



Translating the Strengthening and Stretching for Rheumatoid Arthritis of the Hand (SARAH) Programme from clinical trial to clinical practice: an effectiveness-implementation study

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Abstract:	<p>Introduction The SARAH (Strengthening and Stretching for Rheumatoid Arthritis of the Hand) programme is a hand exercise programme for people with rheumatoid arthritis. It was clinically effective when delivered during a clinical trial but there was a need to evaluate translation into routine care.</p> <p>Methods We conducted an effectiveness-implementation study. We adapted the trial training into an online format for National Health Service (NHS) hand therapists. Educational outcomes included confidence and capability to deliver the programme. Implementation outcomes included training reach and adoption. Therapists were invited to collect clinical outcomes. Patients receiving the programme provided data on function (Michigan Hand Questionnaire (MHQ) function scale), pain and grip strength at baseline, treatment discharge and 4 months follow-up.</p> <p>Results A total of 790 therapists (188 NHS organisations) enrolled in the training. 584/790 (74%) therapists (162 NHS organisations) completed the training. 448/790 therapists (145 NHS organisations) (57%) evaluated the training and were confident (447/448, 99.8%) and capable (443/488, 99%) to deliver the programme with 78% intending to adopt it (379/488). Follow-up data was provided by 116/448 (26%) therapists. Two-thirds (77/116; 51 NHS organisations) reported adopting the programme. 118 patients (15 NHS Trusts) participated. Patients reported improved function (mean change MHQ scores: 10 [95%CI 6.5-13.6] treatment discharge; 7 [95%CI 3.8-10.2] 4 months follow-up). Grip strength increased 24.6% (left) and 22.6% (right). Pain was stable.</p> <p>Discussion Online training was an effective way to train therapists with good reach. Clinical outcomes were similar to the clinical trial providing preliminary evidence of successful translation into routine care.</p>

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Abstract 250 words

Introduction

The SARAH (Strengthening and Stretching for Rheumatoid Arthritis of the Hand) programme is a hand exercise programme for people with rheumatoid arthritis. It was clinically effective when delivered during a clinical trial but there was a need to evaluate translation into routine care.

Methods

We conducted an effectiveness-implementation study. We adapted the trial training into an online format for National Health Service (NHS) hand therapists. Educational outcomes included confidence and capability to deliver the programme. Implementation outcomes included training reach and adoption. Therapists were invited to collect clinical outcomes. Patients receiving the programme provided data on function (Michigan Hand Questionnaire (MHQ) function scale), pain and grip strength at baseline, treatment discharge and 4 months follow-up.

Results

A total of 790 therapists (188 NHS organisations) enrolled in the training. 584/790 (74%) therapists (162 NHS organisations) completed the training. 448/790 therapists (145 NHS organisations) (57%) evaluated the training and were confident (447/448, 99.8%) and capable (443/488, 99%) to deliver the programme with 78% intending to adopt it (379/488). Follow-up data was provided by 116/448 (26%) therapists. Two-thirds (77/116; 51 NHS organisations) reported adopting the programme. 118 patients (15 NHS Trusts) participated. Patients reported improved function (mean change MHQ scores: 10 [95%CI 6.5-13.6] treatment discharge; 7 [95%CI 3.8-10.2] 4 months follow-up). Grip strength increased 24.6% (left) and 22.6% (right). Pain was stable.

Discussion

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Keywords

Implementation, hand exercises, rheumatoid arthritis, online training

Word count=4330

Introduction

Rheumatoid Arthritis (RA) is one of the most common form of inflammatory arthritis. It affects 1.4% of women and 0.7% of men in the UK.¹ RA commonly affects the hands and manifests as pain, swelling, stiffness and muscle weakness resulting in difficulty with everyday tasks and affecting quality of life.²⁻⁴

The SARAH (Strengthening and Stretching for Rheumatoid Arthritis of the Hand) programme is a tailored and progressive 12-week exercise programme designed to improve hand function in people with RA affecting their hands and wrists.⁵ We demonstrated that the SARAH programme was clinically and cost-effective in a large clinical trial at 12-month follow up and national guidelines recommend its use.^{6,7} In the trial, therapists received face-to-face training to deliver the SARAH programme (one-half to 1 day in duration) but it was unfeasible to provide this training to facilitate implementation. Therefore, we adapted the face-to-face training into a free, online training course (iSARAH <https://isarah.octru.ox.ac.uk/>) to provide National Health Service (NHS) therapists with the knowledge and skills to deliver the SARAH programme to their patients and to facilitate the translation of an intervention designed for a clinical trial into routine NHS care.⁸ Online training is easily accessed by large numbers of learners and is cost-effective in terms of time, effort, and travel.⁹ It has the potential to be an effective method of reaching and training health professionals on a large scale.^{10,11} We followed best practice recommendations for developing knowledge translation resources in rehabilitation.¹² A full description of iSARAH development is published elsewhere.⁸ iSARAH was launched in April 2017.

