JRMO Research Protocol for Research Studies

Full Title	**Attitudes to Technology supported Rheumatoid Arthritis Care in Patients and Clinicians**
Short Title	**AtTRA**
Sponsor	Queen Mary, University of London Contact person: Dr Mays Jawad Research & Development Governance Operations Manager Joint Research Management Office Queen Mary University of London Mile End Road London E1 4NS Phone: 020 7882 7275 Email: research.governance@qmul.ac.uk
IRAS Number	**264690**
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Chief Investigator	Dr. Frances Humby Senior Lecturer and Honorary Consultant Rheumatologist Centre for Experimental Medicine and Rheumatology 2nd Floor John Vane Science Centre William Harvey Research Institute Queen Mary University of London Charterhouse Square, London, EC1M 6BQ Email: f.humby@qmul.ac.uk

Co-Investigator	Prof. Paul Curzon Professor of Computer Science Electrical Engineering and Computer Sciences Queen Mary University of London Bancroft Road London, E1 4NS
Patient Recruitment Site:	Barts Arthritis Centre Mile End Hospital Barts Health NHS Trust Bancroft Road London, E1 4DG
Other Collaborators:	Electrical Engineering and Computer Sciences Queen Mary University of London Bancroft Road London, Centre for Experimental Medicine & Rheumatology John Vane Science Centre, William Harvey Research Institute Barts and the London School of Medicine and Dentistry Queen Mary University of London, Charterhouse Square, London, EC1M 6BQ

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Glossary

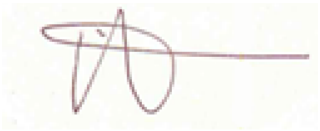
AI	Artificial Intelligence
app	Smartphone Application
CRP	C-Reactive Protein
DAS	Disease Activity Score
EECS	Electrical Engineering and Computer Sciences
ESR	Erythrocyte Sedimentation Rate
EMR	Experimental Medicine and Rheumatology
EPSRC	Engineering and Physical Sciences Research Council
GCP	Good Clinical Practice
mHealth	Mobile Health
PPI	Patient and Public Interest
RA	Rheumatoid Arthritis

1. Signature page

Chief Investigator Agreement

The study, as detailed within this Research Protocol, will be conducted in accordance with the principles of Good Clinical Practice, the UK Policy Framework for Health and Social Care Research, and the Declaration of Helsinki and any other applicable regulations. I agree to take responsibility for the statistical analysis and oversight of this study.

Chief Investigator Name: Dr Frances Humby

Signature: 

Date: **14th January 2021**

2. Summary and synopsis

Short title	AtT-RA
Methodology	*This is a mixed methods study with four arms.* 1. **Patient questionnaire** Patients with Rheumatoid Arthritis cared for at the Barts Arthritis Centre will be asked to complete a questionnaire about Rheumatoid Arthritis and the opportunities/barriers of technology to support care. Questions are a mixture of likert scales and tick box answers 2. **Semi-structured patient interviews** Patients with Rheumatoid Arthritis cared for at the Barts Arthritis Centre will be invited to participate in a ~60 minute semi-structured interview with a researcher from EECS, which will be recorded and transcribed. The interview will focus on the challenges of living with Rheumatoid Arthritis and the opportunities/barriers of technology to support care. Thematic analysis will be used to analyse qualitative data. 3. **Clinician questionnaire** E-questionnaires will be distributed via various Rheumatology mailing lists. Questions are a mixture of free text, tick boxes and likert scales, focussing on the opportunities and barriers of technology to support Rheumatoid Arthritis care. 4. **Semi-structured clinician interviews** Rheumatology Clinicians who agree to participate will be invited to participate in a ~30 minute semi-structured interview with a researcher from EMR, which will be recorded and transcribed. The interview will focus on how clinicians navigate care pathways for Rheumatoid Arthritis and the opportunities and barriers for technology to support care. Thematic analysis will be used to analyse qualitative data. **Covid-19 sub-study** The patients and clinicians who previously participated in an AtTRA interview will be invited by letter (patients) or email (clinicians) to complete a short e-questionnaire to understand whether attitudes to computer supported care have changed in light of the pandemic. Questions are a mixture of free text and likert scales.
Objectives / aims	The aim of this work is to determine the opportunities and barriers for intelligent mobile technology to support Rheumatoid Arthritis Care, targeted at both patients and clinicians as end users. To this end, the study seeks to

