AMPERSAND

Development and evaluation of the My Arthritis App Digital Therapeutic

Innovate UK

Introduction

The Covid-19 pandemic is having a significant impact on the way hospitals look after people with inflammatory diseases, particularly with routine care for people with long term conditions. This change has been driven by the need to free up as much capacity as possible to deal with the influx of Covid-19 cases; and the desire to keep at risk groups out of hospital, where they are at greater risk of infection, the NHS has switched the vast majority of care to a telephone, or digital setting.

In reference to inflammatory conditions, the current situation has emphasised 3 unmet needs that patients experience:

First, a need for better remote monitoring tools, to allow clinicians to identify patients with particular clinical needs and to support triage and follow up at distance. Second, a need for tools to support better self-care by patients, focusing in particular on patient education, patient activation and efficient clinical contact. Third, a need for capacity and flow management tools to minimise the backlog of care from unmet patient needs post Covid.

Ampersand Health develops innovative digital medicines for people with Inflammatory Conditions. The company, which is a social enterprise founded by clinicians and patients, is part of the NHS's DigitalHealth London accelerator and was previously selected for the PWC Scale Health programme.

Working with patients, clinicians and charities, Ampersand Health has developed a behavioural- and data- science based digital therapeutic - focused on supporting better self-care and faster clinical interventions - for people with Inflammatory Bowel Disease (IBD).

For clinicians, our ‘My IBD Care’ platform enables remote monitoring and intervention and supports clinical efficiency: it is shown in studies to facilitate a safe 47% reduction in overall outpatient appointments and is linked to a 50% reduction in out of hours A&E visits. Our clinician platforms, linking up with My IBD Care, My Arthritis, and My Nets Care are used by NHS trusts across the UK, with additional trusts approaching us regularly.

For patients, the intervention uses behavioural and data science to support better disease awareness and improved self-care. In addition to symptom (disease activity, stool tracking) and lifestyle (stress, mood) tracking using PROMs, Likert Scales and wearables. These interventions allow patients to subscribe to expert-led courses that teach and routinise better lifestyle habits, focused on stress management, sleep improvement, medicines adherence and staying active.

By re-using our technology, fine tuning of our behavioural framework, and developing disease specific content, we believe we will be able to help people with Inflammatory Arthritis (IA)— including conditions such as Rheumatoid Arthritis (RA), Psoriatic Arthritis and Ankylosing Spondylitis—live healthier, happier lives.

We note that like IBD, IA is characterised by unpredictable cycles of relapse and remission, leading to a lower quality of life and poor health outcomes. Improving patients' ability to self-care is widely accepted to be essential to addressing these factors but there is a paucity of evidence-based or clinically validated resources available. And as with IBD, the prevailing model of routine, episodic outpatient care rarely reflects a patient's clinical needs, leading to clinical inefficiency and significant quality improvement opportunities.

A basic version of the My Arthritis app has been trialled with RA patients at King's College Hospital and is shown to be equally effective at supporting remote monitoring and improved self-management. That version enables the remote monitoring of patients and the provision of educational content, but does not contain the behavioural science framework or the associated expert led content.

We proposed to build on our existing technology platform; adapt our existing, IBD focused behavioural science framework to meet the needs of patients with RA; and develop novel, disease- specific self-care courses that will support improved outcomes and quality of life (QoL) for another immune-compromised group of patients.

These courses will be delivered through an app that also offers patients a range of utilities and supports remote monitoring by clinicians through a counterpart portal.

Both the app and the portal are part of Ampersand's existing intellectual property and not the subject of the application.

This project seeked to develop and evaluate a novel behavioural science based self-care intervention for people living with inflammatory arthritis. The intervention has three components - an (existing) technology stack, a behavioural science framework and evidence-based content modules developed with leading experts. This project was undertaken via the following 4 work plans:

WP1: IA Patient and Clinician Focus Groups

We ran virtual sessions with patients, clinicians and others to examine the lived experience of IA patients, focusing on symptoms, behaviours and motivations. We conducted a mapping exercise, to identify the delta between the behavioural framework we developed for IBD patients and the needs of IA patients.

Deliverable: write up of our findings, circulated to our clinical steering committee (May 2020)

WP2: Tech and Framework Tweaks

We identified new behaviour change techniques required to meet the needs of IA patients. We allowed time and budget to fine tune the technology platform if required.

Deliverable: A platform that is fit for use with IA patients (June 2020)

WP3: Content Planning & Production

Working with subject matter experts, we developed content plans and detailed scripts for each of the envisaged modules, identifying synergies and agreeing content production plans.

Alongside video and text, we emphasise audio and animation as these were easier to produce remotely.

For more detail on the courses that we created for this project, please see Appendix A.

Deliverable: Five or more unique self-care programmes for IA patients (September 2020) [Please see discussion for comment on this deliverable]

WP4: Test, Learn and Iterate

We will, on an ongoing basis, test and iterate our content and our behavioural framework with patients. Typically we would expect a release each fortnight from the third release onward.

Deliverable: Digital therapy courses made live on production version of the My Arthritis app (November 2020)

Digital therapy assessment

Before launching the digital therapy courses, and making them freely available to all users of the My Arthritis app, we made the content available to a select group of people to test its safety and efficacy. The content evaluation was carried out between November 2020 and January 2021.

This report outlines the method and results from our first evaluation of the behavioural science courses and details learnings for possible iterations and improvements for the next release.

The primary objective of the evaluation was assessing patient-reported outcomes relating to musculoskeletal health following a 14-day digital therapy delivered through the My Arthritis app. As well as, assessing changes in self-reported measures relating to the course taken.

The MSK-HQ is a Patient Reported Outcome Measure (PROM) used to assess musculoskeletal symptoms across conditions and within various healthcare settings. The tool has been validated within several cohorts and found to have good completion rates and high reliability (Hill et al., 2016). The questionnaire is scored on a range of 0-56, and a change in a score of 5.5 or more is considered to be a clinically relevant change. This questionnaire was chosen as it is a reliable tool to determine whether any clinically relevant changes would be detected as result of participation in the trial.

