

Patient and clinician views on an app for rheumatoid arthritis disease monitoring: Function, implementation and implications

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Abstract

Aim: Best practice management for rheumatoid arthritis (RA) involves regular clinical assessment of RA disease activity. This is not achievable with current rheumatology systems of care. We aimed to use opinions from people with RA and their specialist rheumatology healthcare professionals to inform development of a mobile app for people with RA for recording their disease activity data for potential integration into clinical service, and assess usability of the app.

Method: In phase 1 we interviewed nine people with RA and seven healthcare professionals. In phase 2 we developed an app with professional software developers. In phase 3 we evaluated app usability for people with RA using the System Usability Scale (SUS).

Results: Interview data showed four themes regarding functionality and implementation of a patient-held app in RA care: (a) variable app acceptance and readiness; (b) app use to reduce barriers; (c) pros and cons of patient-reported outcomes; and (d) allocation of clinics by need. The app developed has high usability in people with RA using the app on their own device for a month (SUS 79.5, n = 16) or using the app on a study device for 10 minutes (SUS 83, n = 100).

Conclusion: People with RA and healthcare professionals have clearly identified features, benefits and risks of an app for self-assessment of RA and incorporation into clinical care. An app developed informed by these opinions has high usability. Next steps are development and validation of a method of patient-performed joint counts, and implementation, with evaluation, in the clinical setting.

KEYWORDS

mHealth, mobile applications, rheumatoid arthritis, telemedicine

1 | INTRODUCTION

The treat-to-target approach for rheumatoid arthritis (RA) achieves better outcomes for people with RA; however, rheumatology services may struggle to meet the service and care requirements.¹

Treat-to-target mandates initial monthly review for assessment of disease activity, using a composite disease activity (CDA) instrument, and optimization of treatment.^{2,3} Once remission or low disease activity state is reached, review with CDA calculation is recommended every 3–6 months. Even high-income countries have insufficient



rheumatologists to meet this care need^{4,5} with limited rheumatology services in regional and rural areas.^{6,7} Current care does not consistently implement treat-to-target practices, with CDA scores recorded in less than half of clinic visits in real-world settings.⁸⁻¹⁰ Even in rheumatology practices that have enrolled in the Rheumatology Informatics System for Effectiveness continuous quality registry, only 55% of care providers record CDA in at least 50% of clinic visits for RA.¹¹ To achieve widespread and effective adoption of the treat-to-target strategy in RA will require changes in models of care.¹²

New models of service delivery for people with RA, that include nurse-led clinics and patient-initiated review have been shown to be clinically and cost effective¹³⁻¹⁹ but still require personnel and a face-to-face visits for assessment of RA disease activity. A Danish study followed people with established RA with low disease activity, who received telephone monitoring by a rheumatology nurse or rheumatologist. Follow up was informed by a computer-generated self-report RA flare tool, and showed non-inferiority of RA disease activity at 1 year compared to routine clinic visits.²⁰ These data suggest new models of care informed by patient report of disease activity measures may achieve good outcomes for people with RA, without the requirement for regular face-to-face clinical review. This could be implemented via mobile applications (apps) and the internet.^{21,22}

Accumulating evidence suggests the goal of remote patient assessment of RA disease activity via mobile apps or web-based software is feasible, sufficiently accurate and desirable. Preliminary small studies with bespoke mobile apps confirm RA-related impairments do not hinder mobile app data entry²³ and self-reporting may increase empowerment and facilitate shared decision making.²⁴ Over the short term patient self-report of RA disease activity via a web-portal with the Routine Assessment of Patient Index Data (RAPID-3 or -4) has high correlation with rheumatologist-assessed Disease Activity Score of 28 joints (DAS-28) at baseline ($r = .63$) and 12 weeks ($r = .66$).²⁵ A UK-based rheumatology service has overcome the barrier of lack of suitable commercially developed mobile apps^{26,27} by developing a bespoke mobile app for recording and transmission of patient-generated disease activity for people with RA and inclusion of these data in the electronic health record.²⁴ In a 3-month evaluation in a research clinic 20 people with RA and two clinicians found this approach feasible and viewed it as positive in enabling patient-centered consultations. Clinical outcomes were not evaluated and issues of technical implementation in real-world settings, impacts on workflow, and clinical processes were not addressed. Although remote app-based RA disease monitoring has promise, these factors will need consideration in any setting planning to implement RA disease monitoring via mobile technology.

In Aotearoa/New Zealand (NZ) the taxpayer-funded health system has long struggled to provide rheumatology specialist care to a growing, aging and geographically dispersed population.⁵ As smartphone penetrance in NZ is high, even among low socio-economic status communities, and some geographic areas do not have easy access to rheumatology services, exploration of rheumatology service provision supported by patient-generated health data and needs-based appointment scheduling of RA management is of interest.

Any remote monitoring patient management system is more than just software. The input of the users in software development and integration into redesigned services is of utmost importance. In the setting of developing an app for patient-generated health data reporting and needs-based appointment scheduling for follow up of people with RA, our research questions were: what are the requirements for an app for patient-generated health data reporting; what are the opinions and readiness of people with RA and members of healthcare teams caring for people with RA about using an app as part of needs-based service provision; and what are opinions of people with RA on an app developed informed by these data? In particular the aims of this study are to:

1. Assess the opinions of people with RA and healthcare professionals regarding (a) design and functionality, and acceptability and usefulness of an app to complement current service and (b) pros and cons of this approach for assessment of disease activity and organization of monitoring of patient-generated health data and face-to-face visits.
2. Develop an app, informed by information gained from interviews.
3. Assess the usability of the app.

We report a 3-stage study: phase 1 stakeholder interviews; phase 2 app development; and phase 3 evaluation of app usability in research and real-world clinic settings.

