internet access. They were asked to report daily, weekly, and monthly symptoms tracking using the REMORA app (see 'Intervention' below for more detail). No restrictions were placed on the level of disease activity experienced by patients at the point of consent. As the REMORA app was only available in English, we excluded patients who could not speak and understand English and had no support from someone who did.

Potential participants were given a participant information sheet (including a section on 'What is the purpose of the research') and time to review the study information and ask questions, before providing informed consent to take part in the feasibility trial. We also asked consent to be contacted for an additional interview and/or consultation observation. Individuals who declined participation in the feasibility trial were asked consent for being interviewed about their reason(s) for not wanting to take part; we did not keep a record of how many and why people refused to be interviewed or observed. Written or verbal consent before interviews and/or observations was obtained.

Intervention

The REMORA system is a complex mobile health (mHealth) intervention comprising a co-designed smartphone app that enables people living with RA to track their symptoms daily, weekly and monthly. The app is linked to regional data infrastructure for integrating symptom data into participating local hospitals' EHR systems; this facilitates review of the data at forthcoming outpatient consultations. REMORA has been co-designed with members of our patient and public involvement and engagement (PPIE) group, who have been instrumental in developing and refining the app and supporting materials. The REMORA system was well received by patients and healthcare professionals in an initial proof-of-value study at a single site and showed potential to enhance clinical encounters [26].

REMORA users provided daily reports for the seven symptoms from the Rheumatoid Arthritis Impact of Disease (RAID) score [27] on 0–10 visual analogue scales (VAS): pain, function, fatigue, sleep, physical well-being, emotional well-being and coping; they also reported their duration of morning stiffness on a 7-point ordinal scale. They were also asked to submit weekly and monthly questionnaires on domains such as self-reported flares, work productivity [28], and disability [29] (supplementary figure S2 shows screenshots of the REMORA app).

This patient-generated symptom data was automatically sent daily to a secure server managed by the regional Integrated Care Board (i.e., the body responsible for regional healthcare service delivery). Data was then presented graphically via a bespoke, interactive REMORA dashboard available within the local EHR system using single sign-on. This meant that when a healthcare professional logged onto a particular patient's record, they had immediate access to that patient's symptom data without the need to sign-on again or searching for the patient. Healthcare professionals received training for accessing and using the dashboard to support them reviewing the symptom data, discussing this with the patient during their consultation, and making treatment decisions accordingly. Symptom data was not routinely reviewed in between visits and patients were advised to use normal procedures for seeking help in the event of flare or difficulty. Data was only visible to healthcare professionals who had undergone training and been provided with access (see supplementary figure S3 for a screenshot of the interactive dashboard).

Trial procedures under evaluation

We evaluated the feasibility of the REMORA trial's design and processes across four feasibility domains: (1) Recruitment and consent, (2) Intervention uptake: "On-boarding", (3) Intervention adherence: "Completeness of symptom tracking", and (4) Outcome measurement. We specified *a-priori* criteria to assess each domain (Table 1). These criteria were informed by our previous proof-of-concept study [6], discussions with the research team and our PPIE group, and peer-reviewed as part of applying for external funding for the REMORA trial.

Recruitment and consent Sites were asked to recruit as many members as possible of the rheumatology teams primarily responsible for making treatment decisions, to maximise available patient participants and for ease of follow up by teams. Sites were then each asked to recruit up to 30 eligible patients over a period of 13 weeks, with a minimum target of 5 per month (i.e., the 15 participants

per site required to meet the "Trial feasible" threshold). This sample size allowed us to estimate a participant follow-up rate of 80% to within a 95% confidence interval of $\pm 14\%$.

Intervention uptake: "On-boarding" Following consent, trial participants received a welcome email with instructions to download, register with and use the REMORA app (Fig. 1). The welcome email included a link to a baseline web survey for collecting additional demographic data and secondary outcome measures, including work productivity, disability and resource use. Participants were considered 'on-boarded' if they appeared in app registration logs as having successfully submitted their unique study identifier and activation code, completed permissions to link and create/use the NHS login, and submitted at least one symptom report. An active on-boarding window sought to encourage on-boarding within 18 days of the initial email being sent. Non-registration reminders were sent 3, 7 and 14 days after the initial invite, as required, via email. 'Non-tracking' reminders were sent to participants who had registered in the app successfully but had not recorded any symptoms within 3, 7 and 14 days of registration. Participants who had not completed on-boarding by day 18 were considered to have failed on-boarding. Registration after day 18 was possible but was not actively encouraged by further reminders.

Intervention adherence: "Completeness of symptom tracking" An in-app notification prompted participants each day to complete their daily (at 6.30 pm, confirmed as a feasible time in our proof-of-concept study [6]), weekly (at 3.30 pm) and monthly (at 12.00 pm) questionnaires. Participants were followed for up to 6 months. Adherence to symptom tracking was calculated based only on the completion of the daily questionnaires. Additional reminders to symptom track were sent on up to two occasions if people had not completed at least one symptom per day on at least 50% of days between tracking commencement and days 7 and 14. In addition to this formal domain criteria, we explored adherence against *a-priori*

Table 1 A priori assessment criteria used to evaluate the feasibility domains in this feasibility study

Domain	Assessment criteria	Trial feasible	Trial feasible with adjustments	Trial not feasible
(1) Recruitment and consent	Number of patients per site consented to symptom tracking	≥ 15	11–14	≤ 10 per site
(2) Intervention uptake: "On-boarding"	Proportion of consented participants who successfully downloaded and registered with the app and completed at least one symptom report	$\geq 70\%$	50–69%	$< 50\%$
(3) Intervention adherence: "Completeness of symptom tracking"	Proportion of study days on which participants recorded at least one symptom out of all possible days	$> 50\%$	25–50%	$< 25\%$
(4) Outcome measurement	Proportion of participants who had ≥ 1 follow-up visit and at least one disease activity score available	$\geq 80\%$	50–79%	$< 50\%$