Methods

Target population

We set out to recruit individuals who had been diagnosed with a type of the following inflammatory arthritis.

- Rheumatoid Arthritis
- Psoriatic Arthritis
- Enteropathic Arthritis
- Ankylosing Spondylitis

As the digital therapy is delivered via the My Arthritis mobile app, the participants needed to own a smartphone and be digitally literate. In order to consent to participation, we only invited individuals who had reached the age of 18.

Recruitment

We targeted those that may have a genuine interest in our product and courses to help test proof of product and sustainability for us longer term.

We utilised our current user base for recruitment as well as a one-off NRAS local group gathering of around 7 attendees and soft sharing on our social media channel.

Main method of recruitment: Mailchimp mass email to all users on My Arthritis (over 1K- approx 40% open rate) (Google form sign-up sheet)

- Initial outreach
  - Total sent: 1811
- New user follow up
  - Total sent: 21
- New user follow up (2)
  - Total sent: 113

Study design

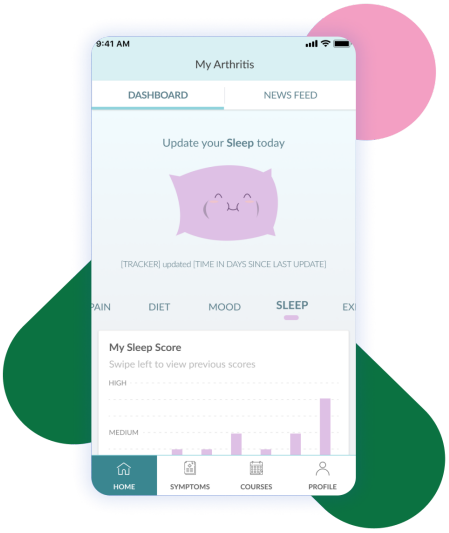
This study was set out to compare patient reported outcomes for individuals who completed a 14-day course to those who used the My Arthritis app without access to the digital therapy (Between subjects design). We were further interested in assessing patient outcomes before and and after the trial (Within subjects design).

Procedures

Throughout the study, we were in contact with the participants via email through our Research Lead for onboarding and offboarding and quick user-help if required.

Onboarding to the study

- Participants were invited to register their interest for participation in the study by completing a google form.
- Once a person had completed the form, they were emailed instructions on how to register for the study. To register, participants had to actively link their app to our clinical portal, specifically set up for the study. This was considered as providing informed consent for participation.
- Once linked up to the portal, participants were pseudo-randomly assigned to one of four groups; Control, General Wellbeing, Living with Symptoms, or Medication Adherence. The only criteria applied during group assignment was that a participant assigned to the Medication Adherence group had at least one daily medication listed.
- Participants who were assigned to taking a course (General Wellbeing, Living with Symptoms, or Medication Adherence), were provided with a link to the iOS Apple and Google Play store where users could update their My Arthritis app to gain access to the new courses. They were further provided with their course assignment.
- Daily activity and progress during course taking were monitored manually through the clinical portal, as well as by database queries run by our Insights & Analytics Lead.
- When a participant had missed over 2 days in a row of their course, they were sent an email requesting that they continue with the course.
- Participants on the control group were monitored in the same manner, and received an email when they had missed over 2 days of tracking their 'feelings' within the app.



- Any requests for withdrawal from the study were recorded and the participants data excluded from analysis.

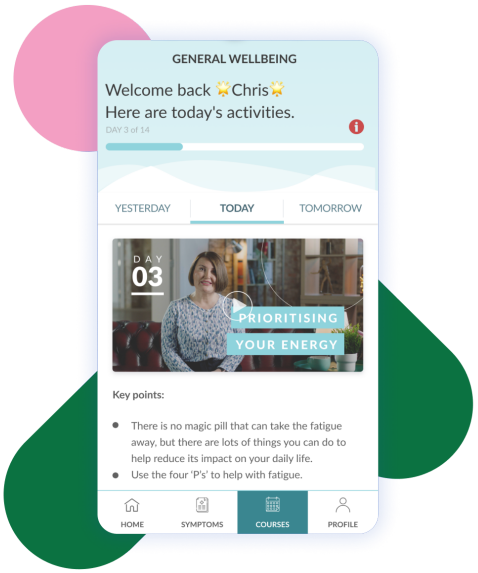
Control group activity

- Participants in the control group were asked to use the My Arthritis app for 14-days, and specifically log-in and track their 'feelings'. Tracking 'feelings' is a likert-scale type reporting of Mood, Stress, Exercise, Diet, Pain, and Sleep on a 7 point scale, ranging from Strongly disagree to Strongly agree. This function can be found on the home screen within the app, and takes about 1-2 minutes to complete. Participants in the control group did not have access to the courses at any time

during the tracking, however, they were given early access to the courses upon successful completion of 14-days of tracking.

- On the first day participants were asked to track their 'feelings' they were sent the MSK-HQ assessment to their app, from our research portal. Once participants had logged their feelings for 6 days, they received MSK-HQ, and again at day 13.

Courses/DTx group activity



- Participants in the intervention group were asked to take one of the three courses, provided to them within an update to their app. They were asked to take a specific course, despite having access to all three courses. Completion of a day on the course roughly takes between 4-8 minutes per day, depending on extra activities such as mindfulness audios or extra videos to explain specific medications.
  Participants in the DTx group were invited to track their 'feelings', however this was not specifically requested.
- The MSK-HQ assessment is built into all three courses so that a participant will naturally complete the questionnaire on days 1, 6 and 13.

Offboarding the study

- Participants were contacted and thanked for taking part with the invitation to fill out a further short survey about their experience of the app and trial itself.
- Participants were also offered a 1-1 interview with Ampersand Health to understand their experience further.
- After the trial ended, participants received an email, asking them to manually unlink from the study portal. If they had not done so after two follow-up emails, they were removed from the by our development team.