2 | METHODS

2.1 | Phase one: stakeholder interviews

2.1.1 | The setting and participants

The Wellington Regional Rheumatology Unit (WRRU) at Hutt Hospital, Hutt Valley, NZ is a referral rheumatology service for a population of approximately 500 000 people, in both urban and rural areas. WRRU employed six rheumatologists (all part-time, total full-time equivalent 2.6), one rheumatology registrar and four specialist nurses. People with RA who had attended WRRU in a 3-month period were phoned in sequence by a research assistant (FR, CAF) inviting participation in an interview about use of apps to monitor RA. Eligible participants were over 18 years of age, had a diagnosis of RA according to the American College of Rheumatology 2010 criteria²⁸ and spoke English. Exclusion criteria were cognitive impairment or inability to be available for a 1-hour interview. Four rheumatologists and three rheumatology nurses from the WRRU volunteered to participate and were individually interviewed.

2.1.2 | Interviews and data analysis

All eligible people with RA telephoned agreed to and completed an interview. Semi-structured interviews were undertaken in person

or by telephone/skype at the participant's preference. Interviews were based on a schedule developed by two rheumatologists (RG, WT) which focused on technology use, use of patient-reported outcomes measures in management of RA, mobile app functionality, barriers and facilitators to app use, and the potential impacts of app implementation on service provision and experience (Appendix 1). The interview schedule was not piloted. Of the nine people with RA interviewed, one research assistant interviewed the first five (FR, female medical student, Bachelor degree) and the remaining four were performed by a second research assistant (CAF, female research assistant previously trained as a dentist, Bachelor degree). Each underwent training with research lead (RG, female, rheumatologist, PhD, experienced in qualitative research). Both interviewers met with RG after the first interview to review the process. Participants were aware of RG's involvement and that interviewers were employed to undertake interviews. Open-ended prompts were used to explore participant opinions. All interviews were audio recorded and transcribed verbatim. Field notes were made at the time of interview to support interpretation of interviews. Interviews were ceased once no new ideas were being offered (ie, saturation reached). The interview schedule for people with RA was adapted for the health professional interviews to explore aspects of app development and how data would be handled at the WRRU and possible impacts on practice (Appendix 2). All interviews with healthcare professionals (HCPs) were undertaken by 1 researcher (CAF).

Data were managed in Microsoft Word documents Version 16.0 (Microsoft Corporation). Content analysis with latent meaning was used as methodological framework²⁹ and subject to thematic analysis.^{30,31} Two researchers (RG, FR) coded the first five participant transcripts by reading the transcripts repeatedly, systematically coding each unit of information (a sentence or part of a sentence) using key words or phrases to set up the basic parameters of the analysis. Codes that clustered into themes were identified and

themes reviewed and named. Where uncertainty or differences in coding occurred, a discussion was held to achieve convergence. A constant comparative approach was taken to ensure coding categories were consistently used. The codes were then grouped together to form categories which became the main themes of the analysis. One researcher (RG) coded the remaining transcripts. Once all the transcripts were coded, RG and CAF reviewed randomly selected transcripts to ensure consistency of coding. Transcripts were not returned to participants for checking or to provide feedback on themes. Data are reported according to the Consolidated Criteria for Reporting of Qualitative Research (COREQ) guidelines³² and the COREQ checklist is provided (Appendix 3).

2.2 | Phase 2: app development

The interview data informed the required content and functionality of an app for patient-generated health data for people with RA in this NZ rheumatology service. A mobile app was developed for both Android and iOS by a commercial software development company (Codeflugel™) using agile project management approach with the design team including a rheumatologist (RG), a computer scientist with expertise in human-computer interface (TL) and a software developer from Codeflugel. The development team met weekly by Skype to review progress and provide feedback, which was incorporated in an iterative manner. User manuals for iOS and Android were prepared to describe how to download the app and instructions on how to download and navigate the app.

The app, called RAConnect, is designed to be held on the phone of a person with RA (Figure 1). Functionality includes: (a) data collection function for RA-relevant validated instruments (all detailed in Anderson et al³³): Health Assessment Questionnaire II (HAQ-II), patient global assessment, 28 swollen and tender joint count,

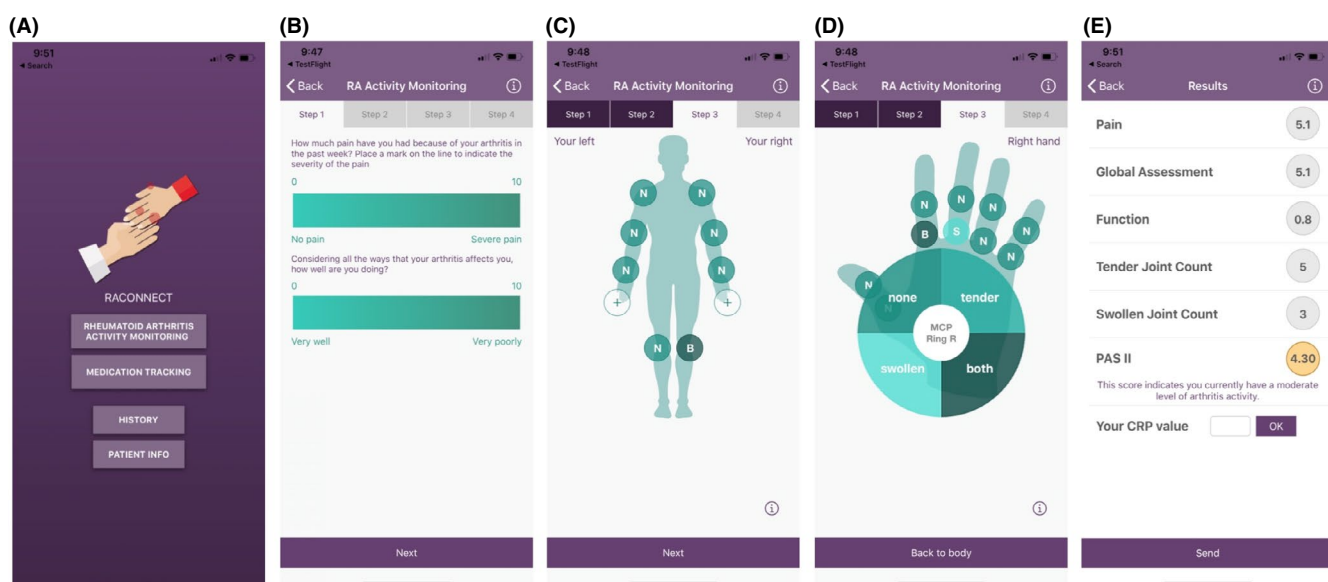


FIGURE 1 RA connect app screen shots. A, Menu. B, Health assessment questionnaire. C, Joint counts-body. D, Joint count-hand detail, E, Summary data