	understand the day-to-day challenges of living with and managing Rheumatoid Arthritis, in order to design technology which meets the needs of the target users; and the expectations patients and clinicians hold for intelligent mobile technology. This understanding will be used in the short term to improve existing apps and in the longer term as a basis for how next generation mobile health technology could provide support for those directly involved in Rheumatoid Arthritis care. Potential opportunities for support of patients include: • Helping patients improve quality of life • Improving clinical outcomes by achieving tighter disease control • Supporting patients' clinical decision making • Supporting patient-clinician communication • Reducing the need for direct patient-clinician contact • Patient-patient support • Educating patients • Supporting behavioural change / attitudes to the disease / disease acceptance The aim is to determine what, if any, contextual and cultural factors exist around the clinical pathway activities (eg around tapering, attitudes to flares, etc). A Covid-19 questionnaire sub-study has been added to understand how the changes in care instituted during the pandemic may have influenced interview participants' opinions on the use of technology to support care.
Number of participants	This is an unpowered study so patient numbers are estimates based upon the literature. Patient Questionnaire 100 Patient Semi-Structured Interview 15-25 Clinician Questionnaire 40 Clinician Semi-Structured interview 10-15 Covid-19 sub-study 15-25 Total 180-210
Inclusion and exclusion criteria	Patients Inclusion: >18 years old, no upper limit on the age range. Rheumatoid Arthritis, diagnosed by a Rheumatologist.

	Comprehension of Patient Information Sheet and Consent. Patients Exclusion: No formal diagnosis of Rheumatoid Arthritis. Insufficient English Language capability to complete the questionnaire or interview. Clinicians: Doctors, Nurses or Allied Health Professionals Specialising in Rheumatology care for 1 year or more.
Statistical methodology and analysis (if applicable)	Due to the study type there is no statistical powering for the patient population. Information from the interview studies and any open text boxes in questionnaires will be analysed using thematic analysis to code emerging themes from patient and clinician interviews and 'free text' questionnaire answers. Descriptive statistics will be predominantly used to analyse the quantitative sections of the questionnaires. However, if no clear trends are identified then further statistical analysis will proceed with support of the Experimental Medicine and Rheumatology Statistician, and is likely to include the following: ● One sample t-tests will be used for Likert scales to compare the mean of scores with the central value of the score ● Chi-square or fisher's exact test to assess the associations between patient groups stratified according to demographic parameters ● Comparison of quantitative variables, two sample t-tests and nonparametric mann-whitney tests will be applied ● Multivariate analysis by binary logistic regression to examine the variables influencing the willingness to use technology.
Study duration	Recruitment & interviews: 18 months Analysis: 12 months

3. Introduction

PAMBAYESIAN is an EPSRC funded project that aims to develop intelligent technological support for those with chronic conditions. One strand of this project is to understand patient and clinician needs within the context of routine clinical care. This group of studies forms one strand of that work and focuses on rheumatoid arthritis: one of the PAMBAYESIAN case study areas.

Rheumatoid arthritis (RA) is the most common inflammatory arthritis affecting 1% of the population. In recent years the outcome for patients with RA has improved significantly although it remains a chronic rather than curable disease, resulting in a health economic burden to the UK of £8 Billion/annum. Good outcomes for patients are associated with tight control of disease measured through a composite disease activity score (DAS), which integrates swollen and tender joint counts, patient visual assessment score of disease activity with markers of inflammation (CRP or ESR). However tight disease control, and so good outcomes for patients, requires intensive monitoring in order to ensure timely adaptation of therapy, a situation that is frequently not possible due to limited health care resources. Remote monitoring utilising smart technology offers the opportunity to deliver frequent disease activity measures, whilst also engaging patients in disease management. There are many commercially available Apps targeted at patients with Rheumatoid Arthritis. However, systematic reviews have found these to be of limited clinical utility, rarely using validated outcome measures, and lacking capacity for information sharing with clinicians.

To date the clinical benefits of AI have disappointed. A lack of close collaboration between clinicians and engineers is an important factor. The PAMBAYESIAN project is a collaboration between computer scientists from the School of Electronic Engineering and Computer Science of Queen Mary University of London, and clinicians from the Centre for Experimental Medicine and Rheumatology / Barts Arthritis Centre, Mile End Hospital, Barts Health NHS Trust. This study aims to understand the decisions made by patients and clinical staff in routine clinical care, what the potential opportunities and barriers to technology supported care are, and the acceptability of decision aids to both clinicians and patients.