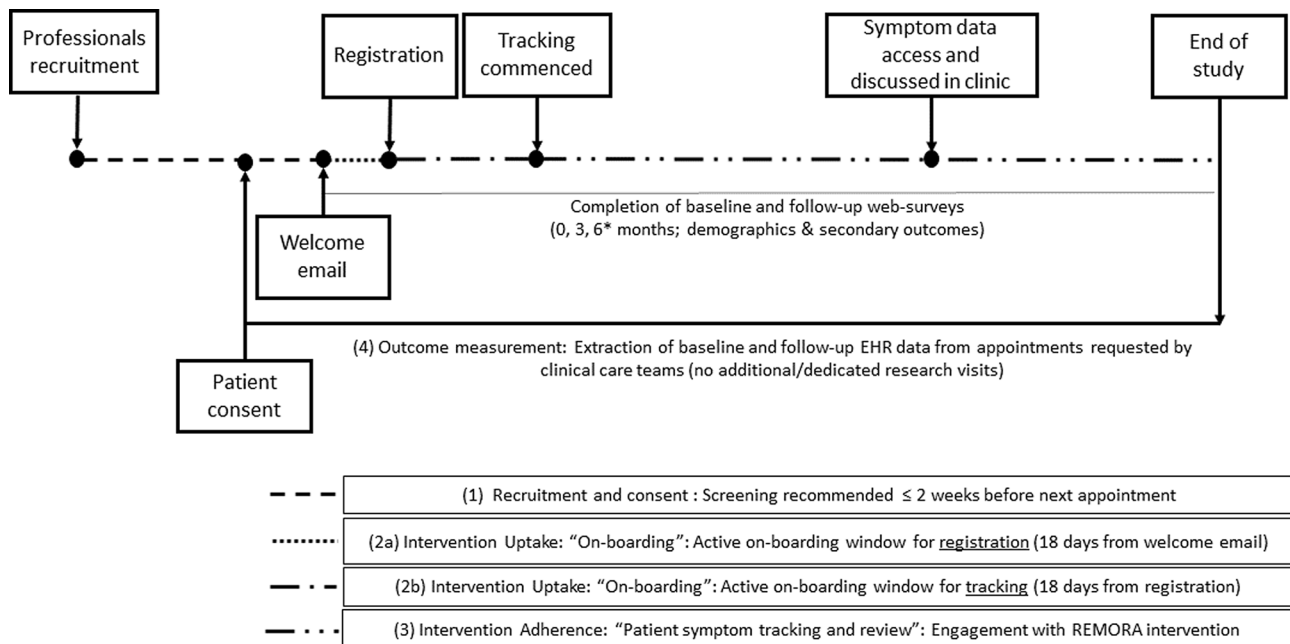


Fig. 1 Study design for the feasibility trial. *Although data collection was intended to run for up to 6 months, no participants achieved 6 months follow-up, so no requests to complete the 6-month web survey were sent

defined adherence clusters of low (<25% days), moderate (25–60% days) and high adherence(>60% days).

Outcome measurement Site staff extracted data from EHRs at baseline and for all follow-up visits that occurred in the follow-up window (up to 6 months). Data included demographics at baseline, clinical history, and disease activity. Collection of disease activity by clinicians during the clinical consultation is the primary outcome of the main trial, via the DAS28 for in-person appointments or CDAI for remote appointments, and thus successful completion of these metrics was the focus for our outcome measurement evaluation.

Data collection

Demographics

Baseline demographic data were primarily collected from the EHR by site staff using a secure study-specific electronic data capture tool hosted at the research team's institution. Extracted data included participants' sex, date of birth (to calculate age), ethnicity, smoking status, Body Mass Index, recorded diagnosis (RA, suspected RA, undifferentiated inflammatory arthritis) and date of diagnosis (to calculate disease duration). Missing data for ethnicity and smoking status were replaced with data from a self-report web survey completed by participants at baseline.

Feasibility evaluation

The data for evaluating the feasibility of our proposed trial design came from a range of sources (Table 2).

Briefly, quantitative data was obtained from sites, the app or via EHR extractions pertaining to screening and recruitment, app registration and daily symptom reports, and availability of disease activity scores. Healthcare professionals were asked to record how REMORA data were used within their consultation and whether they found it useful.

Two researchers (YM and SS) conducted interviews via phone, video call or in person (depending on interviewees' preferences) and observations in clinic using a pilot-tested topic guide. Both researchers were female, had PhDs, worked as post-doctoral research associates at the University of Manchester (UK), had significant experience in qualitative research, and had completed good clinical practice training. No relationship was established between the researchers and participants prior to data collection taking place. Interviews were conducted among (1) patients who declined symptom tracking participation ("decliners"), (2) those who consented to study participation, but did not register with the app by day 18 ("non-registered participants"), (3) those who registered with the app, stratified based on their level of adherence (see 'Quantitative data analysis' below for definitions), and (4) healthcare professionals. Participants were only interviewed once. A series of professional-patient dyads were also observed during consultations, where both parties had provided optional consent for their consultations to be observed. We observed up to a maximum of one and three consultations per patient and professional, respectively. Study team logs were maintained throughout the trial to detail field notes from interviews/

Table 2 Data sources used to explore the feasibility domains: (1) Recruitment and consent, (2) Intervention Uptake: “On-boarding”, (3) Intervention Adherence: “Completeness of symptom tracking”, (4) Outcome measurement