Data analysis

- Quantitative data

We queried the database for MSK-HQ scores, feelings trackers (Control group), course likert-scale answers, select responses to course reflection questions, and demographic information. All data was extracted into Microsoft Excel, and statistical analysis was conducted in SPSS (IBM Corp., 2017. IBM SPSS Statistics for Windows, Version 25.0. IBM Corp, Armonk, New York).

- Qualitative data

We applied simplistic thematic analysis of the survey data, coding themes as positive (green) or negative (red) in valence. Theme titles were chosen based on the frequency of repetition/mention of idea or depth/quality of the idea reported. Direct quotes are chosen to support the themes.

For the intervention group, we also asked participants about the suggested mechanisms of action of the courses - as classified by the Theoretical Domains Framework (Atkins et al., 2017). This was carried out through a simple check-list style question whereby participants identified how they think the course helped them. We also analysed the percentage of participants who thought they had changed their behaviour in some way. Key quotes from interviews with participants and in app feedback/course reflections by the intervention group are also highlighted.

Results

Demographics

Out of the 179 individuals who registered interest to participate in the mini-trial 66 actively provided informed consent by linking their app to the Ampersand Study portal. Of those, 8 withdrew their consent after being assigned to a study group.

Completion of the tracking (control group) was considered when the participant had completed 13 days of tracking feelings, and 2 MSK-HQ assessments, with a minimum of 10 days of tracking in between. Completion of a course (DTx group) was met when a participant had completed the likert-scale question on 13 different days, and had completed the MSK-HQ assessment twice, with a minimum of 10 days in between. Completion rate was overall 33%, with 48% of participants completing the control tracking. Digital therapy completion was between 21-29% for the three different courses.

Twenty-five participants completed the assignments (mean age 47.8 years, SD= 13.3, 80% female), with 14 people completing the tracking using the app without the DTx. Eleven participants completed one of the three courses. All participants had been diagnosed with a type of inflammatory arthritis, having lived with the diagnosis 1-25 years (mean=8.2, SD= 7.94). Less than 3% of participants had received their diagnoses less than 2 years earlier. The average age of diagnosis was 39.6 years (median=44), with 2 participants receiving their diagnosis before the age of 18.

We did detect significant differences in the ages between the control group and the DTx group. This was unexpected as course assignment was fully randomised, aside from the requirement that a participant had to have at least one medication listed within their app. An independent sample t-test was conducted for the age, number of years with arthritis diagnosis and the MKS-HQ score before the start of the trial. There was a significant difference in the age of participants within the control group (M=52.86, SD=11,75) and the DTx group (M=41,36, SD=12,71) at the start of the trial; t(23)=2,34, p = 0,028.
We did not detect a significant difference in the number of years with arthritis diagnosis between the control group (M=7,43, SD=8,43) and the DTx group (M=6,91, SD=7,56) at the beginning of the trial; t(23)=0,16, p = 0,87. There was not a significant difference in the MSK-HQ scores between the control group (M=30,64, SD=11,98) and the DTx group (M=29,93, SD=11,62) before the trial started; t(23)=-0,72, p = 0,48.

Arthritis Type	Number of participants
Rheumatoid Arthritis	18
Psoriatic Arthritis	5
Enteropathic Arthritis	1
Ankylosing Spondylitis	1

Table1. Breakdown of inflammatory arthritis the participants had been diagnosed with.

MSK-HQ

We asked participants to complete the MSK-HQ questionnaire on day 1, day 6, and day 13 after starting the trial. Participants in the control group were sent the questionnaire directly to the app, whereas the questionnaire was built into the courses as an activity to complete after viewing the video.

We examined whether there was any difference in overall MSK-HQ scores as a result of taking part in the trial by either using the app for 14-days, or taking a specific course. Paired samples t-test was conducted for the control group MSK-HQ scores comparing the first and last day of tracking. There was not a significant difference in the scores before (M=30,64, SD=11,98) and after (M=29,93, SD=11,62) the trial; t(13)=0,29, p = 0,77.

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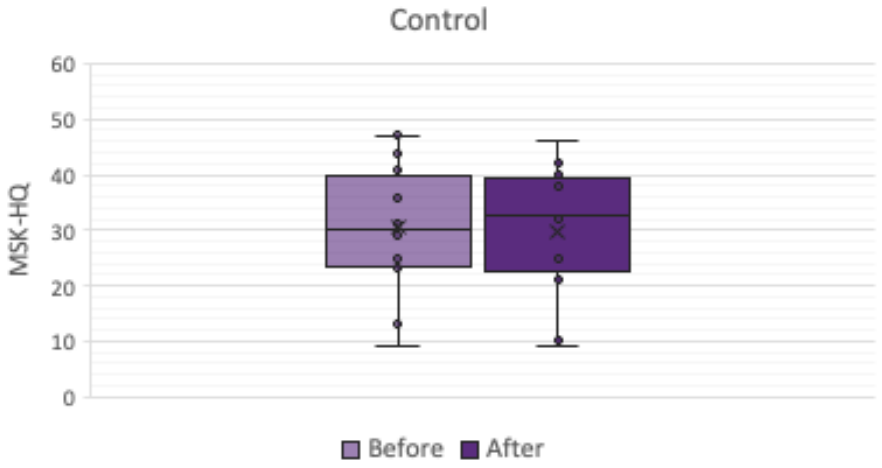