This study combines the planned work to understand opportunities and barriers to the use of technology to support sufferers of Rheumatoid arthritis from both patient and clinician perspectives. The work builds on work with the Rheumatoid arthritis PPI group. This has led to the development of initial personas of patients with rheumatoid arthritis. Personas are realistic but

fictional descriptions of potential users, which are used as design tools to ensure design focuses on the needs of the user groups the applications are intended to help.

The overall study combines patient and clinician interviews and questionnaires. A separate study (using non-NHS routes to recruit patients e.g. charities, social media; via QMUL ethics) will validate the existing personas, with people with knowledge of rheumatoid arthritis. Based on the results we will then conduct usability studies on a series of prototype interfaces. The interfaces and precise nature of the prototypes will depend on the results of these studies.

3.1. Background

Mobile Health (mHealth) is a rapidly growing area due to the ubiquity of smartphone technology, and the potential for these devices as monitoring and communication devices for patients with chronic diseases. The need for technology and Artificial intelligence supported care has been specified in the NHS long term plan (1). However, there is little regulation in the development of commercial apps. Two systematic reviews of commercial apps for RA patients have found that these are of limited utility, due to lack of involvement of clinicians in development (2), lack of use of validated outcome measures for monitoring, poor security features, and inability to share recorded data with clinical teams (2,3).

The need for digital health to support Rheumatoid Arthritis care is already being addressed at EMR with the development of a bespoke mobile app for patients to monitor their DAS remotely (BioT App). The app is currently being tested to ensure validity and acceptability in a pilot study.

To date, the clinical benefits of AI have disappointed. This is due, in part, to the lack of collaboration between computer scientists and clinicians. The collaborative nature of the PAMBAYSIAN project will address this need; however it is equally vital to ensure that the developed technology will meet the needs of target users: both patients and clinicians.

This questionnaire and interview based study aims to address that need, and ensure that the technology developed will be acceptable to the target groups. Whilst some work has been done to investigate the wants and needs of patients and physicians (4,5) this has involved very small numbers and focussed primarily on specific areas e.g. motion sensing data (5). A simple

questionnaire based study explored the desired features of a self-management RA app in one hundred portuguese patients (6). Our study will build on this, to explore deeper the potential opportunities and barriers of remote monitoring technology, and moreover, it will be the first study of it's kind to attempt to understand patient and clinician attitudes to Artificial Intelligence, in the form of decision support tools, in Rheumatoid arthritis care.

Since the onset of the Covid-19 pandemic, remote consultations and monitoring have been rapidly instituted across rheumatology services. A short questionnaire sub-study has been added to investigate whether interview participants' opinions on the use of technology to support care delivery has changed in light of these circumstances.

3.2. Rationale

Developers of software often design without properly understanding the needs of the ultimate users. They solve non-existent problems or do not take the context of users into account. Research is therefore vital to ensure a patient perspective is taken into account from an early stage. Interviews provide a solid way to obtain a deep understanding. Questionnaires help ensure it is widely applicable and so generalisable to a wider population.

There has been an open dialogue with PPI groups from the outset of the project. Draft questionnaires and semi-structured interviews were sent to members of the Rheumatoid Arthritis PPI group, and amended according to feedback. Practice interviews were conducted with volunteers to sense-check and time interviews, with modifications made based on patient feedback.

3.3. Risks / benefits

The study is non-interventional and thus the risks to participants are low. They can withdraw from the study at any point if they find the information being sought is too intrusive.

The main potential risk is of patients' collected data from (security) and appropriate management and oversight of this dataset. Personal data will be stored in line with GCP guidelines to protect patient confidentiality.
There may be no direct benefit immediately to patients for participation in the AtT-RA study. However, in the medium to long term it will shape the development of technology supported care used within the department, which may improve patient's understanding and control of their disease.

4. Study objectives

4.1. Primary objective

The overarching objective is to define the main opportunities and challenges to technology supported RA care for patients and clinicians.

