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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)
EMR clinical trials team: (emrclinicaltrials@qmul.ac.uk)

Contact information

Type(s)
Public

Contact name
Dr EMR clinical trials team -

ORCID ID
http://orcid.org/0000-0002-8160-3131

Contact details
Centre for Experimental Medicine & Rheumatology
William Harvey Research Institute
Barts and The London School of Medicine & Dentistry
2nd Floor, John Vane Science Centre
Queen Mary University of London
Charterhouse Square
London
United Kingdom
EC1M 6BQ
+44 (0)20 7882 3497
emrclinicaltrials@qmul.ac.uk

Type(s)
Scientific

Contact name
Dr Amy MacBrayne

Contact details

Centre for Experimental Medicine & Rheumatology
2nd Floor
John Vane Science Centre
William Harvey Research Institute
Barts and The London School of Medicine & Dentistry
Queen Mary University of London
Charterhouse Square
London
United Kingdom
EC1M 6BQ

Additional identifiers

EudraCT/CTIS number

IRAS number
236940

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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.

Secondary outcome measures
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.

Overall study start date
05/01/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
England

United Kingdom

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

Sponsor details
Joint Research Management Office
5 Walden Street
London
London
England
United Kingdom
E1 2EF

Sponsor type
University/education

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

Publication and dissemination plan
The improvements delivered by the Bio-T-App will be disseminated at different levels:
1. The results will be presented to local commissioners to implement a risk share agreement for

the trust to ensure ongoing funding for Bio-T-App maintenance. In addition the results will be presented to the regional network of rheumatology consultants to support implementation of the Bio-T-App to the netwoek of hospitals within Barts Health and to local trusts.
2. Nationally/internationally - The data analysis will be presented at the Regional British Rheumatology Society Meeting and at National Pharmacy conferences (e.g Clinical Pharmacy Congress) as well as at a future date at International meetings including American-College-Rheumatology (ACR) and European League against Rheumatism (EULAR).

Intention to publish date
31/12/2023

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?
Other files	Final report	03/01/2023	03/01/2023	No	No
Protocol file	version 6.0	07/07/2020	03/01/2023	No	No
HRA research summary			28/06/2023	No	No