Data source	Description	Feasibility Domains			
		(1)	(2)	(3)	(4)
Screening/recruitment logs	Screening and recruitment logs were provided by sites, detailing the number and outcome of patient approaches, and reasons for ineligibility or declining participation.	X			
Quantitative data on registration rates (via app records)	Registration logs (including study identifier and date of registration) were obtained from the app records and used to calculate the rate of registration.		X		
Quantitative data on adherence rates (via app records)	App records provided information about all symptoms reported by participants each day, linked to their study identifier. Participants were considered to have “engaged” with the app on a day on which they provided at least one of the 8 daily symptom reports (see ‘Intervention’ description for more detail).			X	
Quantitative data on availability of disease activity at baseline/follow-up (via EHR extraction)	A comprehensive selection of data was extracted from the participants’ EHRs and inputted into a secure study-specific database. Of interest here are disease activity data only.				X
Healthcare professional reported symptom data use (questionnaire)	A brief survey recorded healthcare professionals use of the REMORA data within their consultation, including information about when they looked at the data, whether they looked at the data with the patient and how useful the data were. A free-text box was provided for any additional comments regarding how data were used during the consultation.			X	
Interviews with patients or clinicians	One-to-one semi-structured interviews (duration 7–35 min) took place by telephone, face-to-face, or using video-conferencing software, depending on participant preference. Discussion topics included the use of technology for health monitoring in general and, where applicable: 1. perceptions of the REMORA system 2. the impact of REMORA system and tracked symptom data on the clinical consultation and decision making 3. reasons for their (lack of) adherence with symptom tracking 4. reasons for declining participation in the study, or for not completing on-boarding	X	X	X	
Observations	Observations (duration 12 to 36 min) of consultations.			X	X
Study team logs	Study team logs comprised field notes from interviews, observations and summaries of contact/correspondence with participants or site staff via phone or email.	X	X	X	

observations and summaries of contact (phone/email) between the study team and participants or site staff.

Data analysis

Quantitative data analysis

We evaluated study performance descriptively against the assessment criteria presented in Table 1, by determining rates of recruitment, on-boarding, adherence (based on the proportion of possible days on which participants tracked their symptoms) and completion of the primary outcome measure. We also explored adherence in terms of membership of one of the a-priori defined adherence clusters (see ‘Intervention adherence: Completeness of symptom tracking’ above), though this did not formally contribute to our feasibility criteria (1) and (2).

Qualitative data analysis

Interviews and observations were audio-recorded, transcribed, deidentified and thematically analysed using [30] NVivo 12 Plus software. The Theoretical Domains Framework guided our analysis of data from patients who tracked their symptoms by providing a lens for considering how the intervention influenced participants’ behaviours [31, 32]. For analysing the healthcare professional

interviews and clinic observations, the Three Talk model of shared decision-making served as a guide [33] to examine the collaborative decision-making process between patients and professionals. The two researchers (YM and SS) systematically collated preliminary codes into potential themes using a constant comparative method, with review sessions with the wider research team to ensure that data extracts effectively represented analytic themes and to identify further subthemes where these emerged from the data. We did not share transcripts or findings with participants for feedback.

Study team logs were reviewed to complement the quantitative and qualitative data analyses by providing additional insight and contextual information.

Mixed-methods interpretation

Following guidance by Aschbrenner et al. [25], we created joint displays to bring together findings from the quantitative and qualitative analyses and interpret them together using an integrative approach.

Results

Recruitment and consent

Across both sites, a total of 130 patients were screened for participation, of whom 78 (60%) were excluded as they either declined participation ($n=38$, 49%) or were otherwise unable to take part ($n=40$, 51%). For the latter group, the most common reason for not being consented was that we lost contact or could not reach people during the consent process ($n=21$, 53%), which is a common logistic challenge in trials. This was followed by a lack of access to appropriate technology (smartphone/email; $n=10$, 25%), an inclusion criterion that research nurses could not assess from information in the EHR when screening. Other reasons are shown in Fig. 2. In total 52 people were consented (20 at site 1 and 32 at site 2), which returned a “Trial feasible” evaluation for Domain (1).

Intervention uptake: “On-boarding”

Among the 52 people recruited and consented (site 1: 32, site 2: 20), two (4%) withdrew before commencing on-boarding and 18 (36%) did not complete on-boarding, with the remaining 32 (62%) successfully completing on-boarding (see Table 3). Thus, we returned a “Trial

feasible with adjustments” evaluation for Domain (2). To support on-boarding we sent participants a total of 76 email reminders. Of those 76, 66 reminders were sent for non-registration to 37 participants, of whom 17 (46%) then completed registration. Table S3 in the supplementary materials shows no substantial differences between those who were consented and those who on-boarded, though more people of white ethnicity appeared in the on-boarded group (94% (95%CI: 79–99) vs 87% (74–94), respectively).

Intervention adherence: “Completeness of symptom tracking”

Among the 32 on-boarded participants, participants provided symptom data on 2384/3771 (62%) of possible days. Twenty (62%) participants achieved high adherence (see Table 3), while the low and moderate groups each comprised six (19%) participants. Nine reminders were sent to seven participants for having less than 50% of days since tracking, with two of them having a final completion rate of 78% and 97%. We observed few differences between low versus high engagers, though low engagers ($n=6$) were younger (median (interquartile range) years: 42 (35–55)) than the high engagers ($n=20$;