The overall aim of this study was to evaluate translation of the SARAH programme into routine NHS care. The objectives were:

- 1) To evaluate the education and implementation outcomes amongst NHS therapists who undertook the online training
- 2) To evaluate clinical outcomes in patients enrolled in a service evaluation and who received the SARAH programme as part of routine NHS care and to compare findings with those from the clinical trial.

Methods

Study design

We used an effectiveness-implementation hybrid study design based on implementation guidance produced by the USA Department of Veterans Health Administration.¹³ We utilized a Hybrid Type III design with two stages.¹³ Stage 1 measured the impact of an implementation strategy and we evaluated the online training as way to facilitate translation into clinical practice using education and implementation outcomes. Stage 2 gathered information about the clinical effectiveness of the intervention being implemented in routine clinical practice rather than during a randomized controlled trial and we collected clinical outcomes to evaluation the impact on patients receiving the SARAH programme as part of routine care.

Recruitment

Stage 1

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We advertised iSARAH to the relevant professional groups (British Association of Hand Therapists, Chartered Society of Physiotherapy, and College of Occupational Therapists). We promoted iSARAH during conference presentations and on social media. Physiotherapists and occupational therapists with an NHS email address were eligible to register and access the iSARAH training.

Stage 2

Therapists who completed the training were invited to evaluate clinical outcomes in their patients who received the SARAH programme as part of routine care. Therapists who agreed to participate invited patients who they deemed suitable for the SARAH programme to take part in stage 2. The SARAH programme is recommended for adults experiencing difficulties with hand function with stable RA (defined as a stable drug regime for at least 3 months or on no drugs). Patients were provided with an information sheet and those who chose to participate signed a consent form that included permission to share their contact details with the SARAH implementation team to collect follow-up data.

Interventions

Stage 1

iSARAH has four modules covering the SARAH trial, SARAH programme, behavioural support strategies, and how to deliver the programme to patients.⁸ The main components of the SARAH programme are described below. We used written text, pictures, videos demonstrating the exercises and delivery of the programme including baseline setting, exercise progressions/regressions and behavioural support strategies, quizzes to check and reinforce knowledge and a library of downloadable patient resources. The training takes 2 to 3 hours. After completing the modules and training evaluation, therapists downloaded their training certificates. The training can be viewed here: <https://isarah.octru.ox.ac.uk/>

Stage 2

The SARAH programme was designed to be delivered to patients in six sessions with a therapist. The programme consists of 11 mobility and 4 strengthening exercises supplemented with evidence-based behavioural support strategies such as an exercise diary, joint goal setting and action planning to encourage exercise adherence. Teaching the patient to progress and regress their exercises in response to their symptoms is a core component of the programme. A detailed description of the SARAH programme is available elsewhere.⁵

We anticipated from speaking with therapists that providing patients with the 6 sessions offered in the SARAH Trial in routine NHS settings would be difficult. Therefore, the number of sessions was left to the discretion of the therapist. We recommended a minimum of four sessions to ensure exercise progression and the use of behavioural support strategies.

Data collection

Stage 1

During registration, therapists provided demographic information, including profession, age, experience in treating people with RA, and the average number of RA patients they treated each month. Therapists provided the name of the NHS Trust in which they worked to determine the reach of the training into the NHS.

On training completion, we collected education and implementation outcomes. Education outcomes included two items from the Perceived Confidence Scale to rate confidence and capability to deliver the SARAH programme.¹⁴ Implementation outcomes, categorized according to the taxonomy proposed by Proctor et al¹⁵, included implementation intention (adoption), satisfaction with the training (acceptability) and any potential barriers to implementation (appropriateness) (Table 1).

Therapists who completed all modules, the self-assessment quiz, training evaluation, and downloaded the training certificate were classified as 'training completers'. Six months post-training, training completers were emailed a follow-up questionnaire to complete online to collect implementation outcomes (Table 1). We sent reminder emails to non-responders 2 and 4 weeks later. We asked if therapists had delivered the SARAH programme in clinical practice (adoption) and if so, the number of patients prescribed the programme in the past six months. We collected ratings on clinical usefulness (appropriateness), patient satisfaction (acceptability) and future intended use (adoption). Therapists were asked details of programme delivery (fidelity) and to identify aspects of the SARAH programme that were helpful or unhelpful in its implementation (appropriateness). Respondents who reported they had not implemented the programme were asked to describe barriers to implementation (appropriateness).