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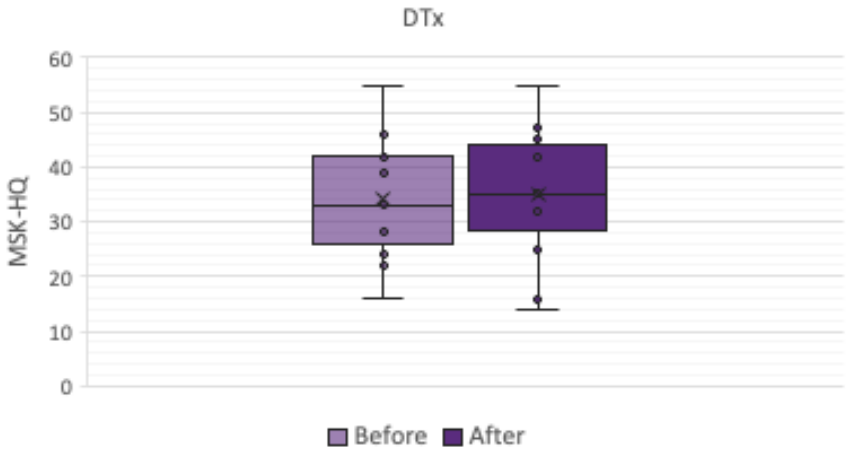

Figure 1. Average (x) and median (horizontal line) scores from the total MSK-HQ assessment shown in box-plot. A) MSK-HQ values plotted from participants in the control group (n=14), before and after 14-days of tracking during the mini-trial. B) MSK-HQ values plotted from participants in the Digital Therapy group (n=11), before and after taking one of the 14-days courses.

We then conducted a paired samples t-test for the before and after MSK-HQ scores from participants who took the courses. There was not a significant difference in the scores before (M=34,09, SD=11,74) and after (M=35,18, SD=12,93) the trial; t(10)=-0,51, p = 0,62. This result suggests that taking a course within the app does not immediately affect the MSK-HQ score. Taken together, these results indicate that there was no measurable change in the MSK-HQ scores as results of participation in the trial.

The MSK-HQ questionnaire assesses many aspects of arthritis symptoms, both physical and mental. Given that the digital therapeutic intervention does not aim to affect or change the physical symptoms of a person with arthritis, we omitted such questions during the additional analysis. We assessed questions 11, 12, 13, and 14 for additional analysis as these questions ask specifically about Emotional well-being, Understanding of the condition and current treatment, Confidence in being able to manage the symptoms, and Overall impact symptoms have on the patient. A paired samples t-test yielded no significant difference in the scores for questions 11-14 on the MSK-HQ before (M=7,07, SD=3,41) and after (M=8,07, SD=3,17) the trial within the participants in the control group; t(13)=-1,41, p = 0,18. Lastly, no significant difference was found in the subset of questions before (M=9,55, SD=4,18) and after (M=10,45, SD=3,48) the trial in the participants who took a course; t(10)=-1,42, p = 0,19. These findings indicate that the responses to questions on the MSK-HQ assessment were not affected immediately after taking a digital therapy course. Although we would have expected to see an increase in the scores for these particular questions, it is likely that the small sample size is a factor here. Other possibilities could be that the behavioural changes learned in the course have not yet been realised. A follow up MSK-HQ assessment would be required to assess any future improvements. Due to these factors it is not possible to draw definite conclusions regarding the efficacy of the courses on MSK-HQ scores within this time-frame.

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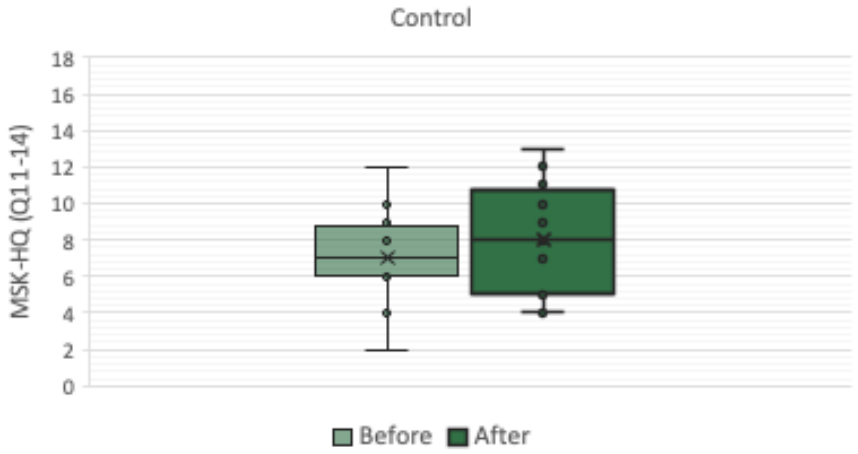

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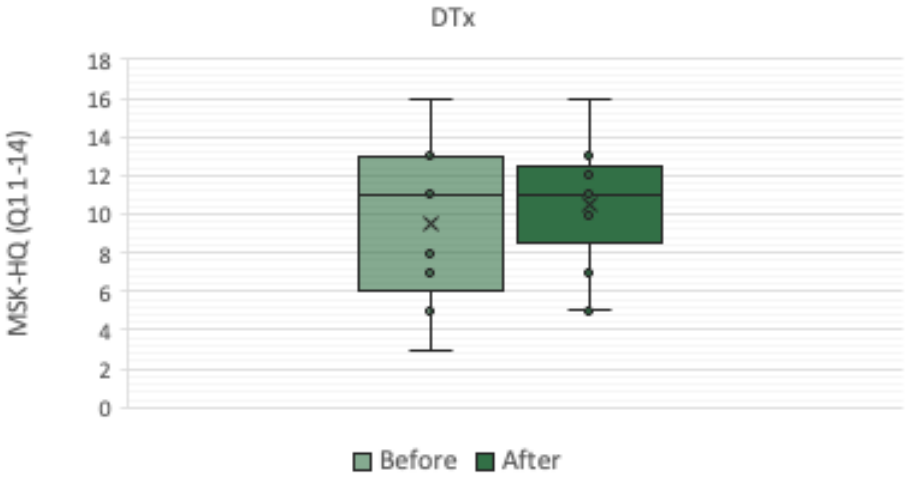

Figure 2. Average (x) and median (horizontal line) scores from select questions from the MSK-HQ assessment shown in box-plot. A) Questions 11-14 from the MSK-HQ plotted from participants in the control group (n=14), before and after 14-days of tracking during the mini-trial. B) Questions 11-14 from the MSK-HQ plotted from participants in the Digital Therapy group (n=11), before and after taking one of the 14-days courses.