4.2. Secondary objective

1. Do the perceived opportunities and challenges vary according to patient demographics e.g. disease activity, disease duration, patient age?
2. What are the challenges of living with Rheumatoid Arthritis? (This will include issues around everyday life, flares, pain, medication and appointments from a patient perspective.)
3. Do the perceived opportunities and challenges vary according to clinician demographics e.g. age, subspeciality?
4. Are there significant differences in patient and clinician expectations for health technology assessed parameters?
5. Have the perceived opportunities and challenges changed since the rapid institution of remote care due to the Covid-19 pandemic?

4.3. Primary endpoint

Thematic Analysis will be used to code emerging themes from patient and clinician interviews and questionnaire responses in order to define the main opportunities and barriers to technology supported care.

5. Study population

Patients with a diagnosis of Rheumatoid Arthritis who are over the age of 18 will be eligible to participate.

Surveys will be distributed to patients attending for outpatient Rheumatology appointments at Mile End hospital, London. Outpatient clinic lists will be screened for appropriate patients, who will be approached whilst waiting for their clinic appointments. Patient interviews will also take place at the hospital. Patients visiting the Rheumatology Department at Mile End Hospital will be recruited while they wait for appointments, and be invited to an interview either on site or remotely, at a later date.

Clinicians eligible will include any with >1 year speciality experience in managing rheumatoid arthritis patients including consultants, registrars, specialist nurses and Allied Health Professionals.

Clinicians across several Rheumatology Centres within the geographical region will be approached by a Rheumatology clinical fellow and asked to participate. Interviews will take place at a location convenient to the interviewee. Clinician questionnaires will be disseminated and administered electronically, via regional and national mailing lists.

5.1. Inclusion criteria

Patients

- Able and willing to give informed consent
- Diagnosis of Rheumatoid Arthritis (made by a Rheumatologist)
- 18 years old or more
- Sufficient English language ability to answer interview questions

Clinicians

- Specialising in Rheumatology
- >1 year speciality experience

Covid-19 sub-study:

- Patients and Clinicians who previously participated in an interview as part of the AtTRA study

5.2. Exclusion criteria

Patients:

- Unwilling or unable to give consent
- Inability to understand written and/ or verbal English (there may be some assistance from a research assistant for Bengali speakers completing the survey; however for the interview there is no translation assistance)

Clinicians:

- Unwilling or unable to give consent
- < 1 year experience in Rheumatology as a specialism
- No longer practicing Rheumatology
- Clinicians working within Rheumatology whom do not routinely look after patients with Rheumatoid Arthritis.

Covid-19 sub-study:

- Patients and Clinicians who did not participate in an interview as part of the AtTRA study

Study design

This is a cross-sectional, mixed methods study, with four parallel arms: Patient questionnaire; Patient interview; Clinician questionnaire and Clinician Interview. Thus the study has both qualitative and quantitative aspects.

Both patient and clinician interviews are Semi-structured. They have been developed by a team of researchers from both EECS and EMR. The interview is structured with 'top' questions, which are open and broad, with sub-questions on important issues to be broached if the interviewee does not volunteer this information when asked the initial 'top' question. A single researcher from EECS will conduct patient interviews, and a single researcher from EMR will conduct clinician interviews, in order to maintain consistency. Interviews will be audio recorded and transcribed by an external transcription service (Bristol Transcription Services) previously used by EECS.

Patient and Clinician questionnaires have been developed by a team of researchers from both EECS and EMR. Patient questionnaires will be paper based with the option for postal return. Clinician questionnaires will be administered electronically.

Patients and Clinicians who participated in an interview will be contacted via letter or email and invited to participate in a brief follow up e-questionnaire (via SurveyMonkey™) regarding how the changes in care due to Covid-19 have impacted their beliefs about the use of technology to support care.

6. Study procedures

Informed Consent
Participants will be be asked if they wish to participate in the study following review of a detailed patient information sheet (PIS). Consent will be implied by the decision to complete and return the questionnaire.

For interviews, consent will be obtained by the researcher conducting the interview. A written information sheet will be provided, with a separate consent form. Interviews will be conducted on a separate date from recruitment, so patients will have a minimum of 24 hours to decide if they wish to participate.

For Clinicians, information regarding the study will be circulated via email, including a detailed participant information sheet. A link to the online questionnaire (hosted by Survey Monkey™) will be provided, and the decision to complete the questionnaire will be taken as their consent to participate. Those who express willingness to participate in the interview study will be contacted and written consent taken at the time of interview.