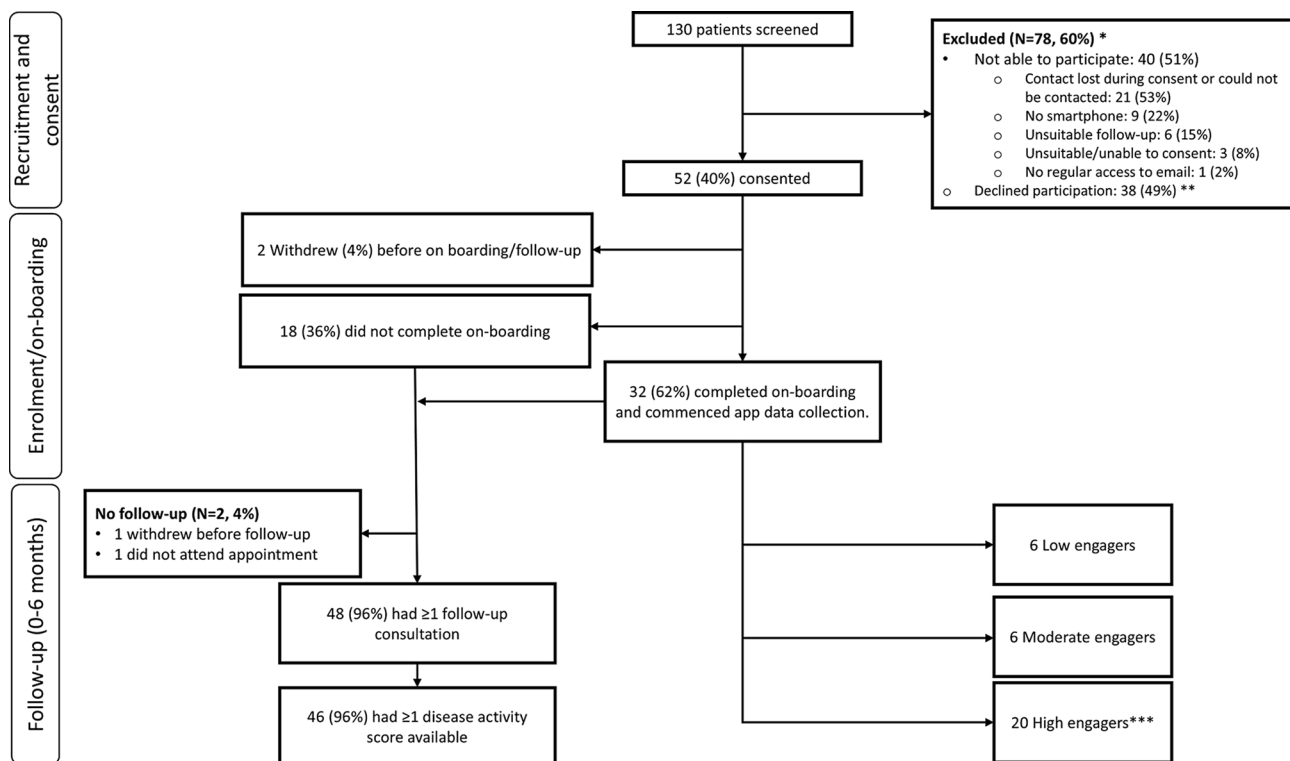


Fig. 2 Flowchart of the REMORA2 feasibility trial domains (1) Recruitment and consent, (2) Intervention Uptake: “On-boarding” and (3) Intervention Adherence: “Completeness of symptom tracking”. Low adherers—symptoms reported on <25% days; Moderate adherers—symptoms reported on 25–60% days; High adherers—symptoms reported on >60% days. *We were unable to collect data on people who were excluded after screening as we did not have their consent to do this; **Some reasons for declining participation, explored during ‘decliner interviews’ can be found in Table 4; ***Includes one participant who withdrew after 9 days but was classified as a high engager while in the study

Table 3 Comparisons of demographic characteristics for a) those who were recruited versus those who on-boarded and b) low versus high adherers¹

		Recruited vs on-boarded participants		Low vs High adherers ¹	
		Recruited (n = 52)	On-boarded (n = 32)	Low (n = 6)	High (n = 20)
Female (n, (%))		36 (69%)	23 (72%)	6 (100%)	13 (65.0%)
Age (median (IQR))		58 (48–65)	57 (48–63)	42 (35–55)	61 (51–65)
White ethnicity (n, (%))		45 (87%)	30 (94%)	4 (67%)	20 (100%)
Smoking ² (n, (%))	Current	11 (21%)	5 (16%)	1 (17%)	3 (15%)
	Former	22 (42%)	13 (41%)	2 (33%)	9 (45%)
	Never	18 (34%)	13 (41%)	3 (50%)	8 (40%)
BMI ³ (n, (%))	Normal	17 (33%)	11 (34%)	2 (33%)	5 (25%)
	Over	19 (36%)	10 (32%)	1 (17%)	9 (45%)
	Obese	16 (31%)	11 (34%)	3 (50%)	6 (30%)
Diagnosis ⁴ (n, (%))	RA	50 (96%)	31 (97%)	6 (100%)	20 (100%)
	Suspected RA	1 (2%)	1 (3%)	0	0
	UA	1 (2%)	0	0	0
Disease duration (median (IQR))		3 (0–10)	4 (0–11)	1 (0–6)	3 (1–11)

Abbreviations CI confidence interval, IQR interquartile range, RA rheumatoid arthritis, UA Undifferentiated inflammatory arthritis

¹Low adherers—symptoms reported on <25% days; High adherers—symptoms reported on >60% days

²smoking status missing from medical record for one on-boarded participant

³No one is underweight, so category omitted

⁴No one suspected IA, so category omitted

61 (51–65) and had a shorter disease duration (years: 1 (0–6) vs 3 (1–11) (Table S3 in supplementary material). Given that adherence rates exceeded the >50% threshold, we achieved a “Trial feasible” evaluation for Domain (3).