calculates CDA measures (Patient Activity Scale II [PASII], and the patient-reported DAS-28 C-reactive protein [DAS-28-CRP]), along with patient-generated free text comments; (b) medication recording for all commonly used conventional and biologic disease-modifying anti-rheumatic drugs (DMARDs, including start date, dose, stop date and free text for reasons for stopping); and (c) generation of an email report of data to a designated email address, intended to be the treating rheumatologist or rheumatology service. The app supports direct integration with Hutt hospital electronic health records using a secure connection. Although it may have been desirable to have 2-way messaging incorporated into app functionality, this was not possible within the information technology infrastructure of the hospital. All data entered is stored on the phone, and can be accessed at any time by the app user. The clinical workflows, for example how healthcare professionals monitor and respond to patient-reported data, and patient data entry management, for example how often patients enter data and reminders for patient data entry, are outside the scope of this manuscript.

2.3 | Phase 3: usability testing

The appropriateness of RACONnect for RA patient-generated health data reporting (ie, usability in a specific context) was assessed with the Systems Usability Scale (SUS).³⁴ Each of the 10-item questions in the scale were contextualized to RACONnect and had a 5-point Likert scale with anchors 0 = strongly disagree and 4 = strongly agree. Mean scores and standard deviations were calculated for each item and overall score calculated.³⁴ SUS scores range from 0 (poor) to 100 (excellent).

Usability testing of the app with people with RA was undertaken in two ways: with people using the app on their own phone or tablet for 1 month and with people with RA using the app once immediately before their routine rheumatologist clinic visit.

2.3.1 | Testing on participants' devices

Participants in stakeholder interviews and people participating in a patient-opinion online platform coordinated by a rheumatologist at WRRU were invited to participate by email, and people attending the rheumatology clinic were invited to participate via a phone call from a research assistant (HT). Formal sample size calculation was not performed and the recruitment period limited to 1 month. After written informed consent was obtained, participants provided demographic and disease information. Participants were then emailed the user manual appropriate for their device and asked to download and install RACONnect. If participants had not been able to download RACONnect, downloading was completed via phone support. Participants were asked to use RACONnect at least once a week for 4 weeks by filling out the 'RA Activity Monitoring' section. This includes the HAQ-II, patient global assessment, 28 swollen and tender joint counts and automatic calculation of CDA. Participants were

not prompted or reminded to use RACONnect. Reports of participant data were sent to a research email address. Participant reporting data frequency were analyzed using summary statistics. After 4 weeks, participants completed the RACONnect-contextualized SUS via an online survey.

2.3.2 | Testing before clinic visit

At rheumatology clinics in NZ public hospitals (WRRU, Christchurch hospital and Dunedin hospital) 100 people with RA were prospectively recruited to use RACONnect on a smartphone (Samsung Galaxy J1ace running Android) immediately before a scheduled clinic appointment. Participants completed data collection in RACONnect. A research assistant was present to answer questions but provided no prompting. Participants then completed a paper version of RACONnect-contextualized SUS.

2.4 | Ethics

The Central Health and Disability Ethics Committee approved the interview and longitudinal usability study (14/CEN/208) and the clinic visit usability study (which was part of a larger project to be reported separately, [16/NTB/102]). Participants provided written, informed consent.

3 | RESULTS

3.1 | Phase 1: stakeholder interviews with people with RA and healthcare professionals

Nine people with RA (seven female, two male) aged 27-79 years, with duration of RA of 1-26 years and current low or moderate RA disease activity were interviewed (Table 1). Seven HCPs (five female [three rheumatology nurses, two rheumatologists] and two male [rheumatologists]) were interviewed. Details of demographics of HCPs are not provided to avoid identification from publicly available information. Mean interview duration was 30 minutes with range from 14-46 minutes. No additional people were present at interviews.

Four main themes were identified in the interview data to inform the research questions: (a) variable app acceptance and readiness; (b) app use to reduce barriers; (c) pros and cons of patient-reported outcomes; (d) allocation of clinics by need. These themes are expanded below with illustrative quotes in Tables 2-5.

3.2 | Variable app acceptance and readiness

People expressed differing enthusiasm and interest for using an app as part of RA disease monitoring, management and health

**TABLE 1** Characteristics of people with rheumatoid arthritis participating in interviews

Gender	Age, y	Duration of RA, y	DAS28-CRP ^a	DMARD	bDMARD	Smartphone ownership	Mode of interview
F	62	10	2.77	Y	Y	N	Phone
F	60	3	3.74	Y	Y	Y	Phone
M	79	1	1.71	Y	N	N	Phone
F	48	6	2.82	Y	Y	Y	Phone
M	58	26	3.51	y	y	Y	Phone
F	33	9	2.80	Y	Y	Y	Phone
F	27	12	1.89	Y	Y	Y	IP
M	48	8	2.21	Y	Y	Y	Phone
F	37	1	2.74	Y	N	Y	Phone

Abbreviations: bDMARD, biologic disease-modifying anti-rheumatic drugs; DMARDS disease-modifying anti-rheumatic drugs; IP, in person.