As mentioned above, participants in the control group logged their 'feelings' for 14-days. In order to assess whether there were any changes in self-reported 'feelings' over the 14-days of tracking we averaged each daily score and conducted a repeated-measures ANOVA on 4 different times throughout the trial. There was not a significant main effect of time on the average tracking score ($F(3, 27) = 1,69$, $p = 0,19$, $\eta p^2 = 0,16$). This result suggests that there is no change in self-reported 'feelings' tracked over the 14-day period for participants within the control group.

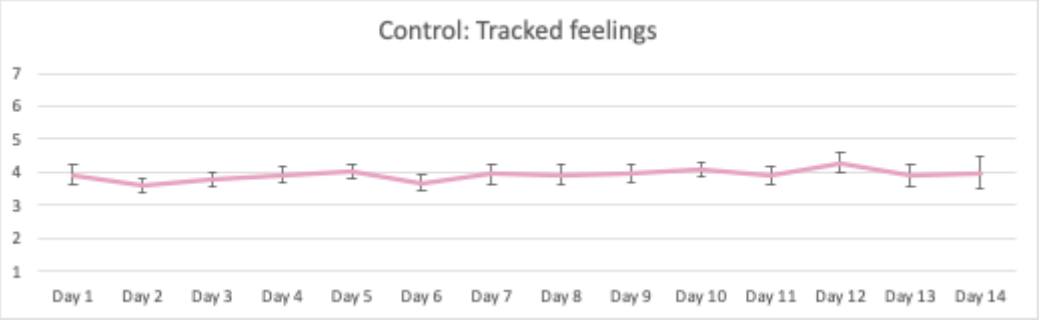

Figure 3. Changes in average scores of feelings per 14-day tracking within the My Arthritis app. The line graph shows the average rating (1-7) of the sliding scales from Strongly disagree to Strongly agree for the 6 feelings within the app. Error bars indicate Standard Error of means.

Participants taking the courses were prompted to respond to the same likert-scale question each of the 14-days of the course. In order to assess whether there were any changes in responses to the likert-scale questions as a result of taking a course, we conducted a repeated-measures ANOVA on 4 different times throughout the trial. There was not a significant main effect of time on the daily likert-scale question responses ($F(3, 30) = 0{,}61$, $p = 0{,}98$, $\eta p2=0{,}01$). This result suggests that taking a course did not influence the way participants responded to the daily likert-scale questions.

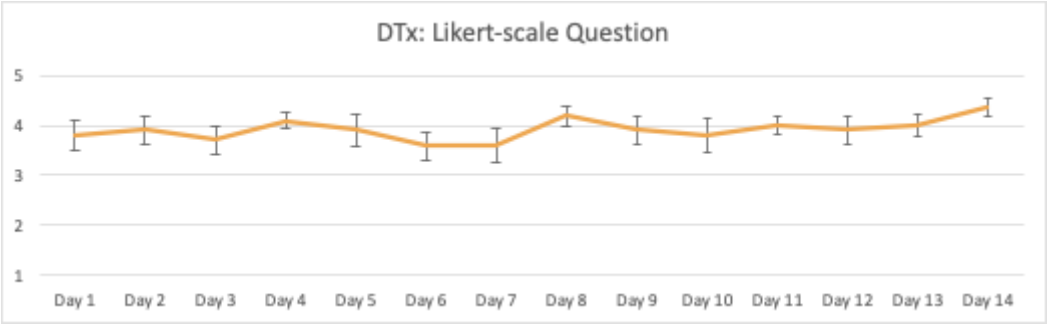

Figure 4. Changes in rating of daily likert-scale questions within the courses. The line graph shows the average rating (1-5) per 14 days of course taking. The three courses had different questions (same each day for a single course). Error bars indicate Standard Error of means.

Follow-up survey and interview findings

Overall experience:

When asked 'how would you describe your overall experience on the app?' all members of the control group reported that their experience was 'positive' (5-6 out of 7). 62.5% of the group testing courses reported that they had a positive attitude towards the course that they completed.

1) Control group

Key highlights

- Ease of use
    - ‘The app is well designed, easy to use’
    - (my highlight was) ‘The ease with which I could record my daily stats.’
    - ‘Simplicity’
    - ‘It was simple and quick to input the data’
- Ability to document daily feelings
    - (my highlight was) ‘Having a bad day can log it’
    - ‘This is already extremely useful and I so wish my RA team were using it. Massive time saver. My recent 6 months review would have been less than 10 mins instead of 22 mins.’
    - (my highlight was) ‘The ability to record daily symptoms and see them in simple graphs.’
    - ‘It was a useful way to log my symptoms’
- Access to condition specific information
    - ‘I liked the the fact that with this app an awful lot of information is at your fingertips’
    - (my highlight was) ‘discovering a new treatment in the Feed’
    - ‘any information about my condition is appreciated and so I may recommend the app if someone else has a similar condition.’
    - ‘Access to the Feed and Library functions was excellent and very welcome.’

Key frustrations

- Desire for increased insights
    - ‘No real feedback about how my answers (to the trackers) are relevant to my condition’
    - ‘Need more answers available to questions like how well i slept - It’s too narrow’
    - ‘More options to log symptoms e.g. swelling’’
    - 'Would prefer to be able to look at a glance to see good and bad days, flares etc. It would be helpful to show the rheumatologist’
- Forgetting to use
    - ‘Forgetting to complete on some days’
    - ‘I wish the app would prompt me to use it’

2) Intervention group

Key highlights

- Opening up and reflection
    - (my highlight was) ‘challenging my attitude’