Patients and clinicians who participated in the interview arm of the study will be contacted via email or letter to invite them to participate in a short electronic survey (via SurveyMonkey™) regarding how the changes in care during the Covid-19 pandemic have impacted their beliefs about the use of technology to support care. Completion of the electronic questionnaire will be considered as sufficient consent to participate.

Screening and Recruitment
Patients:
Patients will be identified via outpatient clinics at Mile End Hospital and following discussion with a member of the study team will be provided with a patient information sheet. Patients will be asked to complete a questionnaire and post to return, and if participating in the interview a follow-up visit will be booked to arrange an interview at a convenient time. Patients may agree to participate in either or both arms of the patient study (i.e. questionnaire, interview, or both). Following completion of the interview the patients will have no further issues.

Clinicians:
Clinician e-questionnaires will be disseminated through the contacts of a Rheumatology Clinical Research fellow. Regional and National Rheumatology e-mailing lists will be asked to distribute the questionnaire, including North and South London and KSS (Kings Surrey Sussex) Registrar mailing lists, and the British Society of Rheumatology (BRiTs) mailing list.

Clinicians will be recruited for interview via the contacts of a Rheumatology Clinical Research Fellow. A “snowball” sampling method will be employed, so that those who have been interviewed will recommend other potential participants in the study. Potential sites which will be approached include Whipps Cross Hospital, University College Hospital, Homerton Hospital, and Northwick Park Hospital.

Procedures for Collecting Data:

Data will be collected using an ethically approved questionnaire and/or semi-structured interview designed to capture patient’s experiences around the following aspects of RA care:

- Living with Rheumatoid Arthritis
- Managing Flares
- Medication management, monitoring, and adverse effects
- Accessibility of Care and clinic appointments
- Perceived Opportunities and Barriers of technology
- Current technology usage

Paper Questionnaire: The questionnaire itself will act as the source data. The questionnaire will have the patient’s unique study number and initials to identify it but no other patient identifiable information. Clinical information including disease duration, up to date disease activity measures,

comorbidities and medication history will be obtained from the patient record and recorded on a separate record sheet labelled with the patient's unique study number.

Online Questionnaire: The online tool SurveyMonkey™ will be used to distribute and collect data for clinical questionnaires. The questionnaire will have the participant's email address, initials and place of work; but no other identifiable information.

Semi-structured interviews: Will be anonymously recorded and transcribed by an external transcription service previously used by the EECS team. Transcriptions will be analysed and coded at EECS. Once analysed the transcripts will be returned to the site file, stored within a secure locked room in the Department of Experimental Medicine. Participants in semi-structured interviews, who have not participated in the questionnaire arm of the study, will also complete an abridged questionnaire to establish current technology usage and demographics. Clinical information including disease duration, up to date disease activity measures, comorbidities and medication history will be obtained from the patient record and recorded on a separate record sheet labelled with the patient's unique study number.

Participant Withdrawal:
Participants may choose to withdraw from the study at any time.

End of Study Definition:
Interview studies will end when researchers agree that 'meaning saturation' has been reached; i.e. that further interviews will not add any further new information. Questionnaire studies will end when the specified target numbers have been reached.

7. Statistical considerations

Due to the study type there is no statistical powering for the patient population. Although the majority of the study is qualitative, analysis of the quantitative aspects of the questionnaires will be planned with the support of the Experimental Medicine and Rheumatology Statistician to ensure appropriate statistical methods are used in any and all analyses

7.1. Sample size

Patient questionnaire:
100
This target sample size has been set based on the sample size of other similar studies(6).

Clinician questionnaire:
40
This target sample size has been set pragmatically, based upon anticipated responses.

Patient interview:
15-25 participants.
The interviews will be analysed using thematic analysis, which advises stopping data collection when no new information is being gathered. Based upon the literature, "meaning saturation", when researchers have a full understanding of all aspects of the topic tends to occur between 16-24 interviews[7].

Clinician interview:
10-15 participants.
As above, the interviews will be analysed using thematic analysis. However, in this case a smaller sample size has been chosen, as the pool of potential participants is smaller. Additionally, we anticipate a smaller number of interviews to be required to reach "meaning saturation" as the interviews will be conducted by a Rheumatology clinical research fellow, and knowledge of the researcher has been demonstrated to reduce the required sample size[8].