^aEuropean League Against Rheumatism Disease Activity Score of 28 joints C-reactive protein (DAS-28-CRP)³³ criteria at most recent clinic visit, within 3 mo of interview.

care. Some people with RA were very enthusiastic, while others expressed interest moderated by concerns about sufficient technical skills or reduction in clinician contact. One person with RA had no interest in app use but acknowledged that younger people with RA were likely to have high interest. HCPs accepted that their patients, current and future, will expect use of apps as part of RA management. However, HCPs were concerned technical demands could exceed their own abilities, and those of their patient', especially in terms of app download and training. There was also concern about increased workload and change in workflow to monitor and respond to patient-generated health data.

3.3 | App use to reduce barriers

People with RA felt that having an intuitive app designed specifically for people with RA and integrated with their rheumatology service would enhance their engagement in care and reduce barriers to accessing care. An app was perceived as an easy method to seek information and reassurance from rheumatology nurses and rheumatologists via short messages. RA was not considered a barrier to data input on a smartphone by any people with RA,

acknowledging that smartphone screens are small. People with RA required a simple mechanism for data input. People with RA were not concerned about the security of data or risk of privacy breaches.

3.4 | Pros and cons of patient-reported-outcomes

Two-thirds (6/9) of people with RA recalled completing paper-based patient-reported outcomes at rheumatology clinics. However, none were familiar with the concept of 28 tender and 28 swollen joint counts contributing to a composite disease activity instrument or indeed the existence of CDAs. Despite this, all people with RA saw some personal benefit to completing the RA-relevant health data instruments on an app on their smartphone, if this summarized their current RA disease activity as low, medium or high. Some participants were concerned that the proposed RA-related instruments failed to capture some pain and function aspects of their lived experience. They wished to have ability, within the app, to add free text to communicate the current impact of RA disease. HCPs expressed some ambivalence over the concept of patient-generated health data as they felt people with RA may report frequently, as often as daily,

TABLE 2 Quotes supporting variable app acceptance and readiness themes

Quotes	Age (y) and gender
I use my phone all the time...like every 5 minutes that I'm awake. I don't think anyone my age or under would have a problem doing that but... some older patients might not be interested.	33 female
I'm believing on...talking to humans on the phone instead of machines. That's preferred to me, cos you guys were born to this stuff.	79 male
Some patients will be freaked out by the technology aspect of the app. They will need good education on how to use the app and a good patient help desk where any questions could be answered by someone who spoke in lay person's language.	Nurse



Illustrative quotes	Age (y) and gender
I can...tap something twice without meaning to so...it will just require you to, you know, think about things for a minute	58 male
You can find the phone's a little bit small to do some things on	48 male
It's good to be able to email or text somebody because at the moment if something is not quite right you gotta go through the booking or usually I go to the GP and then another referral and...it's takes a bit of time	48 male
I think that would be useful as sometimes it's a bit scary for me, not understanding something properly, if you could send a text, that way it makes you feel more reassured	60 female
Cos sometimes I've had things to ask about and just a few texts back and forth can answer the problem and I didn't need to go all the way in and they didn't need to make a time to see me	48 female

TABLE 3 Quotes supporting app use to reduce barriers in interview data

Illustrative quotes	Age (y) and gender
I think it's important to know where you are at quite honestly. The app would answer a lot of questions to know why you're feeling so rotten	60 female
Somewhere there should be some inclusion about feet though, but I don't know where they'd put it if it isn't part of that calculation. Because me feet are quite affected	33 female
Would there be any room for comment instead of just yes or no...because some of the questions are, just ah, don't quite suit. Well, like getting in and out of a car, that a good one for me because I am a mechanic so I have a lot of difficulty doing that. But also we work underneath cars and you're lying on the ground and getting up from the ground and things like that is very difficult also	48 male
If they came and said 'my DAS has changed it is getting better or worse, it means they have some feeling it is flaring. Them having some control over it I think would be brilliant.'	Rheumatologist

TABLE 4 Quotes supporting app pros and cons of patient-reported outcomes in interview data

Abbreviation: DAS, Disease Activity Score.

which they felt would be excessive. Furthermore, HCPs had concern that people with RA seeing quantification of self-reported measures could have an increase in RA-related anxiety. Conversely, providing an app for self-reporting health data was considered a mechanism to empower self-management. Rheumatologists felt that this would give useful information about patients' disease between clinic visits to give a more comprehensive view of the patient lived experience.

3.5 | Allocation of clinic by need

People with RA highly valued face-to-face clinic visits with rheumatologists and nurses. However, they acknowledged that prioritizing allocation of clinic visits, according to patient-generated RA disease activity via an app, would be acceptable and fair when demand exceeded capacity. HCPs also valued face-to-face care but recognized that patient-generated health data reporting via an app could enable less frequent review in an equitable manner. In contrast, one rheumatologist felt that a remote reporting system could lead to people

without smartphones or technical expertise being disadvantaged with respect to access to care.

3.5.1 | Usability testing

Sixteen people with RA were recruited, from various sources, to use RACONnect on their device for a 4-week period. Seven of the 46 people with RA enrolled in the patient-opinion online platform participated, a response rate of 15%. Four of the nine people with RA interviewed in phase 1 participated, a response rate of 44%. Five participants were recruited from rheumatology clinics held at WRRU. Most participants were female (11/16, 69%), mean age was 56.6 years (range 28-71 years); only one participant was under 40 years of age, nine were 41-60 years and six aged over 60 years old. Devices used were iPhone (n = 7), iPad (n = 2), Android smartphone (n = 5), and Android tablet (n = 2). All participants had completed secondary level education and 75% (12/16) had tertiary level education. Participants completed the RA Activity Monitoring

TABLE 5 Quotes supporting app use for allocation of clinic by need in interview data

Illustrative quotes	Age (y) and gender
I am very lucky with my rheumatoid as there are a lot of people that have got it much worse. So I would rather that they have the appointment that I have... this way (the app self-report) Dr X can see that I'm alright and somebody else can have that appointment	62 female
There would probably be less interaction with your specialist...but I'd like to think that you know, if things were bad enough I actually could still get to see her as often as I needed	60 female
I like the face-to-face appointments but great if it means that you wouldn't need to go in unless you needed to	33 female
I think it would probably streamline appointments a bit because they wouldn't need to sit there questioning you about the last 2 weeks when they've probably already seen what is going on	33 female
Yeah, just so they're not booking unnecessary appointments but also you're not falling under the radar if you are actually really in a lot of pain. Because I know some people with go, like nearly a year, you know, without an appointment but they haven't actually said they need one or rung up and said "Actually I'm pretty miserable. I do need an appointment sooner than a year"	33 female

component of RACONnect a mean of 3.5 times (SD = 1.26) in the 4 weeks. All participants used RACONnect at least twice, and one participant used RACONnect 6 times. The SUS score of RACONnect for the 16 participants was 79.5.