Stage 2

Therapists were provided with booklets to collect patient data at the 1st and last (discharge) session. During session 1, patients provided demographic information and baseline ratings of hand function and pain. Hand function was measured by the Michigan Hand Outcomes Questionnaire – overall hand function scale (range 0-100; higher scores indicating better hand function.¹⁶ This was the primary outcome for the SARAH Trial, which would enable us to compare findings with the trial. Pain in hands and wrists was measured by a 5-point Likert scale ranging from "Very mild" to "Very severe". If a dynamometer was available, therapists measured full-hand grip strength. The average of the three measurements was calculated for each hand in Newton, Kilograms or PSI (Pounds per Square Inch).

At the discharge session, patients provided ratings of hand function and pain, perceived usefulness and satisfaction with the programme, and self-rated improvement. Patient perceived usefulness and satisfaction were measured with 5-point Likert scale ranging from "Not at all useful" to "Extremely useful" and "Very dissatisfied" to "Very satisfied" respectively. Self-rated improvement used a global rating of change (GROC) scale consisting of a 7-point Likert scale (Completely recovered to vastly worsened). Handgrip strength was re-assessed, where possible, by the therapist. The therapist also completed a treatment log to record patient attendance and use of the core components of the SARAH programme delivered during each session. On discharge, therapists returned the booklets to the SARAH implementation team. If the booklets were not returned then the study team contacted the therapists to encourage their return.

All patients were sent a 4-month follow-up postal questionnaire and a postage-paid envelope to return it to the SARAH implementation team. Patients were asked to rate their pain, hand function, self-rated improvement, and adherence to SARAH exercises at home. If the questionnaire was not returned after two weeks, then another was sent. If it was still not received after a further two

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4 weeks, then the patient was contacted by telephone and follow-up was completed over the phone
5 where possible to minimise the amount of missing data.
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7 Sample size

8 *Stage 1*

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10 The British Association of Hand Therapists had 500 members at the time of planning this study. We
11 aimed to reach 50% of hand therapists so we set a target of training 250 NHS therapists to deliver
12 the SARAH programme.
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14 *Stage 2*

15 We proposed a target of enrolling 100 patients in the 16-month study period. This was a pragmatic
16 target based on the timeframe we had available.
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19 Analysis

20 *Stage 1*

21 We summarized the post-training evaluation responses from the therapists. Ratings of capacity and
22 capability to deliver the SARAH programme, satisfaction with training and intention to implement
23 were categorised as described in Table 1. Barriers to implementation were grouped into categories
24 (by CS and checked by EW), and their frequency summarised. We compared characteristics of those
25 completing the training with those who did not using a Mann Whitney test.
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29 Similarly, we summarised the 6-month follow-up data as described in Table 1. Helpful and unhelpful
30 aspects of the programme and barriers to implementation were grouped into categories (by CS and
31 checked by EW), and their frequency summarised. We compared the characteristics of implementers
32 and non-implementers, and, those who completed follow-up and did not complete follow-up using a
33 Chi-square test.
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36 *Stage 2*

37 The MHQ overall hand function scale and pain ratings were collected at session 1, final session and
38 follow-up (4 months). We anticipated that patients would complete their final session before the 4-
39 month follow-up. However, if patients attended the therapy sessions over a longer time frame than
40 anticipated, we analysed the MHQ and pain rating in chronological order for those patients based on
41 the date of data collection. We estimated changes in hand function, pain and grip strength between
42 baseline and each follow-up point as mean or median difference (95% confidence interval, CI) using
43 a paired t-test or Wilcoxon signed-rank test as appropriate. We also calculated Cohen's d in order to
44 estimate an effect size which were interpreted as small (0.2), medium (0.5) and large (0.8).¹⁷
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48 We summarised the number of hand therapy sessions provided, the core components delivered
49 during the sessions and the number and proportion of participants in each response category for
50 self-rated improvement, usefulness and satisfaction with the programme, home exercise adherence,
51 and frequency of home exercise sessions.
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54 For all analyses, we used all available data, and as missingness varied, the contributors are not the
55 same in all analyses.
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Results

Stage 1

A total of 790 therapists were registered between 3rd April 2017 and 30th September 2018. Therapists were from 188 NHS organisations across the UK and 6 non-NHS providers of NHS treatment (England) (Supplementary Table 1). Their demographic characteristics are presented in Table 2. The majority of registrants were female occupational therapists with a good spread across age groups. The majority reported a graduate-level professional education and less than five years of work experience. Over 90% of therapists reported treating at least some patients with rheumatoid arthritis each month, ranging from <5 to 11-15 per month.