    - ‘Making myself log in each day to complete the course and reflect on my feelings’
    - ‘Opening up to the benefits of mindfulness’
    - ‘It was a reminder to think of my wellbeing as a whole. Also, reflecting on how far I have come and how my attitude has changed and adapted in the past two years’
    - ‘A good opportunity to reflect on how far I have come since diagnosis’
    - ‘I really enjoyed the well-being course, especially the mini videos where we could try out mindfulness exercises in the comfort of our own homes where we're less likely to feel self-conscious trying something completely new’
- Learning
    - (the content was) ‘Excellent! Thought-provoking and useful.’
    - ‘I found each section interesting and accessible, in bite size chunks.’
    - ‘Many of the activities resonate with what I learnt during CBT so it was a bit like having a refresher course!’
    - ‘I feel that my disease is massively impacted by my wellbeing and levels of stress. This taught me ways to combat that’
- Reassurance and support
    - ‘I am very open to the course to provide me with support and focus in managing my condition better’
    - ‘Some of Dr Prior's statements really hit home. Ideas like looking after your well-being is not selfish, it is self-help. Putting your own health first is not just good for you it enables you to be the best version of you for your family etc. You are as important to your health as your health is to you. It's OK to give yourself permission to stop and rest or to say "no". Be kind to yourself’
    - ‘It was uplifting and a reminder that I am doing well in how I manage and cope with my RA.’

Key frustrations

- Courses are delivered too fast
    - ‘Moving along too fast. Not enough time to digest some of the information. Not to say it’s not valuable or beneficial.’
    - ‘It was quite rushed, I felt there were too many things to focus on each day. It could be done over 4+weeks to allow more time to work on each activity.
    - ‘I found them (the activities) quite hard to complete in one day, and would have liked new content ever 2-3 days to allow more time’
    - ‘It was hard to fit it all in in the time allotted but it was interesting’
- Functionality barriers
    - ‘The app seems buggy’
    - ‘Every time I clicked on a link in the text (to external resources e.g. NRAS pdfs) I had to sign back into the app which was frustrating’
    - ‘I think the programme was great but the issues lie in the technological behind the app’
    - ‘A daily pop up reminder would have been great for us forgetful folks!’

    - 'Weekly report didn't say too much. Needs more context and more data fed back to the user'
    - 'Would like notification reminders and access to the tools to continue learning after finishing a course'
- Relevancy for stage of journey
    - 'It would have been good to have had this at the beginning of my diagnosis.'
    - 'It was all information I already knew.'
    - 'For me personally, I found it less interesting to take part in. I got quite bored and would miss days of the course because it was boring'
    - 'It was stuff I already knew. It would be perfect for newly diagnosed people'

Evidence of early behaviour change

Participants were asked 'Do you think you've changed your behaviour in any way since using the course?'

37.5% said Yes
37.5% were Not sure
25% said No

What, if anything, has changed for you since using the course?

- 'I am practicing mindfulness daily and have committed to delivering actions against my values as part of my New Year resolutions.'
- 'I've learnt new techniques such as framing behaviours and breathing techniques'
- 'Nothing majorly, been more a reassurance that I'm doing okay'

Intervention mechanisms of action (MOA)

How did the intervention help them to change relevant health and wellbeing behaviours targeted by the courses?

Self-reported mechanisms of action of the courses - as classified by the Theoretical Domains Framework (Atkins et al., 2017).

Top 6 MOAs:

- Knowledge
- Beliefs about capabilities
- Optimism
- Beliefs about consequences
- Goals
- Emotion

(Theoretical Domains Framework is developed from a synthesis of psychological theories as a vehicle to help understand interventions aimed at behavior change. It comprises a list of domains which can represent barriers, facilitators or mechanisms of action of behaviour change. Definitions of mechanisms of action can be found in the top row of the Theories and Technique tool.)

Interview highlights (intervention group):

'I am enjoying it now and I'm still continuing with it as well.'

'Overall I thought the course was excellent, a great concept and the presentations were easy to understand (both content and clarity of delivery).'

'It's been really, really interesting. You learn about different things and obviously it builds your own awareness of what works for you and what doesn't.'

'My mental health is decreasing as my condition is progressing so it is very important to be aware of this and work on ways to maintain my mental health, and this course helped to do that.'

'I've tried lots of apps over the last five years and this is, this is one of the best I've done, if not the best. When I was diagnosed, I had some CBT one to one with a health professional. There is a distinct overlap with these courses, particularly things like pacing and and setting realistic goals, etc. The ACT (Acceptance and Commitment therapy) itself was the first time I'd seen it. I'm really open to this and that's why I'm so excited. What I literally did was I took the targets I made on the course, and I set them as my new year's resolutions, it was perfect timing. And I've got them in the diary and I've got commitments to deliver against them. So I'm actually living the course. It's amazing.'

'I think, in my case, it was perfect timing. I was diagnosed five years ago. I've had a bit of a rocky time with the drugs. And now you could argue that this might have helped that, but actually I probably wasn't in a place until about nine months ago when my medication finally sorted out. And I entered remission. Now I feel that I could then start work on the mental side of things. And also the physical side of things, both in terms of upping my exercise, and, you know, growing my mind and using these tools. I definitely love it (the courses). But obviously every person's journey is different with rheumatoid arthritis. There's no set path for when you're in remission.'

'Ideally I would like to do this type of course on a macbook, so the course could be bigger and it would be easier to print out resources. I also also ended up creating my own notebook based on the course and I think more resources and worksheets to print out would be useful'

Overall I enjoyed the course and thought it very worthwhile. I think it's something that would be useful to revisit several times before you fully absorb the content and are able to

put some of the exercises into regular practice. I like the idea of "keep learning" - it was one of the things mentioned during a talk at my local NRAS group by a therapist from MIND.'

Course specific reflections (intervention group):

ACT FOR CHRONIC SYMPTOMS

'I found this course very interesting. I haven't noticed any difference to my pain levels but mentally I do feel a bit better and calmer.'

'It has helped me to focus on what is in my control. You can't control pain, but you can control how you are affected by it.'

'An excellent course and I am already benefiting from a better focus on managing my pain and fatigue.'

'Very interesting. It would have been more useful for me if I was in pain, but my pain is well controlled. I need to do the course again to absorb the information properly.'