The 100 people recruited from clinics were predominantly female (77%), mean age 60.2 years (range 33-83 years), duration of RA 17.0 years (range 0.25-55 years) and 45% were using a biologic DMARD. The overall SUS score for RACONnect for the 100 people using RACONnect for 10 minutes before a clinic visit was 83.

4 | DISCUSSION

Our study reports that people with RA and their HCPs have similar, cautiously positive opinions regarding a mobile app for people with RA to record and report RA disease data. They offered similar potential benefits and risks, and challenges of using patient-generated health data in new models of care. An app developed, informed by these views, received high usability scores from people with RA, after use on their own device over the short term or brief use on a provided phone. These scores were above the mean (69.69) and median (70.91) SUS reported in its evaluation from inception in 1986-2008.³⁵ The RACONnect SUS scores are on or above the 90th centile (80) indicating high usability and are similar to the SUS reported for online RA disease self-reporting software.²⁵

Patient and HCP opinions have been obtained in other settings to inform the development of web or mobile apps for children and adolescents with juvenile idiopathic arthritis^{36,37} and adults with arthritis.^{38,39} In a UK study young people with inflammatory arthritis were positive about an app for self-monitoring, but felt ambivalent about tracking symptoms at times of good disease control.³⁶ Security or privacy issues were not a concern and young people expressed a clear preference for social and peer support and engaging design, including gamification. Our older patient group did not

request peer interaction via an app, with their design advice focusing on function over enjoyment, perhaps as this was outside the scope of an app proposed to them in the setting of service development. In our study HCP ambivalence about patient-generated health data reporting related to potential for increased anxiety about RA, not reporting burden; while rheumatologists identified potential benefit in gaining insight into daily lived experience of their patients. Indeed, a recent UK study has reported that reviewing daily RA symptom reporting in rheumatology clinics gave rheumatologists deeper insight into day-to-day RA impact and enabled more patient-centered consultations.²⁴ Recently a Belgian study that interviewed adults with inflammatory arthritis to inform self-management app development also reported varying opinions about personal value of an app for arthritis monitoring.³⁸ Our study participants clearly identified logs for reporting disease activity and medication reminders as key desirable features for an app. Again, even people who felt app features were not relevant to them personally acknowledged that other people with arthritis might find them useful. This was also found in a Swedish study engaging people with arthritis to inform development of web software for self-management.³⁹ This emphasizes an app for RA monitoring might be useful and of interest to anyone with RA, but not everyone with RA.

The findings of our study have some parallels with the key findings of a recent meta-synthesis of 43 qualitative studies of patient views on mHealth interventions for chronic diseases.⁴⁰ Key strengths of mHealth identified were patient empowerment and engagement, which was expressed by participants in our study in the theme of reduced barriers, with practical examples like the ability to send short messages to clinical team members. Limitations identified in the meta-synthesis included the technical and knowledge trustworthiness, personalization to the disease, appropriateness and accessibility. In our study we have addressed a priori trustworthiness as the developers are the HCPs for the participants, and disease personalization, and appropriateness as the scope and purpose of the



proposed app was carefully predefined. Our participants did identify accessibility as a potential disadvantage of an app for RA, expressing that not all people with RA would be interested in an app for RA disease monitoring and communication, which creates potential for inequitable service access. Interestingly our study identified potential challenges when incorporating mHealth into current healthcare services as concern for both patients and HCPs, which was not identified in the meta-synthesis of extant literature. This might be because literature to date has largely focused on chronic disease apps being considered as a patient-facing tool only, not as a mechanism for interaction with HCPs to supplement or assist clinical care. This is an important point as successfully leveraging of the potential of mobile health will require people to be pro-active in self-management of health conditions in partnership with HCPs.⁴¹ Although recording of patient self-reported RA-related activity or impact is an accepted and encouraged component of high-quality clinical care, the assessment of tender and swollen joint counts is usually done by a rheumatologist. Therefore patient-self-reported joint counts, which people with RA and rheumatologists endorsed to be included in a patient-held app for RA, are not yet fully validated for use in evaluation of disease activity. A systematic review of the literature on joint counts reported high reliability for tender joint counts for HCPs and patients, while reliability for swollen joint counts was poorer for patients than HCPs.⁴² However, previous work has confirmed that scores in CDA measures for RA are similar to those derived from ultrasound-determined joint inflammation.⁴³ Therefore sufficient data exist to support further research to evaluate the reliability of patient self-joint count as a component of disease activity measurement in RA, which would be required before implementation of patient reporting as a means for remote monitoring and allocation of clinic appointments. Furthermore, the frequency of app-reporting of RA disease activity by people with RA, and if this is sufficient for clinical purposes, will also need to be evaluated. In a feasibility study in the USA, people with RA using an app to report symptoms for research, showed a steady drop in use until only 11.3% of participants were engaging with the app after 12 weeks.⁴⁴

The limitations of this study need to be acknowledged. This qualitative approach by necessity limited sampling to a smaller number. Although data saturation was reached, it is possible other participants may have provided different opinions. The participants also volunteered their time so may have biases about the topic of exploration, either favorable or unfavorable, that influenced the results. Furthermore, qualitative data from a single site study may not be generalizable. Interviews were chosen for logistic flexibility and to allow participation by telephone of people from across the geographic bounds of our service. It is possible that data collection by a focus group could have elicited more nuanced information or other ideas. It is possible that positive bias may have influenced the usability responses, as participants were patients of the service which developed the app. Results must be interpreted with these limitations in mind; however, this study still signposts major areas of concern for people with RA and their HCPs when considering implementation of mobile collection of patient-generated health data for monitoring and service allocation.