Outcome measurement

Figure 3 shows that, among 50 consented participants who did not withdraw before on-boarding, 49 were eligible to have a follow-up visit during the study window as one participant withdrew after nine days in the study, prior to follow-up. Of those 49, 48 (98%) had ≥1 appointment, of whom 46 (96%) had ≥1 disease activity score completed by a clinician in the consultation. Compared to the upper threshold of ≥80%, we therefore achieved a “Trial feasible” evaluation for Domain (4).

Overall evaluation of feasibility domains

In summary, when comparing our quantitative findings to the assessment criteria outlined in Table 1, we confirmed that the REMORA trial was feasible for domains (1), (3) and (4). However, we found on-boarding rates were sub-optimal, suggesting that domain (2) (intervention uptake) required adjustments to enhance its feasibility.

In total, we interviewed 28 patients, ranging from 23–80 years old and mostly women identifying as white and British. In addition, we interviewed seven healthcare professionals and observed five consultations. Interviews and observations lasted 7–35 and 12–36 min, respectively. Analysis of our qualitative data sources suggested thematic saturation and identified five challenges which differentially impacted on all four of the feasibility domains and should therefore be considered for modification in the main trial. The challenges which affected domain (2) will be discussed in detail below, with all other challenges being summarised and illustrated with quotes (where available) in Table 4.

Clarity of communication and guidance

Site staff and patient participants brought up issues around the clarity of communication and guidance. For example, some patient participants reported problems

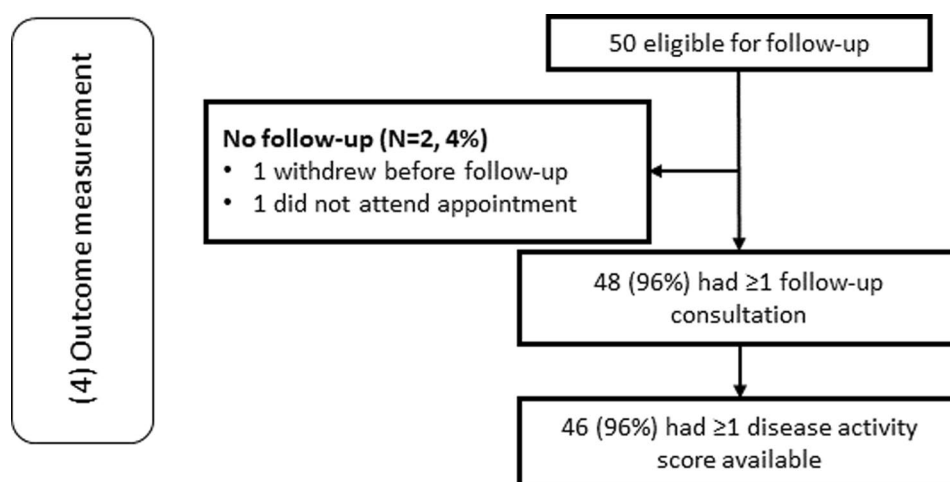
**Fig. 3** Flowchart of the REMORA2 feasibility trial domain (4) Outcome measurement

Table 4 Description of challenges and the feasibility domains they affected; (1) Recruitment and consent, (2) On-boarding, (3) Symptom tracking and review, (4) Outcome measurement

Challenge	Sub-themes	Description and illustrative quotes from qualitative data sources	Affected feasibility domains			
			(1)	(2)	(3)	(4)
Clarity of communication and guidance	Clarity of app use at recruitment	Without access to an app demonstration account, staff reported they had struggled to verbally explain the functionality of the REMORA app and what patients would be required to do.	X			X
	Privacy statement	The lack of a comprehensive privacy statement may explain why some people who declined to take part raised concerns about privacy and data security. "Yeah, but still, I am not sure I am not too keen about who uses the data and then if it lost that's stressful." (PD03) Although some of those who consented but did not on-board shared these concerns, others stated they had no concerns about this or asked for and got reassurance about data privacy. "Well, yeah, I mean, obviously I wouldn't want anybody knowing all my information, but I understand, I'm sure it would be, you know, fine, to be honest." (PNR03) "I think it was [name of clinician] that phoned me and initially went through it all, I think I bombarded her with questions really about it all, because we were so up on data protection and everything. So I was a bit concerned, but she just allayed any of my fears really." (PT19) Some participants reported problems with patients downloading or using the app due to a lack of communication or unclear/complex guidance. "[Patient] hadn't downloaded the app. She said that she couldn't understand the instructions. She still wanted to take part in the study, contact number for research team given for advice." – (HPQ01) "No, the only issue I had using your app was the fact that they didn't send me the link. A colleague emailed me saying, I'm sorry we didn't send you the link. So that's why I couldn't get on it. I didn't know what it was looking for." (PNR04) "Yeah, I was told the study would be online through an app or something, but when I got the email... see if I can get a copy. When I click on the pages, it had three attachments and I clicked on one of them and it just came up with a blank screen." (PNR05) A number of additional app features, such as the diary function, were not appropriately described within instructions. "Yeah, and I went through the instructions when I first set it up. Unless I've totally missed something, I don't know, I've never been highlighted or sign-posted towards a diary, but that could be me, I could've missed that. I don't remember anything in the instructions but maybe there was." (PT15)				
	IT requirements for taking part	IT requirements meant some people were unable to participate. A lack of access to a smartphone device, accounting for just over one-fifth (22%) of those who were ineligible to participate. "I had to get a new phone because it didn't have the right issue [version] on. It was obviously a little bit older because I hadn't gone in and updated it on my contract thing." (PT08) "If I didn't need the pin on my phone. It sounds silly doesn't it, but it's just something [...] that I don't want to do. So it's a shame, because like I say, the study itself, everything else, I don't have an issue with at all." (PNR09) Many participants indicated that they only checked emails irregularly or not at all, meaning that communication from the research team were often missed and therefore not actioned. "Yeah, it's like I don't use the computer every day so it's not like I'd re-checked or was aware this was happening. Yeah, like I say, because I wasn't using the computer every day it's not that I didn't want to but never checked the emails." (PNR05) "I don't check the emails regularly." (PNR08)				
	Accessibility				X	X