Training outcomes

Of those registered, 448 therapists (57%) were classified as “training completers”. There was at least one training completer from 145 different NHS organisations and 6 non-NHS providers of NHS treatment. However, a further 136 therapists (17%) completed all the modules but did not complete the self-assessment quiz or training evaluation so were unable to download the certificate. Module completers were from 85 different NHS organisations. In total, 584 (74%) therapists had undertaken all the modules needed to deliver the SARAH programme representing at least one therapist from 162 NHS organisations and 6 non-NHS providers of NHS treatment. 206 therapists (26%) did not complete the modules. The characteristics of training completers were compared to module completers and those who did not complete the modules (Table 2). Training completers and module completers reported treating more patients with RA than those who did not complete ($p<0.001$).

The majority of training completers felt confident (447/448, 99.8%) and capable (443/448, 99%) to deliver the SARAH programme and were satisfied (443/448, 98.8%) with the training. Nearly 85% (379/448) of training completers intended to use the programme, but 70% (314/448) anticipated potential barriers to implementation. Lack of time was the most anticipated barrier ($n=80$) followed by low numbers of suitable patients in their caseload ($n=48$) and lack of exercise equipment ($n=29$). A small number of therapists anticipated difficulty booking follow-up appointments and patient attendance, limited clinic space, and changes in work role to be potential barriers.

Implementation

116 out of 448 therapists (26%) provided 6 month-follow-up data. At least one therapist from 70 NHS organisations and 2 non-NHS providers of NHS treatment responded. There was a higher proportion of therapists with post-graduate qualifications amongst the responders (25% versus 15% of non-responders). Two-thirds of respondents (77/116) implemented the SARAH programme, and it was implemented by at least one therapist in 51 NHS organisations across the UK. Approximately, a third (33%) of implementers (25/77) had used the SARAH programme with 1-5 patients each month, 40% (31/77) used it with between 5 and 15 patients per month, and around 27% (21/77) of respondents used it with 15 or more patients each month. The majority of implementers reported that the programme was useful (75/77, 97%), would continue using the programme (67/77, 87%) and that their patients were satisfied with the programme (72/77, 93.5%).

Most commonly, therapists provided 4 sessions (25/77, 32.4%) with three sessions (20/77, 26%) and five sessions (15/77, 19.5%) being the next most commonly reported. A small proportion delivered

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the SARAH programme in one to two sessions (5/77, 6.5%) or six sessions (7/77, 9.1%). A small number of therapists (5/77, 6.5%) reported alternative methods of delivery, such as incorporating the SARAH programme into a Lifestyle Management Programme. Many therapists (48/77, 62%) provided exercise equipment to their patients while the remaining advised patients on how to purchase equipment.

Patient education, exercises and the progression or regression of the exercises were the core components delivered by most therapists (Table 3). Therapists reported less frequent use of the behavioural elements. Forty percent of therapists rarely or never used the exercise diary with their patients and 17% rarely or never used goal setting and exercise planning. Advice to continue the exercises long term was common (80%) but 8% of therapists rarely or never provided this advice.

Implementers described aspects of the programme that helped to implement it. They described the SARAH exercises as simple, clear, comprehensive, and easy to implement and felt that the structured format and evidence-based background of the SARAH programme was helpful. The programme was appealing to patients as the exercises had been thoroughly tested, easy to follow, and improved their hand function. Therapists said patients felt empowered to manage their hand arthritis symptoms and were motivated to adhere to the programme.

Fifty percent of implementers described aspects that were unhelpful. Some felt it was time-consuming (including too much paperwork), that the number of recommended review sessions was not always feasible for them or patients and they had difficulty providing exercise equipment. Around 20% of therapists had not encountered any barriers to implementation.

Non-implementers reported the main barriers to implementation were lack of appropriate patients and time. Staff shortages, changes in current work role, difficulties in arranging follow-up sessions, and using another hand exercise programme were also reported. These barriers were similar to those reported in the post-training questionnaire. The only difference between implementers and non-implementers was that implementers treated more patients with RA than the non-implementers.