While these results can guide implementation of an app into rheumatology care, there are areas for further research. These include the accuracy of patient-performed joint counts, the most effective methods to teach patients to perform their joint counts, technical and logistical barriers to implementation of self-monitoring in the clinical setting. Although we have reported high usability and interest in incorporating apps in RA clinical care, it remains unknown if ongoing engagement in such apps would be sufficient to support triage for clinic or supplement care. Lastly, although this app was developed primarily for implementation into clinical care pathways, the utility of this app for data collection in research or for quality improvement could also be explored.

5 | CONCLUSIONS

People with RA and their healthcare providers have clear opinions about the content and functions for an app for remote self-monitoring of RA and how it could be incorporated into clinical care, including risks and benefits. An app developed with these considerations in mind demonstrates high usability for people with RA. Next steps are development and validation of a method of patient-performed joint counts, including training of patients, and careful implementation in the clinical setting with evaluation.

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AUTHOR CONTRIBUTIONS

RG, TL and WJT designed the overall study with HRT, CAF, FER also contributing to practical aspects of study design. RG, HRT, CAF and FER acquired the data. RG, HRT, CAF, FER, TL and WJT all contributed to data analysis. RG and HRT wrote first draft of the manuscript and critically revised it for intellectual content, with CAF, FER, TL and WJT all providing critical revision for intellectual content. RG, HRT, CAF, FER, TL and WJT all approved the final manuscript for publication and all agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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APPENDIX 1

SEMI STRUCTURED INTERVIEW SCHEDULE FOR PATIENTS AND PATIENT-ADVOCATES

The following questions are grouped by the topics that will be explored in the interview. The questions themselves are 'examples' because not all of these might be used, or the phrasing may vary from person to person. In addition to questions, generic prompts (such as, please tell me more about that, please could you give an example, could you please expand on that idea) will be used to elicit more detail. The interviewer will sometimes paraphrase what a participant has said in order to check understanding (eg, what I am hearing is that you think.....). The interviewer will aim to use neutral language and questioning strategies to attempt to avoid biasing participant responses. This document gives an outline of the interview with specific questions indicated in italics.

A. Introduction and consent

1. Interviewer introduces self and thanks participant for time.
2. Aims of interview outlined: to explore patient perspectives on an mobile software that can be used on smartphones for patient initiated monitoring of RA disease activity and communication with treating health care teams, including rheumatology team.
3. Logistical details outlined:
 - the interview will be recorded and transcribed,
 - the responses are confidential and will be de-identified and secure data storage will be used.
 - The study has ethical approval under 14/CEN/208. You can withdraw your consent and discontinue the interview at any time with no impact on you or your health care. Any questions can be answered by the research team with contact details on information sheet. Checks participant has information sheet and has signed consent form.
 - We expect the interview will take 30-45 minutes. Please indicate if you need a break at any time or wish to stop the interview.

B. Demographics and current technology access and use

Interviewer will collect basic demographic details and experience and exposure to relevant technology (hardware, applications and access) in interview sheet (attached).

Based on the collected data, the interviewer will tailor the questions to the technology access of the participant.

eg, Participant with smartphone, familiar with use and apps

How would you feel about using an app on your smartphone to self monitor your RA symptoms?

eg, Participant with no smartphone or experience in use but computer and internet access and use

How would you feel about having a smartphone and learning to using an app on this smartphone to self monitor your RA symptoms?

Would you be interested in using similar software on a computer (laptop or desktop)? How would computer access compare for you with smartphone access?

Are there any reasons why you would not want to use an app on a smartphone (privacy, intrusion, difficulty doing things with hands etc)?

C. Semi-structured interview

Thanks for the background information. It helps me frame the rest of the interview to match your current technology exposure.

We are interested in four main areas; 1. the software content, 2. how users might prefer to access the software, 3. how the software may need to function and 4. how the software will interact with the rheumatology service.

1. Software content and function

There are some basic groups of information and measurements of rheumatoid arthritis activity the RA software could include and want to get your feedback on this. Here is a list (shows sheet "Possible RA app content" [attached], an A4 page)

Take a moment to read through these. (waits) Are there any that you would like to ask about or understand better? I'd like to get your thoughts about each of these sections.

*First I'd like to know your thoughts on the **summary data**. This data would be entered by you and act as a portable health record that you could show to health care providers as you wished.*

Does this look right to you?

Is there any other information that you think is important that should be recorded in this section?

Any other comments?

Now I'd like to know about the **patient assessment section**. The patient assessments may not look familiar to you.



2. Joint counts

The tender or swollen joint count would be according to your own assessment and be entered on a body by tapping the area. Although many areas of your body could be affected by RA, rheumatologists standard assessments focus on a subset of joints. These are in the hands, arms and legs. We have three options of how this information could be entered on an app. It could look something like this (show GUI 1—hands) and this (GUI 2—other joints).

Takes a few minutes to explain—the app would feature use designs similar to A (Stick and box) B (body outline) OR C (body outline with skeleton). Date could be collected in two ways 1. There would be two screens for right hand (tender and swollen), two screens for left hand (tender and swollen) and two screens for body (tender and swollen). Joints on each diagram that were tender would be tapped, then same for swollen. 2. There are three screens (right hand, left hand, body). For each joint, one tap for tender, tap again, swollen, tap a third time tender and swollen).

Do you prefer one of the three GUI's (A, B or C)? Why do you say that? Which of the two ways of entering data would most suit you?

How do you think it would be for you completing this? Are there any ways that RA might impact on you completing this data?

Are there any comments about how the body should look or about how the tender/swollen areas should be entered?