Table 4 (Continued)

Challenge	Sub-themes	Description and illustrative quotes from qualitative data sources	Affected feasibility domains			
			(1)	(2)	(3)	(4)
Personal barriers	Personal barriers	Personal barriers to participation included: 1. RA-related challenges (e.g. high levels of pain, dexterity, forgetfulness or brain fog) 2. non-RA related challenges (e.g. dyslexia, a lack of confidence with using technology) 3. difficulty integrating the study into everyday life (i.e. when people were too busy, ill, or otherwise committed) at the time of study 4. motivations and perceived benefits, particularly regarding the use of the collected data in clinic, or of health apps more generally. "It's hard for some people, like me, I say, me with my bad fingers. I cannot possibly do such things I will not be able to sustain what I start because of my hands." (PD03) "Because I haven't been well and my brain has been fog. When I got over that bout, I'm still quite poorly with getting over the flu. I've had a bad run of ill health at the moment. I would be willing to download the app and do everything once my medication is ..." (PNR01) "Was unable to enter data - issues with her phone and not being tech savvy. Did seek support but unfortunately did not rectify the issues." (HPQ02) "Maybe, yeah. I'm just that busy that I knew that something was missing but I just didn't follow it up right away because I was mad busy elsewhere." (PNR11) "I [Patient is] Happy to track but found the weekly one not relevant & was busy." (HPQ03) "To be honest, I've not really searched for apps that would help me. The trouble with apps is, there are so many, you don't know if you've got a good one." (PNR10)				
		It was highlighted that those who were more nervous about their ability to participate would have benefitted from greater support available during on-boarding and commencing data collection. Some people had sought additional support from outside of the study team (e.g. friends/family, in clinic). "... patients really want to participate in these trials and want to join in, but it's just way too complicated. Unless... we can have that time to say, 'alright, well if you're happy we'll do it with you there and then' and get them set up and running." (HP101) "... and on top of that I didn't know how to use these devices and would need a lot of help." (PD01) "I didn't realise I had to put a pin code in my phone to stop anybody getting into my phone. It was my daughter that sorted it. I told you I'm not very technical." (PT03)				
		Provision of support				
Symptom data collection	Data collected (type and frequency)	Patient participants queried the type and frequency of data collected, noting: 1. an inability to attribute symptoms like pain solely to RA, rather than also to other diagnoses or concurrent injury. 2. a desire to report only their more severe symptoms, rather than also monitoring minor health issues 3. a preference only to report data during periods of flare or instability, as reporting the absence of symptoms during periods of good health was felt to be unnecessary and a waste of time. "... we've had a few patients that have been saying, 'I don't know what to do about that bit of my pain because that pain I know is not related. So, do I include it or not include it?' (HP101) "... like sometimes my knee or my hip will be hurting, and I'll think, well it is my rheumatoid, or is it because I've done a bit much, or is it a bit of osteo?" (PT05) "Pt reported questions were a bit monotonous. Pt has significant foot symptoms which weren't asked about." (HPQ04) "... daily feels slightly too much. I mean, I do appreciate with RA that it can literally change day-to-day. I do get that but from a user point of view, I think you could risk it being really genuine and reflective because it feels repetitive and it's more like, 'just get it done' sometimes." (PT15) "Well, I just put, 'I'm fine' and that's why I've stopped doing it." (PT01)				
		Engagement				
		Engagement was impacted both by intentional choice to report as much or as little as they wanted, and unintentionally forgetting to use the app, or otherwise missing the reminders. Others indicated that they were interested in the study, but had competing alternative health priorities (e.g. new diagnosis, health anxiety). "I just thought, this isn't going to be a good idea for me, 'cause I'm going to start to struggle with my health anxiety again and I didn't want to go down that road." (PT02)				
					X	

Table 4 (Continued)