Stage 2

Between December 2017 and March 2019, 15 NHS trusts in England and 1 from Wales participated. 118 patients were enrolled from 15 trusts. Therapists returned 108 patient booklets to the SARAH implementation team. Data were available for 90% of patients at baseline (106/118), and 65.3 % (77/118) at discharge. Approximately 85% (100/118) of patients returned the follow-up postal questionnaire or completed the follow-up over the telephone.

Of the 108 booklets, 6 patients had baseline data only. Five patients withdrew from the study (one prior to the treatment, three during treatment and one after treatment). A total of 97 patients with baseline and discharge or follow-up data were included in the analyses.

The majority of the patients were British (73/97, 75%) and female (78/97, 80%). Their mean age was 61.6 (SD 13.6) years. The median duration since their RA diagnosis was 6 (Inter-quartile range, 1 to 17.1) years. Around 47% of patients were retired; 37% were employed full-time or part-time or self-employed, and 15.5% were not working. 88.7% of the patients were right-handed.

SARAH programme delivery

The median number of therapy sessions was 4 (IQR 2 to 5), but 48% of patients received less than the 4 recommended sessions. A small proportion (8/97, 8%) received a single session, 29% (28/97) received two sessions, 14% (14/97) received 3 sessions, 21% (20/97) received 4 sessions and 27% (26/97) received 5 or 6 sessions.

The median duration between baseline and discharge sessions was 108 (90 to 141) days. 15 out of 97 patients (15.6%) attended the therapy sessions over a longer time frame than anticipated (more than 12 weeks duration).

Content of sessions

Nearly 75% of patients received joint protection education during their first therapy session. 97% of patients were taught the exercises in the first session, and exercise progression/regression was carried out in over 80% of the review sessions. Many patients were taught goal setting and exercise planning strategies during the initial sessions (70% during session 1), but this was done less in later sessions. Reviewing progress using the exercise diary was reported in 70% of sessions. More than 80% of the patients received discharge advice, and 98% were advised on continuing the SARAH programme on a long-term basis. See Supplementary Table 2 for details.

Clinical outcomes

The median duration between baseline and postal/telephone follow-up was 147 days. Improvements in hand function were significant ($p < 0.05$) at both discharge and at follow-up (Table 4). At discharge, we observed a medium effect size (Cohen's $d = 0.7$ (95% CI 0.45 to 0.91)). At 4 months, the effect size had reduced but was still approaching a medium effect size (Cohen's d was 0.45 (95% CI 0.32 to 0.58)). Pain was stable over time. There were statistically significant improvements in grip strength at discharge. The left and right-hand strength improved by 24.6 % and 22.6% respectively.

The majority of patients (85%) rated themselves as improved (slightly improved or much improved) at discharge with 74% rating themselves as improved at 4-month follow-up (Figure 1). Most patients were satisfied with the programme (99%) and found it useful (95%). Ninety percent reported that they were continuing to exercise at 4-month follow-up. Around 33% had continued their exercises daily while about 32% and 30% were exercising 1-2 times and 3-4 times/per week, respectively. No adverse events relating to the exercises were reported.

Comparison with the SARAH clinical trial

Patients in the current study were similar in regards to age, sex and baseline hand function to participants in the SARAH trial (Supplementary Table 3). However, SARAH trial participants reported having RA for longer (median duration 10 versus 6 years) and higher baseline handgrip strength. The patient-reported outcomes in this study were similar or better than those reported for the participants allocated to the SARAH programme in the SARAH Trial. Improvements in hand function were similar in both studies, but we observed greater improvements in grip strength in this study. Pain remained stable both in the current study and the SARAH Trial.

The proportion of patients who rated themselves improved at follow-up was higher in this study than the SARAH trial (current study=74%; SARAH trial=51.5%). Ninety-nine percent of patients

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reported they were satisfied with the SARAH programme compared to 55% of the SARAH programme participants in the trial. A similar proportion of patients to participants in the SARAH trial reported that they were still exercising at 4 months. However, fewer patients in this study reported doing their home exercises daily compared to the trial participants (33% vs. 44%).

Discussion

We have demonstrated that the online training is an accessible, acceptable and effective way to train therapists to deliver the SARAH programme. The iSARAH training had a good reach into the NHS. Therapists from 188 NHS organisations across the UK registered for the training, and at least one therapist from 162 NHS organisations completed all the training modules. Non-completion is common for online courses¹¹, and, although a proportion of therapists did not choose to complete the training evaluation, most (75%) registrants in our study completed all the training modules. On completion of the training, the majority of therapists were confident they could deliver the programme and intended to do so. We were interested to see whether these intentions translated into adoption. Around two-thirds of iSARAH trained therapists responding to follow-up implemented the SARAH programme in their daily practice and were very positive about the programme. The clinical outcomes collected in Stage 2 suggest that patients selected to receive the SARAH intervention by their therapist will achieve similar outcomes to participants in the SARAH Trial.