Covid-19 sub-study:
15-25 participants (Patients and Clinicians combined).This target sample size has been set based upon an anticipated ≈50% response from previously interviewed participants

7.2. Method of analysis

Quantitative Analysis
Descriptive statistics will be predominantly used to analyse the quantitative sections of the questionnaires. However, if no clear trends are identified then further statistical analysis is likely to include the following:

- One sample t-tests will be used for Likert scales to compare the mean of scores with the central value of the score
- Chi-square or fisher's exact test to assess the associations between patient groups stratified according to demographic parameters
- Comparison of quantitative variables, two sample t-tests and nonparametric mann-whitney tests will be applied
- Multivariate analysis by binary logistic regression to examine the variables influencing the willingness to use technology.

Qualitative Analysis
Interviews will be transcribed and analysed using thematic analysis, with the assistance of coding software. This involves first reading and re-reading the transcripts to gain familiarity with the data; iterated coding leading to the

generation of overarching themes from patterns emerging from the data; reflection on and definition of the themes and how they contribute to an understanding of the data; and finally the writing of a thick description of the data. Free-text questions from questionnaires will be analysed in the same manner. To increase reliability coding will be done by both a clinician and computer scientist who will monitor and discuss themes emerging throughout the process.

8. Ethics

This study will be carried out in accordance with the ethical principles in the Research Governance Framework for Health and Social Care, Second Edition, 2005 and its subsequent amendments as applicable, and applicable legal and regulatory requirements.

Summary of Main Issues

- Confidentiality and Data Storage:

Data will be stored in compliance with Data Protection Act. All data will be pseudo-anonymised where data of birth and initials will be linked to a unique participant identifier for the patient in an encoded fashion.

- Interview Transcription:

Interviews will be audio-recorded and transcribed by an external company (Bristol Transcription Services). Participants' identity will be confirmed at the start of interview, prior to commencement of audio-recording. Once audio-recording has commenced only the participants' unique study number will be used. The audio recording will be deleted once transcription is complete. Transcripts will be labelled with the participant's unique study number and no other patient identifiable information will be included. Transcripts will be analysed and coded at EECS. Once analysis is complete the transcripts will be stored within a secure locked room within the Department of Experimental Medicine and Rheumatology.

- Inclusion/Exclusion:

Correct adherence to study inclusion/exclusion criteria will be observed, following appropriate recruitment, screening and consent methods.

- Consent:

A member of the study team will discuss the study with patients and answer any questions the patient may have. Once the patient has read the Participant Information Sheet, and have had time to consider whether they wish to

participate, consent will be taken. For the Covid-19 sub-study, the completion of the questionnaire will be considered as sufficient consent to participate.

8.1. Annual Safety Reporting

There are no safety considerations for patients enrolled in this study. Their care while taking part in AtT-RA is according to national standards as outlined by NICE. There are no additional interventions that would pose a risk to the patient.

9. Public involvement

There has been an open dialogue with the MATURA PPI group from the outset of the project. Draft questionnaires and semi-structured interviews were sent to members of the Rheumatoid Arthritis PPI group for feedback. Practice interviews were conducted with volunteers to sense-check and time interviews, with modifications made based on participant feedback.

10. Data handling and record keeping

10.1. Data management

Paper Questionnaire
The questionnaire itself will act as the source data. These will be anonymised, labelled only with participant's unique study number. Once completed questionnaires are returned, data on the patient's demographic and clinical information (including age, ethnicity, disease duration; current disease activity; current and previous DMARDs) will be collected and recorded on a pseudo-anonymised excel spreadsheet using only patient's unique study number. A separate electronic database will match the patient's unique study number to their hospital number. All electronic databases will be stored within the EMR drive on Barts Health Trust Network, with access restricted to those directly involved in EMR research team.

E-Questionnaire
The e-questionnaire itself will act as the source data. These will be anonymised and labelled only with the participant's unique study number.