Challenge	Sub-themes	Description and illustrative quotes from qualitative data sources	Affected feasibility domains			
			(1)	(2)	(3)	(4)
Symptom data use in clinic	Data availability	<i>I tend to set a reminder on my phone... I think the reminder bit that's built into the app doesn't seem to work that well. (PT14)</i> <i>My problem now is I miss some days because I either miss the notification, if I don't see it on my phone straight away... You don't get more than one reminder. I do sometimes miss it, especially if I am working because I work until eight o'clock. It comes through quite early, the notification to do it. (PT18)</i>				
		Clinicians reported that data were often absent or patchy. In one case it was noted that the participant was recording data in conflict with the experience they reported to their healthcare professional. <i>"Everybody else has tended to, it's just reinforced what they're saying... the only one that's changed is that one lady, because... I looked at her data before she arrived and I thought, 'oh, she's doing really well, this will be an easy consultation'... so she was probably the only one I've had where it's not matched what she's said." (HP101)</i>			X	X
	Confidence and/or motivation to use the data	Interest in using the REMORA app data seemed variable. Several patients mentioned that they were interested in using the data in clinic, but they felt their clinicians were not. Conversely, some clinicians commented that their patients did not seem interested in the use of the data. <i>"I had a rheumatology nurse appointment and I think she did look at it [REMORA dashboard], but after I said that I was on the trial. Whether she would have done or not, I honestly don't know." (PT14)</i> <i>"I had one [appointment] a couple of weeks ago, but he didn't really, he got all the data up on the screen, but he didn't really sort of discuss it... I think it was helping him, 'cause he said, oh brilliant, you know, I can see from this, you've filled it all in ...but he didn't sort of go into much more detail than that." (PT19)</i> <i>"Patient did not seem very engaged in reviewing data but had been tracking" (HPQ06)</i> <i>"I'd turned the computer screen round and encouraged her to shuffle in to look at it. But she didn't really, kind of, take the invitation. Whereas a previous patient had been quite excited and animated about the thought of looking at the data." (HP102)</i> Clinicians highlighted that they would have appreciated more training in data interpretation and use. It was also noted that temporary technical issues prevented data being viewed in consultations in some instances. <i>"I think that it would have been nice to have had some test data to have actually looked at in advance." (HP102)</i> <i>"... we've all struggled to understand what we're looking at. We've had no formal, like, you know, even just an idiot's guide... we had information about the study, and we had meetings about the study, all of us together, as a rheumatology team, but no information... about how to interpret it when we got it. We've just, sort of, figured it out." (HP101)</i> <i>"... the one thing I would've found beneficial is to be able to have a go at it myself." (HP107)</i> <i>"... so we know graphs, that's fairly easy to understand but, obviously, you need to know whether going up's good, or going down's good... a couple of things that were on there weren't things that I was au fait with, I don't think." (HP105)</i>				
Infrastructure	-	The size of available participant pools were impacted by the geographical boundaries of sites and their case-mix (e.g. new diagnoses versus established and controlled diagnoses) of patients. It was felt that issues of staffing and resource availability at specific sites may have impacted on site interest, adherence with the app data, and collection of the primary outcome.	X		X	X
PDxx Patient decliner interview, PNRxx Patient not-registered (or on-boarded) interview, PTxx Patient tracker interview, HP1xx Healthcare professional free text note on symptom data use questionnaire						

with downloading or using the REMORA app due to a lack of communication from the study team or unclear/complex guidance. It was specifically highlighted that the duration of the active on-boarding window was unclear, leaving some participants unsure if they could still register after a delay.

The study materials did not include a comprehensive privacy statement, which may explain why some patients who declined participation raised concerns about privacy and data security (e.g., safety of personal data). Although some patients who consented but did not on-board shared these concerns, many stated they were not concerned about this. This suggests this primarily affected recruitment, and to a lesser extent on-boarding.

Accessibility

Issues of accessibility were defined as any issues impacting only specific groups of patients, such as those who were older, less technologically literate, or more unwell. Accessibility issues had an extensive impact on the on-boarding rates, with some more modifiable than others.

With regards to modifiable accessibility issues, difficulties were experienced among consented participants whose device did not meet the specific requirements (e.g., an older phone running an out-of-date operating system, lack of a PIN code on the device to prevent unauthorized individuals from accessing tracked symptom data). Not all participants were aware of these requirements at the time of recruitment, leading to some being consented without then being able to on-board.

A second substantial challenge was that many participants indicated that they only checked emails irregularly or not at all, meaning that communications from the research team were often missed and therefore not actioned. For some participants, irregularly or not checking emails was normal, while others mentioned that this deviated from their normal email-checking behaviour because they had been busier than normal or had other competing priorities. Regardless, not reading the study instructions sent via email meant patient participants could not on-board.

Some participants also perceived issues surrounding the provision of on-boarding support: those who were more nervous about their ability to participate suggested they would have benefitted from greater support, while others had sought additional support from outside of the study team (e.g. from friends and family, or in clinic). Although participants could request support via email, some found it problematic that no telephone contact information was provided.

Patient participants felt that it could be difficult to integrate the study activities into their everyday life if they were busy, ill, or otherwise committed during the active on-boarding window. It was observed that the

short active on-boarding window did not appropriately account for such events. Additional challenges included personal motivations and perceived benefits. Despite having consented to take part, several patients who did not on-board queried the specific benefits of the data collected within the app and its use in clinic, while others had not engaged with health apps in general or felt overwhelmed by how many were available.

Other, less modifiable personal barriers to participation included RA-related challenges (e.g., high levels of pain, dexterity, forgetfulness or brain fog) and non-RA related challenges (e.g., dyslexia, non-fluency in English, a lack of confidence with using technology).

Discussion

Our mixed-methods feasibility trial demonstrated that our plans to evaluate REMORA within a multi-centre trial would be feasible with respect to recruitment, adherence, and outcome measurement. However, we also found that we require modifications to optimise intervention uptake, as many consented participants struggled to on-board successfully. The most common barriers identified in relation to this included a lack of clarity of communication and guidance relating to downloading and using the app, as well as accessibility issues (e.g., technical and personal challenges).

Comparison to previous studies

In our study, the principal threat to the success of our proposed trial was intervention uptake. Previous studies showed that the limited uptake of smartphone apps among specific groups of people negatively affect their access, use and benefits of mHealth solutions [34]. For example, older people and those with lower socioeconomic backgrounds may be more likely to lack the necessary equipment [35] than their younger or more affluent counterparts. This may be a particular concern among those with RA, where prevalence and prognosis are associated with both age and deprivation [36]. In our study, we found that just over one-fifth of screened but excluded participants could not take part because they did not have access to a smartphone at all, or had one that was not compatible with the REMORA app. Furthermore, irregular checking emails and a lack of familiarity with apps in general were reported as barriers to intervention uptake. While we could not link these health equity issues directly to individuals' demographics, it is likely that it included older and more socially deprived patients within our target population.

