Bio-T-App final report

Details of Chief Investigator

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Details of Study

Full Study Title – Driving improvements in disease outcomes for Rheumatoid Arthritis patients using digital health remote sensing

IRAS ID – 236940

Name of the Research Ethics Committee that issued a Favourable Opinion for the study- East of Scotland Research Ethics Service

Sponsor Organisation Name – Queen Mary University of London

Study start date – 15th November 2018

Study end date – 13th July 2021

Funder's reference number – MGU0378

Name of Registry – ISRCTN registry

Study Registration Number/Identifier – ISRCTN79368292

Date of registration – 13th February 2019

Is the study protocol publicly available? – Yes

DOI/URL for most recent protocol -https://doi.org/10.1186/ISRCTN79368292

Date original protocol was published- 3rd Jan 2023

Summary of Results

Lay summary of results

Thank you to study participants.

Study title: Driving improvements in disease outcomes for Rheumatoid Arthritis patients using digital health remote sensing

This study was carried out by researchers at Queen Mary University of London and was funded by Bart's charity.

A total of 61 people with rheumatoid arthritis (RA) were recruited to the study at Mile End Hospital, London between November 2018 and November 2019. The purpose of the study was to find out if a

mobile phone app (the Bio-T-App) can reliably be used to remotely monitor people's RA symptoms. The study also aimed to find out if doctors could make decisions on medication dosage and when a patient requires an appointment using the Bio-T-App.

During the study, 31 people with RA were enrolled to the "active" arm of the study and used the Bio-T-App. 30 patients were recruited to a control arm and received routine NHS care. Patients were recruited at routine rheumatology outpatient appointments.

In the "active" arm participants were given training on how to assess their swollen and tender joints and additionally how to use the Bio-T-App. Demographic and clinical data (for example: disease duration and medications) were also recorded on the Bio-T-App. After being set up on the Bio-T-App, patients then received reminders for when their medication is due and were also prompted to count their tender and swollen joints to submit on the Bio-T-App. The study nurse checked the data uploaded on a daily basis and also entered in important clinical data to enable a DAS28 score to be worked out through the Bio-T-App. The patient could then check their DAS28 score on the Bio-T-App. The DAS28 score is a measure of disease activity in RA. DAS stands for 'disease activity score,' and the number 28 refers to the 28 joints that are examined in this assessment.

If a patient had high disease activity (DAS28 greater than 5.1) or a disease flare (rise in DAS28 of more than 1.2) then they were contacted by the study nurse to discuss and a face-to-face appointment was arranged if needed. Patients who did not require a telephone consultation within the first 3 months of the study received an automatic scheduled telephone consultation with the study nurse after 3 months in the study. Patients were in the study for 6 months and at the end of the study seen for a face-to-face clinic visit with the study nurse to assess their DAS28. At this visit patients completed patient satisfaction questionnaires and also a questionnaire to assess how user-friendly the Bio-T-App is.

30 patients took part in the control arm of the study where they received NHS routine care. These patients gave permission for the study team to collect data on their demographics, out-patient appointments and DAS28 scores. Information was collected from NHS clinical records. The control arm patients were asked to complete a patient satisfaction questionnaire after 6 months.

31 patients were recruited to the App arm of the study. One participant was withdrawn due to inability to submit test tracking via the app, and a further patient failed screening due to a DAS-28 >5.1 at their enrolment, thus 29 participants completed the App arm of the study. Thirty patients were recruited to the control arm, however, due to the covid-19 pandemic, most participants were unable to attend for their 6-month follow-up appointment and repeat disease activity assessment. A substantial amendment to the study permitted retrospective data collection (i.e. using a DAS28 score from six months prior to enrolment in the study). Overall 13/30 control patients completed the study; eight with a prospective DAS28 assessment (6 months after enrolment, as planned), and five with retrospective DAS28 assessment.