Semi-Structured Interview Data
Interview participants will complete a short questionnaire including technology usage and limited demographic information at the end of the questionnaire. Following completion of the interview, data on the patient's demographic and clinical information (including age, ethnicity, disease duration; current disease

activity; current and previous DMARDs) will be collected and recorded on a pseudo-anonymised excel spreadsheet using only patient's unique study number/paper record form.
Interviews will be recorded on two audio devices (one to act as back-up in the event of the first failing), and transcribed by an external company (Bristol Transcription Services). Participants' identity will be confirmed at the start of interview, prior to commencement of audio-recording. Once audio-recording has commenced only the participants' unique study number will be used. The audio recordings will be deleted once transcription is complete. Transcripts will be labelled with the participant's unique study number and no other patient identifiable information will be included. Transcripts will be analysed and coded at EECS. Once analysis is complete the transcripts will be stored within a secure locked room within the Department of Experimental Medicine and Rheumatology.

10.2. Source Data

The completed paper and e-questionnaires will be the source data for this arm. Completed transcripts will act as source data for the interview studies. Clinical and Demographic data will be collected in an anonymised electronic spreadsheet kept within the EMR drive on Barts Health NHS Trust Network. Following analysis these will be stored within a secure locked room within the Department of Experimental Medicine and Rheumatology.

10.3. Confidentiality

Audio recording will not include participant's names or other overtly patient identifiable data to ensure confidentiality at the point of transcription. Questionnaires will be assigned a unique study number with no further identifiable information.

Data will be stored in compliance with Data Protection Act. All data will be pseudo-anonymised where data of birth and initials will be linked to a unique participant identifier for the patient in an encoded fashion.

10.4. Record retention and archiving

During the course of research, all records are the responsibility of the Chief Investigator and must be kept in secure conditions. From the end of the study, it is a requirement of the Research Governance Framework and QMUL Policy that all records are kept for a further 20 years. Electronic data will be stored and archived for 20 years in compliance with QMUL archiving SOP in encoded password protected format. The data collected and generated as part of this study's objectives will be analysed at the School of Electronic Engineering and Computer Sciences, Queen Mary University of London, and

following analysis will be stored in the Centre for Experimental Medicine and Rheumatology.

11. Safety reporting

Due to the nature and design of this study, safety reporting of adverse events will not occur.

12. Monitoring and auditing

Monitoring activities will be commensurate to the risk of the study. As this is a low-risk study “on site monitoring” will not be required but a triggered visit may occur if warranted, or may be arranged as a part of the Centre for Experimental Medicine & Rheumatology ongoing quality management system procedures. Such on-site monitoring activities would include data verification checks against patients’ medical notes to monitor the accuracy of the data being collected. For a study of this nature, central monitoring activities will be more appropriate and this will be developed as a part of a central data management plan to monitor timely transfer of study data to the study database, review of completeness and accuracy of the data, and to look for any anomalies or unusual patterns in the data that prompt and ‘on-site’ monitoring visit. The Sponsor or delegate retains the right to audit any study, study site or central facility. In addition, any part of the study may be audited by the funders where applicable.

13. Study committees

As the study is classified as low-risk, the study will be overseen by a Trial Management Group Committee. This will consist of the Chief Investigator, Co-investigator(s), study manager, research nurse, other clinical team staff, database manager.

The committee will meet to review data collection and will be responsible for the day-to-day running of the study and overseeing implementation of the protocol. The committee will meet monthly at a time and date dictated by the Chief Investigator and a copy of all agendas, papers and minutes shall be stored in the Trial Master File.

14. Finance and funding

This project is funded through the EPSRC funded PAMBAYESIAN grant (EP/P009964/1) procured by the School for Electrical Engineering and Computer Science, within Queen Mary University of London. The project has been designed and developed by staff working within the School for Electrical Engineering and Computer Sciences and the Centre for Experimental Medicine and Rheumatology.

15. Insurance and indemnity

The insurance that Queen Mary University of London has in place provides cover for the design and management of the study as well as "No Fault Compensation" for participants, which provides an indemnity to participants for negligent and non-negligent harm.

16. Dissemination of research findings

The results of the AtTRA study will be disseminated at different levels. Firstly, the results will be presented to researchers within the PAMBAYESIAN project to inform the design of prototype technology interfaces. The results of the project will be disseminated amongst local patient groups including the local National Rheumatoid Arthritis Society patient group (https://www.nras.org.uk/groups/east-london-nras-group). Research findings from the AtTRA study will form a significant part of the M.D. thesis of a EMR research student, and be disseminated Nationally/Internationally, through routine publishing in academic journals, and presentation at conferences, e.g. European League Against Rheumatism (EULAR) & American College of Rheumatology(ACR), either as speaker or poster.

17. References

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