Another digital determinant of health is digital literacy [37], here referring to an individual's ability to find, create and/or use health related information on or from electronic platforms. Greater digital literacy is associated with a higher belief in the usefulness of solutions

such as health apps [38], which tends to be lower among older populations [39, 40]. In this study, several interviewed patients identified themselves as feeling too nervous to use the REMORA app, or as otherwise lacking adequate skills to participate without further support from the study team. In keeping with other studies [8, 39, 41], our findings suggested potential benefits from providing more structured guidance and tailored education for patients and varying methods of contact with the research team (e.g., email, SMS, phone calls). Evidence also indicates that healthcare professionals' recommendations influence patients' decisions to adopt an app [41]. However, others have found that rheumatologists may be reluctant to use apps such as REMORA due to concerns that mHealth-based symptom monitoring may increase their workload [42]. We note too that in this study both patients and professionals expressed interest in using the app data during consultations but some perceived disinterest from the other party. This suggested that further training and support may be needed to enable integrated symptom tracking to be used effectively as part of shared decision-making during consultations.

Study limitations

One limitation of our study was that, due to a lack of data on the date and approximate time of appointments, it was not possible to triangulate patients' and professionals' perceived use of the symptom data with actual use of this data in clinic as recorded by the interactive REMORA dashboard. We have therefore modified our data collection approach to mitigate this in the REMORA trial. This will now include the date and (approximate) time of the consultation when patients are seen, interactive REMORA dashboard data access logs, and information on both the patients' and healthcare professionals' perceived data use.

A second limitation was that, because of time constraints and logistical challenges, we did not recruit patients to a standard-of-care group, despite this being the case in the main trial to serve as the comparator group. This leaves it unknown if, and how, not receiving the intervention may affect recruitment rates and outcome measurements, as well as whether there may be operational challenges in sites switching over from recruiting to standard-of-care to recruiting to integrated symptom tracking. Mitigations to try and alleviate concerns regarding this include blinding site staff involved in recruitment to the time of switch-over, and extensive and continued engagement with participants as well as those involved in delivering the REMORA trial.

Lastly, a lack of translated versions of the REMORA app into other languages meant we could not recruit individuals who did not read English and had no-one who could help with this. Acknowledging this limitation,

we conducted a separate piece of work to understand barriers to participation among those who do not receive their healthcare in English; a manuscript reporting the findings of this work is currently in preparation.

Implications for trial design and conduct

This feasibility trial was designed to inform the delivery of a multi-centre stepped wedge cluster randomised trial to evaluate the effectiveness of integrated symptom tracking on disease activity and patient-reported outcomes, such as pain, fatigue and mood. We designed the REMORA trial to overcome a number of key methodological challenges from previous studies, such as small sample sizes, non-randomisation and use of low-tech interventions (e.g. web platforms, SMS services) [14–18, 43–46]. Our findings show that it is feasible to overcome these limitations and contribute the much-needed evidence to determine the effectiveness of similar digital health interventions to improve the care and outcomes of people with RA and other long-term conditions.

Based on the findings from the current feasibility trial, we made several modifications to the design of the REMORA trial, which is reflected in our trial protocol [19]. Key modifications include:

1. Clarification of our inclusion criteria, including the technical requirements of devices, to streamline recruitment of eligible participants;
2. Procedures and materials to ensure potential participants are more fully informed about what is required to initiate and maintain symptom tracking; these include co-produced patient information documentation; the development of video-based instructions, and provision of demonstration apps to site recruitment teams;
3. Extending the active on-boarding window for people to join the study, to better reflect that individuals may experience delays in ability to on-board including competing interests or the experience of ill-health, and diversify the method of reminders provided to include telephone calls by the research team;
4. Expanding the ways in which people can obtain support, including the use of a telephone, as well as email, helpdesk and peer support offered by our PPIE group. To further mitigate any issues with individuals infrequently accessing emails, we have also incorporated the use of text messages to alert participants to new email contacts, including welcome and reminder emails.

Conclusions

This study demonstrated that it would be feasible to conduct a trial to test the effectiveness of REMORA, a

co-designed smartphone app with integration of tracked symptom data into electronic health records. We have shown that several challenges impacted on the availability and use of technologies for mobile health studies and intervention uptake. These findings ensured that we are equipped to provide optimised support to enhance the success of the trial and the implementation of the intervention being tested. We believe that the REMORA trial will contribute robust evidence to determine the impact of integrated symptom tracking on key care and disease outcomes among individuals with long-term conditions such as RA.

Supplementary information

The online version contains supplementary material available at <https://doi.org/10.1186/s41927-025-00464-4>.

Supplementary Material 1

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Conceptualization: KLD, YM, SS, DD, JM, CS, SvdV, WGD; Methodology: KLD, YM, SS, DD, JM, CS, SvdV, WGD; Formal analysis/Investigation: KLD, YM, SS, RDBS, DD, JM, CS, SvdV; Data curation: KLD, YM, SS, RDBS, DGJ, DD, JM, CS; Writing - Original Draft: KLD, YM, SvdV; Writing - Review & Editing: KLD, YM, SvdV, HC, SS, DGJ, RDBS, PB, JF, CAS, CJA, DD, JM, CS, WGD; Funding acquisition: SvdV, PB, JF, CAS, CJA, DD, JM, CS, WGD.

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Data availability

Requests for access to data and other study materials should be made in writing to the corresponding author.

Declarations

Ethics approval and consent to participate

The study received ethical approval from the UK Health Research Authority, South Central - Berkshire B Research Ethics Committee (ref: 22/SC/0103). All participants provided informed written or verbal consent prior to participation in the study.

Consent for publication

Not applicable

Competing interests

WGD has received consultancy fees from Google, unrelated to this work. None of the other authors have any conflicts of interest to declare.

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