We collected information about the treatments delivered in both stages to measure fidelity of the intervention being implemented. The behavioural strategies (goal setting, exercise planning, and exercise diary) were not always used. The strategies are an integral part of the SARAH programme to facilitate adherence to the exercises. From the SARAH Trial, we know that behavioural support from the therapist was a key factor in the participant’s long term adherence to the exercise programme.¹⁸ In future iterations of the iSARAH online training, we plan to strengthen this element of the training as it is the aspect of the intervention that may be unfamiliar to therapists and require greater emphasis.

Translating intervention developed in clinical trials into routine practice is challenging.^{19,20} We identified facilitators related to the SARAH implementation at four levels: intervention, patient, therapist and organization.^{20,21} For example, the structured and comprehensive format and face-validity of SARAH exercises (intervention level) and perceived treatment benefits by both patients and therapists (patient and therapist level) facilitated the application of SARAH programme. The most common barriers to implementation were associated with the capacity of therapy departments to deliver the programme (organizational level). This may not be easily addressed in the current NHS climate. A potential solution would be to use alternative methods to deliver some of the sessions including online, telephone/videocalls or in a group. In both stages, therapists reported delivering less sessions than in the trial. Some patients only received 1-2 sessions. We were unable to examine if clinical outcomes were similar regardless of the number of sessions provided due to the small sample size. However, in the SARAH Trial, those who attended more sessions did have better clinical outcomes.⁶

Strengths and limitations

The iSARAH training is a theory-based intervention providing an easily accessible training opportunity. During the 18-month study period, therapists did not report any technical issues with the online training. We attribute these to our iterative usability testing of the website before its

launch and working alongside clinical stakeholders throughout.^{8,22} Therapists who registered and provided feedback represent a national-level sample from diverse demographic and geographic backgrounds.

There are some limitations of this study. We used a strict definition of training completers, and only followed up those participants who fulfilled the criteria. Seventeen percent of participant completed all the modules but did not complete the evaluation. Following up these participants as well would have provided more complete follow-up data. The follow-up response rate from therapists was low, which may limit the generalisability of the findings. We also relied on self-reports and did not include fidelity assessments to evaluate therapists' competence while delivering SARAH programme. Therefore, it is unknown if the interventions were delivered to the same standard they were in the SARAH Trial when fidelity assessments were undertaken.

We did not do a formal sample size calculation but based the patient recruitment target on what was potentially achievable during the study time frame. The relatively small sample size precluded us from doing subgroup analysis such as examining the impact of the number of treatment sessions. Therapists were able to select patients they felt were suitable for the SARAH programme. This may have resulted in a biased sample of patients more likely to do well with the SARAH programme and it is unknown how representative the study population is of patients with RA presenting to NHS therapy departments. However, this approach does reflect therapists' clinical decision making about treatment options for patients in a real world setting and is a valid evaluation of the SARAH programme. We have made comparisons with the SARAH trial to understand the clinical impact of delivering the programme in routine care. The results were similar suggesting successful translation from clinical trial to routine care. However, we acknowledge that the small sample size and lack of randomization in this study means that this comparison should be interpreted cautiously. Finally, we did not measure sustainability of the programme over time so our study represents preliminary evidence of successful translation rather than long-term implementation.

Conclusion

Online training had good accessibility and reach and was an effective way to train therapists. Clinical outcomes were similar to the clinical trial providing preliminary evidence of successful translation from clinical trial into routine care.