3. Patient self reports

If you have attended rheumatology clinics through Hutt Valley DHB you have completed a form that looks like this while you wait for the rheumatologist (Card 3—Hutt Valley DHB Rheumatology assessment form—patient global and HAQII). You would enter these data on screens that might look like this (GUI 3—Patient globals and HAQ II).

How do you think this might work for you? Do you have any concerns?

The composite scores are a measure of RA disease activity that incorporate the above data. Usually your rheumatologist will calculate these in clinic but may or may not share them with you. They are often grouped into low, medium and high RA disease activity. This is sometimes displayed using a traffic light system, green – low disease, orange – medium activity, red—high disease activity. Red is used for high as it reminds the rheumatologist that something needs to be done! Here is a way that these have been presented on a web site (shows attached DAS28 severity visuals).

How would you feel about seeing these?

If these scores showed that your RA was very active, or had got more active recently, the app could automatically send an email or text your rheumatology service. How do you feel about this?

How long would you be prepared to wait for a response when you have sent information?

How would you feel about the time frame if you received a generic acknowledgement of the receipt of the information? How long after that would you expect a personal/detailed reply?

Could the reply come via text alert to the app or would you expect to speak to a health professional on the phone?

This leads me on to a more general discussion of **communication**. The app could have three communication capabilities. The first is the ability post reminders to you as an email or an alter that appeared within the

app (like a text box, or little message within the app), for example, get a blood test, enter your data or attend appointments.

Is this useful to you?

What are the advantages and disadvantages of these reminders for you?

The second is that you could write and send a text message or email to your treating rheumatology team from within the app.

Is this useful to you?

What are the advantages and disadvantages of this message function (email/text) of the app for you?

4. Interaction with specialist rheumatology team

Now I'd like to know a little about how you think use of this smartphone app might impact on your interaction with your rheumatology care team (rheumatologist and their nurses). What are your thoughts?

Further comments could be elicited around the following:

face to face appointments could be less frequent

- how the data may be incorporated into face to face appointments
- completing an assessment just before appointment (in waiting room, no need for paper review).
- How participant would feel if the rheumatologist or rheumatology nurse did not use the app data the patient had collected.

RA App interview data sheet

Section A Demographics

Interview number

Subject initials

Age

Gender

Years since RA diagnosis

DMARDS (y/n)

Biological DMARDs (y/n/)

Section B Technology familiarity/access

Smartphone

Do you own an internet capable smartphone (y/n)

If Y

What type of device (iPhone, Android, etc)

Do you use your device to access the internet? (y/n)

Do you use "apps" on your smartphone?

Do you use your device to access email?

Do you use your device to send or receive text messages?

Do you have a dataplan on your device?

Do you use wifi (when available) on your device?

Computer use and usage

Do you own a computer? (y/n)

If Y

Do you use your computer to access the internet? (y/n)



Do you use your computer to access email?

Do you own another internet capable device such as a tablet or iPad?

If N

Do you use computers to access the internet, for example at work or a public library?

Possible content of an RA app

1. Summary data

- Contact details of patient, next of kin and health care professionals
- Medical history and hospital admissions
- Medications (current and previous, including reasons for discontinuation and adverse effects)

APPENDIX 2

SEMI STRUCTURED INTERVIEW SCHEDULE FOR HEALTH CARE PROFESSIONALS

Version A. Rheumatologist

The following questions are grouped by the topics that will be explored in the interview. The questions themselves are 'examples' because not all of these might be used, or the phrasing may vary from person to person. In addition to questions, generic prompts (such as, please tell me more about that, please could you give an example, could you please expand on that idea) will be used to elicit more detail. The interviewer will sometimes paraphrase what a participant has said in order to check understanding (eg, what I am hearing is that you think.....). The interviewer will aim to use neutral language and questioning strategies to attempt to avoid biasing participant responses. This document gives an outline of the interview with specific questions indicated in italics.

A. Introduction and consent

1. Interviewer introduces self and thanks participant for time.
2. Aims of interview outlined: to explore health care professional's perspectives on an mobile software that can be used on smartphones for patient initiated monitoring of RA disease activity and communication with treating health care teams, including rheumatology team.
3. Logistical details outlined:
 - the interview will be recorded and parts may be transcribed,
 - the responses are confidential and will be de-identified and secure data storage will be used.
 - The study has ethical approval under 14/CEN/208. You can withdraw your consent and discontinue the interview at any time with no impact on you or your health care. Any questions can be answered by the research team with contact details on

2. Patient assessments

- Tender and swollen joint count
- Other patient assessed indices (eg, pain, global well-being, HAQ-II)
- Generation of composite score measures of RA activity (eg, DAS-28, SDAI)

3. Communication

- Reminders to user (appointments, tests, data input eg, laboratory data)
- Alerts to user or health care provider if patient assessments fall outside pre-set parameters
- Email or text message of patient assessments or patient concerns to health care providers.

information sheet. Checks participant has information sheet and has signed consent form.

- We expect the interview will take 20-30 minutes. Please indicate if you need a break at any time or wish to stop the interview.

B. Demographics and current technology access and use

Interviewer will review the details and completeness of the RA app interview data sheet (attached) that the rheumatologist has completed before the interview. This includes demographic and professional practice details and experience and exposure to relevant technology (hardware, applications and access).

C. Semi-structured interview

Thanks for the background information. It helps me frame the rest of the interview to match your current technology exposure

We are interested in three main areas; 1. the software content, 2. how the software may need to function and 3. how the software will interact with your rheumatology service

1. and 2. Software content and function

There are some basic functions that the app could have. These include a record of patient details including medical information, measurements of rheumatoid arthritis activity and means of communication or feedback to the user (the patient) and the health care team. I would like to get your feedback on this. Here is a list (shows sheet "Possible RA app content" (attached), an A4 page)

"Take a moment to read through these. (waits).

(Note Rheumatologists should be familiar with most of the patient reported indices.)

I'd like to get your thoughts about each of these sections."

*First I'd like to know your thoughts on the **summary data**. These data would be entered by the patient and act as a portable health record that they could show to health care providers as they wished.*

Does this look right to you?