GENERAL WELLBEING

'I have definitely noticed a difference in my mood and so have my partner. I wish it was longer.'

Discussion

This project has been a pleasure to undertake alongside patients, clinicians and other subject matter experts. We have examined the lived experience of IA patients through 1-1 interviews, a combined Ampersand Health x NRAS workshop, literature review and through collaboration with experts in the field. We identified new behaviour change techniques required to meet the needs of IA patients and wrote bespoke courses alongside a consultant Rheumatologist , an ACT therapist, specialist Rheumatologist nurse and Occupational Therapist/researcher in rheumatology/patient living with RA (see website for more information on our expert collaborations). The result of this work are newly developed courses that make a difference to patients' everyday self-reported sense of well being and optimism to self-manage going forward.

Despite the unprecedented circumstances, we were pleased to be able to film three 14-day courses (and an array of 'single videos' for one of selection) with collaboration from highly credible experts in the field (Dr James Galloway, Dr Yeliz Prior, Dr Jonathan Marks, Alison Kent, Dr Whitney Scott) who dedicated themselves to this project alongside their highly critical roles within the NHS. This itself truly emphasises and captures the importance of and commitment to the shift to digitalised care for rheumatology patients.

My Arthritis digital therapy mini-trial

Mid-November 2020 we set out to trial the newly developed digital therapy courses for My Arthritis. The expert lead courses are designed to help people diagnosed with inflammatory arthritis manage their condition and improve their quality of life.

The courses cover a range of topics, such as General Wellbeing, Medication Adherence, and Living with Symptoms. Each course was carefully developed by Ampersand Health with subject matter experts and includes a series of videos and activities to be completed within the app.

The three 14-day courses were made exclusively available to volunteer individuals through an update to their application. The participants were asked to sign up to one of the courses and complete over the coming weeks.

We chose the MSK-HQ questionnaire, a validated patient reported outcome measure developed by the University of Oxford to assess the status of arthritis over a 2 week period, as an indicator of whether the courses had an affect on the arthritis symptoms. The trial ran until mid January 2021, commencing with participant interviews on their experiences with a completed course.

Overall, the participants had positive experiences of using the app and course feature. There was a high emphasis on desire for increased reminders/notifications from the app to complete daily tasks that they view as worthwhile. In regards to the courses feature, the main theme of concern was the speed of content delivery. Due to the nature of the study procedure, participants were asked to complete courses daily which some individuals found hard to consistently engage with. In contrast, other participants found the bite sized nature of our content and activities appealing.

Study limitations:

This small study has demonstrated that the newly developed digital therapy is well received and generally safe for inflammatory arthritis patients to use to support self-management of their condition. The study does come with some limitations, which is mainly highlighted in the relatively low number of participants that completed the trial; 14 in the control group and 11 in the intervention group. The considerable drop-off of participants, starting during recruitment and throughout the last days of assignment completion is of some concern.

We encountered technical difficulties in communication with individuals who registered interest in the trial. It is unclear whether this is a result of emails failing, however, these issues resulted in a lower number of participants getting on-boarded onto the Ampersand Study research portal. We further encountered drop-offs during the process of providing participants the access to the beta version of the application. These technical issues resulted in a lower number of participants getting involved in the digital therapy trial.

Throughout the trial, we regularly engaged with participants and collected all feedback they relayed to us, both on usability of the application itself, and the content within the digital therapy courses. The main, and consistent, feedback we received was that the pace of the courses was fast, and that participants would have liked the 14 daily courses to be spaced out over a longer period of time. This feedback is likely to have been a result of us following up with participants by email, if they had missed more than 2 days in a row of courses, or tracking their feelings (control group). It is highly likely that this increased pressure to complete the courses in a relatively short amount of time has contributed to further drop-offs. Although not a limitation of the trial, we have taken this feedback into consideration for future course development.

Looking forward:

Through our research activities and scoping review undertaken so far, we believe there are key drivers to engagement of the courses feature for those living with inflammatory arthritis. The following points capture how we are considering steps to improve engagement with the app and courses feature going forward.

- ❏ Help users to more deeply understand ‘why self management is important’ and ‘how digital health can remote monitoring can aid with this’
- ❏ Emphasise the flexible cadence of use for courses
- ❏ Improve in-app feedback and responsiveness (e.g. weekly reports and tracker

insights)

- ❏ Introduce personalisation (e.g. app onboarding which reflects the needs that users have identified)
- ❏ Implement more motivation-based behavioural techniques (e.g. social support and gamified interactions with the app features)
- ❏ Vary the mode of delivery and accessibility (e.g. prints outs)
- ❏ Address usability interruptions in experience (e.g. links taking the user out of app and having to log in again)
- ❏ Continue to host expert-led webinars that address topics of self-management and bring the community closer together.

Impact and future implications

Our app and clinical portal makes virtualised outpatient care of a vulnerable group safer during the pandemic and in the longer term. For patients who are being required to shield and whose care has been transferred to a virtual setting, we provide a double safety net - firstly, we will give them the knowledge and the tools to look after themselves better and secondly, we provide them with the peace of mind that their clinical team is aware of how they are doing and can intervene remotely if necessary. If virtualised care becomes the norm, these benefits could be expected to extend into the long term.

After the dangers and social restrictions of Covid-19 are lifted, we expect to be able to help the NHS manage capacity and flow by identifying patients with the most urgent needs, so they can be seen more quickly; and by identifying those who are well, so they can be kept away from hospital.

In the longer term, we expect that patients using our app will improve their self-care and consequently their QoL and health outcomes; while at the same time giving them the peace of mind that they are being properly monitored. The current study has shown a high acceptability towards therapeutic self-management courses for those with IA and we aim to demonstrate positive outcomes for patient health and wellbeing through the continued use of the Digital Therapeutic.

For the NHS, our platform will support the short term objective of enabling safer virtual care for another vulnerable group. Post Covid, in response to an inevitable explosion in pent up demand, clinicians will be able to easily identify the patients in the greatest need of face-to-face care and will be able to prioritise their attendance at clinics.