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For Peer Review

Table 1: Data collection

Stage 1:		Outcomes	Scales
On completion of online training			
Educational outcomes		<i>Perceived confidence and capability:</i> I feel confident/capable to implement the SARAH programme	1-Not at all true - 7- Very true Responses 1-3 = not confident or capable/Responses 4-7 = confident or capable
Implementation outcomes	<i>Adoption</i>	<i>Implementation intention:</i> I intend to use the SARAH programme in my clinical practice	1-Strongly disagree - 7-Strongly agree Responses 1-3 = not intending/Response 4= unsure/Responses 5-7 = intending
	<i>Appropriateness</i>	<i>Barriers:</i> Do you foresee any barriers to delivering the SARAH programme?	Yes/No, if yes, please indicate: Lack of time; Lack of suitable patients; No exercise equipment available; Other (Free text response)
	<i>Acceptability</i>	<i>Satisfaction:</i> Please indicate how satisfied/dissatisfied you are with the training	1 Not at all satisfied - 5 Extremely satisfied Responses 1-2 = not satisfied/Responses 3-5 = satisfied
6-month follow up			
Implementation outcomes	<i>Adoption</i>	<i>Actual use in practice:</i> During the last 6 months, how many patients have received SARAH programme ?	0, 1– 5; 5 – 10; 11– 15; 16– 20; 21 – 25; ≥ 25
		<i>Future intended use:</i> During the next 6 months, I intend to use the SARAH programme in my clinical practice.	1-Strongly disagree - 7-Strongly agree Responses 1-3 = not intending /Response 4= unsure/Responses 5-7 = intending
	<i>Appropriateness</i>	<i>Clinical usefulness:</i> Please indicate how useful you think SARAH programme has been for helping your patients?	1. Not at all useful - 5. Extremely useful Responses 1-2 = not clinically useful/Responses 3-5 = clinically useful
		Implementers: what do you find 1) useful and 2) unhelpful Non-implementers: what were the barriers?	Free text
	<i>Acceptability</i>	<i>Patient satisfaction:</i> Please indicate how satisfied you think patients have been with SARAH programme?	1. Not at all satisfied - 5. Extremely satisfied Responses 1-2 = not satisfied/Responses 3-5 = satisfied
	<i>Fidelity</i>	Number of sessions used to deliver the SARAH programme	1-6 sessions
		Frequency of delivering individual components of the programme and provision of exercise equipment	Always; Often; Sometimes; Rarely; Never
Stage 2:	Clinical Outcomes		Time points
	Demographics: age, sex, ethnicity, employment, handedness, disease duration		1 st session
	Self-reported hand function and pain		1 st session, Discharge, 4 months follow up
	Grip strength (if possible)		1 st session, Discharge
	Self-rated improvement		Discharge, 4 months follow up
	Patient satisfaction and perceived usefulness of the programme		Discharge
	Self-reported home exercise adherence		4 months
	Attendance, components of the SARAH programme delivered		Each session – recorded in treatment log by therapist

For Peer Review

Table 2: Demographic characteristics of therapists registered between April 2017 and September 2018

Characteristics		Total registrants N=790 n (%)	Training completers* N=448 n (%)	Module completers N= 136 n (%)	Did not complete modules N=206 n (%)
Age	21-30 years	181 (23%)	98 (22%)	27 (19.8%)	56 (27.2%)
	30-40 years	270 (34%)	151 (33.5%)	44 (32.3%)	75 (36.4%)
	40-50 years	212 (27%)	131 (29.3%)	38 (27.9%)	43 (20.9%)
	>50 years	127 (16%)	68 (15.2%)	27 (19.8%)	32 (15.5%)
Gender	Male	89 (11.2%)	51 (11.4%)	17 (12.5%)	21 (10.2%)
	Female	701 (88.8%)	397 (88.6%)	119 (87.5%)	185 (89.8%)
Profession	Occupational therapy	523 (66.4%)	313 (70%)	84 (61.76%)	125 (60.7%)
	Physiotherapy	267 (33.6%)	135 (30%)	52 (38.24%)	81 (39.3%)
Qualification	Graduate	552 (69.8%)	311 (69.6%)	97 (71.3%)	143 (69.4%)
	Post-graduate	143 (18.2%)	78 (17.2%)	22 (16.2%)	43 (20.9%)
	Other	95 (12%)	59 (13.2%)	17 (12.5%)	20 (9.7%)
Professional experience	< 5 years	375 (47.5%)	207 (46.3%)	61 (44.9%)	104 (50.5%)
	5-10 years	178 (22.6%)	101 (22.6%)	35 (25.7%)	43 (20.9%)
	11-15 years	114 (14.3%)	68 (15%)	16 (11.8%)	31 (15%)
	>15 years	123 (15.5%)	72 (16.1%)	24 (17.6%)	28 (13.6%)
Average RA patients treated per month	None	19 (2.3%)	4 (0.9%)	3 (2.2%)	12 (5.8%)
	Less than 5	285 (35.9%)	141 (31.3%)	52 (38.2%)	93 (45.1%)
	5-10	219 (27.9%)	124 (27.7%)	35 (25.7%)	61 (29.6%)
	11-15	267 (33.7%)	179 (40%)	46 (33.8%)	40 (19.4%)

*Therapists who completed modules, self-assessment and training evaluation survey, and downloaded training certificate

Table 3: Self-reports on the delivery of SARAH programme in daily practice (n=77).

