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# Driving improvements in disease outcomes for rheumatoid arthritis patients using digital health technology (Bio-T-App)

**Submission date**
03/01/2019

**Recruitment status**
No longer recruiting

**Registration date**
13/02/2019

**Overall study status**
Completed

**Last Edited**
20/05/2024

**Condition category**
Musculoskeletal Diseases

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

## Plain English summary of protocol

Background and study aims
The Bio-T-App is a mobile phone app that is downloaded to a persons' phone, laptop or tablet. The aim of the Bio-T-App study is to evaluate the Bio-T-App as a tool to facilitate remote monitoring of RA disease activity. It is believed that increased monitoring will help to reduce symptoms and disease flares. The study will achieve this by supporting patients to submit regular joint counts via the app and examining regular blood tests. A cohort of patients using the app will be compared to a cohort of patients in routine care. This will allow us to determine whether it is possible to customise the treatments we provide to individual patients.

Who can participate?
Participants will be eligible to participate in the study if they are men or women older than 18 years who have been diagnosed with Rheumatoid Arthritis and are not currently in high disease activity (DAS <5.1). 30 participants will be recruited to the Bio-T-App arm of the study and will need access to a smartphone/tablet or laptop. 30 participants will be recruited to the routine care cohort and will not need access to the app. These patients will be observed in routine care.

What does the study involve?
For patients in the Bio-T-App arm, at screening, baseline and at 6-month time point participants will attend a clinic visit. At baseline patients will undergo physical assessment and be shown how to use the app and complete a self-assessment joint count. Following baseline visit, participants will submit a joint count via the app each time they take their medication. This will be either weekly, fortnightly or monthly depending on which medication they take. At 3-months there will be a telephone consultation with the Clinical Research Nurse who will discuss participant care and disease management. Participants who are in the control arm will not have interaction with the app. Control patients will be recruited and will be observed in routine care only. At the study exit, both cohorts of patients will be asked to complete a patient satisfaction questionnaire.

What are the possible benefits and risks of participating?
The level of risk in the study is low. Participants who use the app may encounter technical difficulties. The research team will assist participants to download the app and set it up at

baseline visit. Training will be provided and follow-up phone calls will help identify, support and resolve any technical issues. For patients, there will be the benefit of regular on-going support through the research team. Patients will benefit from an educational element focused on understanding disease activity scores in Rheumatoid arthritis.

Where is the study run from?
The study is sponsored by Queen Mary University. Patients will be recruited and seen at Mile End hospital, London. Mile End hospital is the only study centre.

When is the study starting and how long is it expected to run for?
November 2018 to May 2021

Who is funding the study?
Barts Health Charity

Who is the main contact?
The Chief Investigator: Prof. C. Pitzalis (c.pitzalis@qmul.ac.uk)
Principal Investigator at Mile End: Dr Fran Humby (f.humby@qmul.ac.uk)
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# Contact information

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# Additional identifiers

### Integrated Research Application System (IRAS)
236940

### Protocol serial number
012369, IRAS 236940

# Study information

### Scientific Title
Driving Improvements in disease outcomes for rheumatoid arthritis patients using digital health remote sensing (Bio-T-App): an observational pilot study

### Acronym
Bio-T-App

### Study objectives
Evaluate the integration of a bespoke mobile app (Bio-T-App) for remote monitoring of RA patients by self-assessment as a reliable tool to measure RA disease activity.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
East of Scotland Research Ethics Service, 18/09/2018, ref. 18/ES/0102.

### Study design
Single centre prospective observational pilot study

### Primary study design
Observational

### Study type(s)
Other

### Health condition(s) or problem(s) studied
Rheumatoid Arthritis

### Interventions
Participants will receive either Bio-T-App or routine care. Patients will not be randomised. 30 patients will be recruited to Bio-T-App arm and following this 30 patients will be recruited to routine care arm and will not have any interaction with the app.

Participants on the Bio-T-App arm will have clinic visits at baseline, 12 weeks (telephone consultation) and 6 months. At every medication time point the patient will submit a joint count via the app. The clinical research nurse will submit recent blood results to calculate the patients disease activity. The control arm of the patient will have no encounter with the app and will progress through routine care as normal. At the end of the study (6 month time point) patients in both arms will complete a satisfaction questionnaire.

### Intervention Type
Other

### Primary outcome(s)
The proportion of patients who adhere to the study schedule by recording disease activity scores (DAS28) which will be measured over a six month period from baseline.

### Key secondary outcome(s))
1. The number of patients in low disease activity (defined as DAS <3.2) in Bio-T-App group v's routine care group will be measured using DAS28 score at 6 months.
2. The validity of submitted scores when evaluated against other clinical parameters of disease activity and overall clinical picture will be measured using blood results, DAS28 scores, medical history and reported symptoms at each joint count submission point.
3. Health economic impact will be measured using a comparison of biologic drug cost and number of outpatient visits in Bio-T-App group versus routine care at 6 month time point.
4. Patient satisfaction in Bio-T-App group versus routine care will be measured using a non-validated patient satisfaction questionnaire at 6 months.

### Completion date
18/05/2021

## Eligibility

### Key inclusion criteria
1. Aged >18 years
2. Diagnosis of rheumatoid arthritis
3. Baseline DAS score <5.1
4. Access to smart phone/tablet/laptop to access the app
5. Prescribed a subcutaneous biologic drug for rheumatoid arthritis

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

**Lower age limit**
18 years

**Sex**
All

**Total final enrolment**
60

**Key exclusion criteria**
N/A

**Date of first enrolment**
16/11/2018

**Date of final enrolment**
31/12/2019

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Mile End Hospital**
Rheumatology Research
Bancroft Road
Mile End
London
United Kingdom
E1 4DG

# Sponsor information

**Organisation**
Queen Mary University of London

**ROR**
https://ror.org/026zzn846

# Funder(s)

**Funder type**
Other

**Funder Name**
Barts Health Charity

**Funder Name**
EPSRC - Pambeyesian: patient managed decision support using Bayesian networks.

# Results and Publications

## Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary
Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Other files | Final report | 03/01/2023 | 03/01/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | version 6.0 | 07/07/2020 | 03/01/2023 | No | No |