Final remarks

We have demonstrated our technological abilities to design and implement expert led digital therapy within an app that is well received and comfortable to use. We will continue to assess the effectiveness of the digital therapy and revisit the dataset once more people have completed the course activities on their own time.

We are grateful for the opportunities for numerous expert collaborations allowing us to put together the digital therapy courses. These collaborations have provided direction and credibility that will yield higher trust in our products in the long run. Future collaborations will further aid us in moving forward at the same pace as before.

The overall positive response and acceptability of the technology, both from clinicians and subject matter experts is extremely promising. We further continue to have good ongoing patient support, and have had many people begin to advocate for the value in the app and courses. This type of support comes in many forms, from patients speaking up at our new webinar events, to writing blogs about their stories and how the app, along with the digital therapy, continues to help them self-manage. One of these blogs has been recently published. Read about Clive's journey with RA: The Good, the Bad, the Funny.

The successful project of launching the My Arthritis application and the digital therapies has been encouraging for our team. This journey has also given us valuable insights to continue to develop and build our technology in the coming future.

We highlight the fantastic contributions of Innovate UK, and their ongoing support of the development of Ampersand Health's digital therapeutics.

Appendix

Brief description of the three courses:

Our courses focus on key self-management behaviours and levers for enhancing wellbeing- such as sticking to medication, pain management, staying active, sleeping well and even incorporates techniques and exercises from Acceptance and Commitment therapy. All our courses are tailored to the lived experience of patients with Arthritis.

Key features include expert advice from those who understand living with arthritis most, daily videos and activities to help you reflect, learn and make changes in their life that work best for you, weekly reports to help track progress with control of symptoms and self-management behaviours and a growing library of Singles (quick advice, videos, tools and practical tips to use).

Weekly report - after every 7 days of using the courses you will find a new weekly report generated that summarises your progress in the areas of focus you are working on - whether that is general wellbeing or how well you are sticking to your meds.

See below for course descriptions as seen in-app:

1. ACT FOR CHRONIC SYMPTOMS

How will this course work?
This is the FULL 14-day course, based on Acceptance and Commitment Therapy (ACT), that can help an individual cope with chronic symptoms. Weekly reports will help the user understand how the ACT for Chronic Symptoms course impacts health and wellbeing.

What will be covered?
- Introduction to ACT for inflammatory arthritis
- Reflection on your current management of symptoms
- Learn the 3 ACT skills (Be present, Open up and Do what matters)
- Follow 9 audio led exercises to help you practice your ACT skills
- Set up your values compass
- Goal setting - plot a path to success, moving towards your values
- Develop a new mindset - you are more than your thoughts, feelings, and bodily sensations

Why was this course developed?
Living with inflammatory arthritis can be challenging. Chronic pain and fatigue can really impact well-being and some days, it can feel really difficult to cope. This course is based on ACT, developed by people who have years of experience in understanding chronic symptoms in conditions such as inflammatory arthritis. Studies have shown that, on average, ACT can improve people's daily functioning and mood when they have chronic pain. Even at 6 months after ACT treatment, some improvements have been shown to be maintained. Evidence also has shown it can be useful in reducing anxiety and depressive symptoms.

Supported by our experts…
This course has been developed by Dr Yeliz Prior and Dr Whitney Scott. Yeliz is a clinical therapist and researcher specialising in behaviour change interventions for the management of rheumatic and musculoskeletal diseases. She also lives with arthritis. Dr Whitney Scott is a clinical psychologist who has spent over 12 years working to understand chronic pain and its management. For the last 6 years, she has been conducting research into ACT to help improve the lives of people with chronic pain.

We also worked with others living with inflammatory arthritis, to make this course the most relevant to our users, and with Behavioural Scientists, who help our users maintain positive changes they make.

2. GENERAL WELLBEING

How will this course work?
This is the FULL 14-day course to help improve wellbeing! Weekly reports help our users understand how the General Wellbeing course impacts your health and wellbeing.

What will be covered?
- How Inflammatory Arthritis and mental health are linked
- The relationship between stress and inflammation
- The 5 steps to wellbeing
- How to improve your wellbeing through exercise, sleep, diet and in your work life
- Embracing social connection
- Mindfulness and the power of your breath
- Gratitude and Acceptance
- How to prepare for future challenges
- An introduction to Cognitive Behavioural Therapy techniques

Why was this course developed?

Inflammatory arthritis and psychological wellbeing are very closely linked, anything that impacts us physically is bound to impact us mentally or emotionally.

Supported by our experts…
This course has been developed by Dr Yeliz Prior. Yeliz is a clinical therapist and researcher specialising in behaviour change interventions for the management of rheumatic and musculoskeletal diseases. She also lives with arthritis. We also worked with others living with inflammatory arthritis and Behavioural Scientists to help you improve your general wellbeing and maintain positive changes you make.

3. MEDICATION ADHERENCE

How will this course work?
This is the FULL 14-day course to help you improve your wellbeing! Weekly reports will help you understand how the Medication course impacts your health, wellbeing and adherence.

What will be covered?
- The importance of tracking your medication
- Getting your head around the medication you are taking
- Your relationship with medication
- Trusting in your treatment and the Rheumatology Team
- I don't think my medication is right for me!
- What can you achieve through improving my adherence?
- How to stay on top of your medication
- Addressing common barriers affecting adherence

Why was this course developed?
Your inflammatory arthritis disease activity and medication adherence are very closely linked. Medication helps bring your condition into remission and helps maintain these changes.
During this course, you will explore different techniques that you can use to help you form strong habits that help you remember to take your medication.

Supported by our experts…
This course has been developed by Dr Jonathan Marks, a Consultant Rheumatologist, and Alison Kent, Rheumatology Specialist Nurse and Health Coach. We also worked with others living with inflammatory arthritis and Behavioural Scientists to create a course to help you improve your medication adherence and maintain positive changes you make.

References

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