The two groups of patients were broadly similar, although there was a higher proportion of men in the app group (41.4%), vs. 25.0% in the control arm. Mean age was 55.8 in the App arm (SD 12.0), 57.6 in the control arm (SD 14.9). Mean DAS28 score at enrolment was 2.46 (IQR 1.65-3.28) in the App arm; 2.80 (IQR 1.95-3.90) in the control arm. The majority of participants were on a TNF inhibitor (69.0% App; 75.0% controls). Most patients were taking at least one conventional synthetic disease modifying drug (csDMARD) in addition, although 37.9% app group and 23.3% controls were on bDMARD monotherapy. Of note, a significantly higher proportion of control patients had received steroid treatment within the preceding 6 months (32.1% controls vs. 6.9% app patients).

The study found that participants adhered well to the study schedule for recording their disease activity over the six month period. Submissions remained at ≥75% throughout the six month period, only falling below 80% at month four (77.5% submissions), and returning to 83.8% for month five and 80.0% for month six. Over the complete six month period the mean completed submissions was 80.1%, SD 16.35. Comparing DAS scores performed by rheumatology specialist nurses at face-to-face baseline visit and DAS scores self-submitted by participants via the app, patients tended to score their DAS score approximately 0.5 points higher than the nurse (bias 0.56; Upper limit of agreement 1.91; lower limit of agreement -0.79). At study completion, fifteen patients had submitted a DAS score via the app within a week of their face-to-face final visit, similarly showing an approximate 0.5 point increase in self-DAS to clinician DAS (bias 0.46; Upper LOA 1.64; Lower LOA -0.53). At study completion, both groups were in low disease activity or remission, Mean final DAS-28 score was 2.36 (SD 0.98) for the control group, App group mean 2.66 (SD 0.78). During the six month period, two participants recorded a DAS >5.1 on the app, triggering contact from the clinical team. One patient attended for f2f review where flare DAS >5.1 was confirmed by clinical examination and ultrasound, triggering a switch from biosimilar to bio-originator drug. The other patient declined face-to-face review, opting to self-manage, and their DAS-28 improved on further submissions. Five patients who had initially recorded low disease activity persistently recorded a moderate DAS-28 during the six-month period, suggesting that there are increases in disease activity which go unobserved in patients who have scheduled follow-ups at six month intervals.

5/29 App patients underwent biologic tapering. Dosing intervals were extended by 50%, thus weekly biologics were extended to every 10 days; fortnightly to four-weekly; monthly to six-weekly. Two participants undergoing biologics tapering flared during the study period, within three dosing cycles of the initiated taper. Whilst both exhibited a rise in DAS scores; neither met the DAS definition for flare of >1.2. Both patient's flares were confirmed on face-to-face clinical review including musculoskeletal ultrasound. Patients were treated with steroids (intra-articular or IM) and returned to their original biologics dose, with re-capture of low disease activity subsequently. Three patients remained on a taper without flare throughout the six-month period.

App participants rated the app highly on the Systems Usability Score (SUS), with a mean score of 77.4 (SD 12.72) (a score of >68 on SUS is above average). A bespoke patient satisfaction questionnaire at the study final visit (26/29 App patients completed; 16/28 controls) showed no difference in patient satisfaction between the app and control groups, mean score 84.1% App patients; 84.2% controls.

Due to the outbreak of the covid-19 pandemic during the study period, this confounded our ability to analyse healthcare resource utilisation.

Has the registry been updated to include summary results?

Yes

Please enter the URL to summary results –https://doi.org/10.1186/ISRCTN79368292

Dissemination Plan

Did you follow your dissemination plan submitted in the IRAS application form (Q A51)?

Pending, expected December 2023. Preliminary results were presented as a poster at BSR 2020.

Informing Participants

Have participants been informed of the results of the study?

Pending, expected June 2023.

Sharing of Data and Tissue

Have you enabled sharing of study data with others?

Pending

Have you enabled sharing of tissue samples and associated data with others?

N/A