Is there any other information that you think is important that should be recorded in this section?

Any other comments?

"Now I'd like to know about the **patient assessment section**

A. Joint counts

The tender or swollen joint count would be entered by the patient according to their own assessment and be entered on a body by tapping the area. We have three options of how this information could be entered on an app. It could look something like this (show GUI 1—hands) or these (GUI 2—other joints and GUI 3)."

Takes a few minutes to explain—the app would feature use designs similar to A (Stick and box) B (body outline) OR C (body outline with skeleton). Data could be collected in two ways;

1. There would be two screens for right hand (tender and swollen), two screens for left hand (tender and swollen) and two screens for body (tender and swollen). Joints on each diagram that were tender would be tapped, then same for swollen.
2. There are three screens (right hand, left hand, body). For each joint, one tap for tender, tap again, swollen, tap a third time tender and swollen).

Do you prefer one of the three GUI's (A, B or C)? Why do you say that?

Are there any comments about how the body should look or about how the tender/swollen areas should be entered?

B. Patient self reports

Do you currently measure and/or record any patient reported indices in your clinical assessment of people with RA? These could include patient assessment of pain, patient global assessment of disease, the Health assessment questionnaire (the HAQ) or others?

If yes, how do you do this?(paper, electronic etc)

In your current clinical management of people with RA, do you calculate any composite disease activity measures eg, DAS28 or CD4I?

What impact would it have on your practice if your patients with RA, arrived with completed patient reported outcomes, recorded at intervals, and calculated composite disease activity measures

The RA app we propose would send the data recorded data to the DHB and these data would be entered into the electronic medical record (concerto), much like the way blood tests are entered. We are proposing that disease activity would be calculated and "forced sign off" generated if the disease activity indices showed the patient had highly active RA (Probably signed off by rheumatology nurses). We are envisaging that this would trigger a phone call from the nurse to the patient to get more information and assist the patient in planning appropriate management (eg, see GP, appt with rheumatology). Would this have any impact on your practice? Would this be useful or create problems?

Would your practice have the ability to respond to these alerts? How would you respond – phone call, email, text, arrange and appointment? Who would do this? How long might it take to respond and how long do you think is reasonable?

While on the **communication** functionality, the App could also have the ability to post **reminders** to the patient as an email or an alert that appeared within the app (like a text box, or little message within the app), for example, get a blood test, enter joint patient reported assessment data or attend appointments.

Would this be useful to the RA patients in your practice?

What are the advantages and disadvantages of these reminders for your patients?

2. Interaction with specialist rheumatology team

Now I'd like to know a little about how you think use of this smartphone app might interact with your current patient management arrangements? We are interested how it may influence the way appointments are scheduled, change the way patients communicate with the rheumatology team between appointments, change work flows within the rheumatology team. What are your thoughts?

Further comments could be elicited around the following

face to face appointments could be less frequent

- how the data may be incorporated into face to face appointments
- do you see any issues with patients who were completing the data and want time to review it in the clinic visit (or how they may react if you are not seen to review the data?)
- completing an assessment just before appointment (in waiting room, no need for paper review).

RA App interview data sheet

Section A Demographics

Interview number

Subject initials

Age (decade is fine)

Gender

Practice setting (public, private, NGO)

Years of practice

Section B Technology familiarity/access

Smartphone

Do you own an internet capable smartphone (y/n)

If Y

What type of device (iPhone, Android, etc)

Do you use your device to access the internet? (y/n)

Do you use "apps" on your smartphone?

Do you use your device to access email?

Do you use your device to send or receive text messages?

Do you have a dataplan on your device?

Do you use wifi (when available) on your device?

Computer use and usage

Do you own a computer? (y/n)

If Y

Do you use your computer to access the internet? (y/n)

Do you use your computer to access email?



Do you own another internet capable device such as a tablet or iPad?

If N

Do you use computers to access the internet, for example at work or a public library?

Notes:

Possible content of an RA app

1. Summary data

- Contact details of patient, next of kin and health care professionals
- Medical history and hospital admissions
- Medications (current and previous, including reasons for discontinuation and adverse effects)

2. Patient assessments

- Tender and swollen joint count
- Other patient assessed indices (eg, pain, global well-being, HAQ-II)
- Generation of composite score measures of RA activity (eg, DAS-28, SDAI)

3. Communication

- Reminders to user (appointments, tests, data input eg, laboratory data)
- Alerts to user or health care provider if patient assessments fall outside pre-set parameters

Email or text message of patient assessments or patient concerns to health care provider.

have not included this information, either revise your manuscript accordingly before submitting or note N/A.

APPENDIX 3

COREQ (CONSOLIDATED CRITERIA FOR REPORTING QUALITATIVE RESEARCH) CHECKLIST

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349–357.



A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	8
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	8
Occupation	3	What was their occupation at the time of the study?	8
Gender	4	Was the researcher male or female?	8
Experience and training	5	What experience or training did the researcher have?	8
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	8
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	8
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	8
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	9
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	8
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	8
Sample size	12	How many participants were in the study?	13
Non-participation	13	How many people refused to participate or dropped out? Reasons?	not reported
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	8
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	13
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	13, Table 1
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	8
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	No
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	8, 9
Field notes	20	Were field notes made during and/or after the interview or focus group?	9
Duration	21	What was the duration of the interviews or focus group?	13
Data saturation	22	Was data saturation discussed?	9
Transcripts returned	23	Were transcripts returned to participants for comment and/or	9

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	9
Description of the coding tree	25	Did authors provide a description of the coding tree?	no
Derivation of themes	26	Were themes identified in advance or derived from the data?	9
Software	27	What software, if applicable, was used to manage the data?	9
Participant checking	28	Did participants provide feedback on the findings?	9
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	27,28,29,30
Data and findings consistent	30	Was there consistency between the data presented and the findings?	13,14
Clarity of major themes	31	Were major themes clearly presented in the findings?	13,14
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	n/a

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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