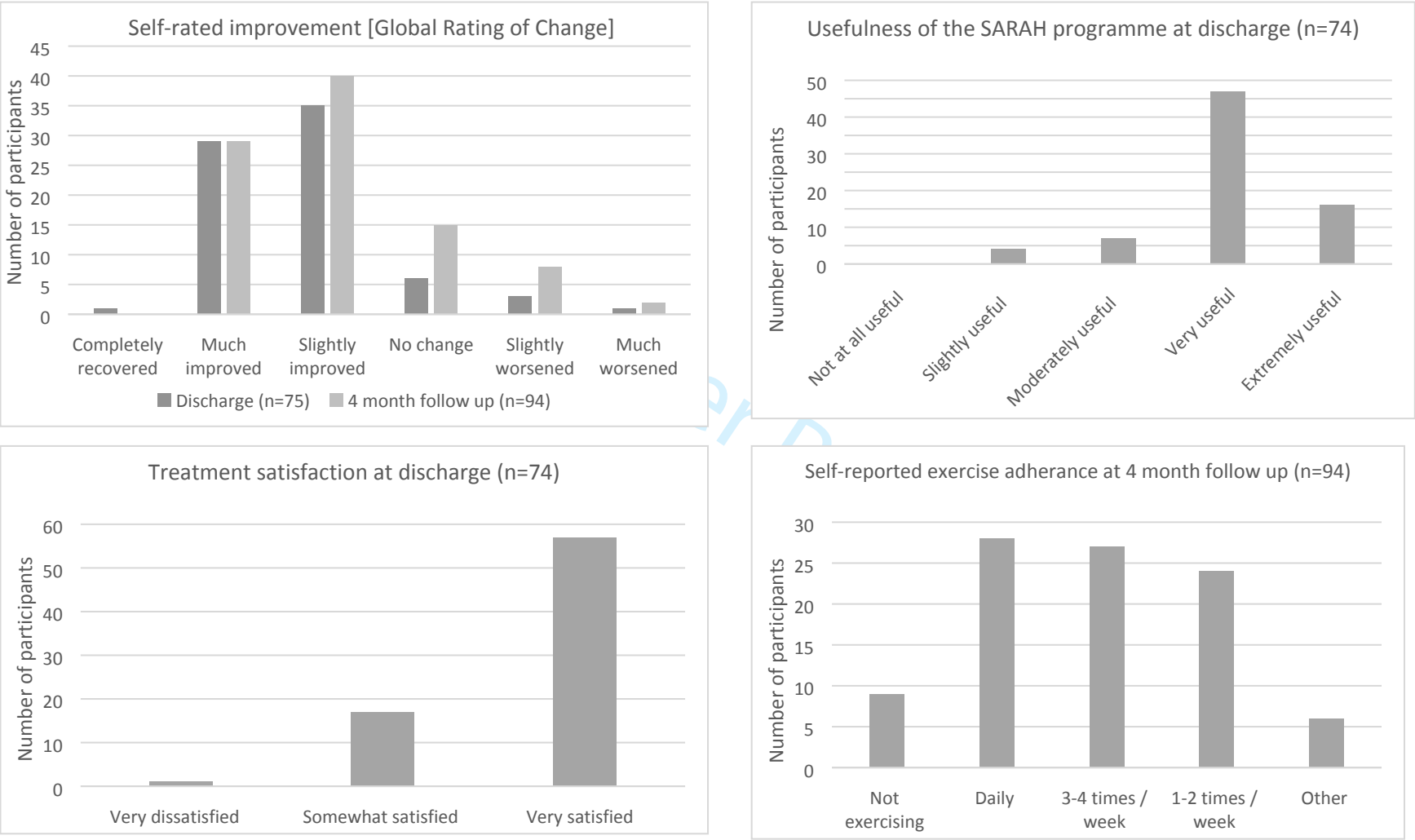
SARAH components	Always n (%)	Often n (%)	Sometimes n (%)	Rarely n (%)	Never n (%)
Patient education	47 (61)	20 (26)	7 (9.1)	3 (3.9)	0 (0)
Exercises	39 (50.6)	24 (31.1)	12 (15.6)	2 (2.6)	0 (0)
Progression/Regression	27 (35.1)	38 (49.4)	6 (7.8)	4 (5.2)	2 (2.6)
Goal setting, Exercise planning	18 (23.4)	22 (28.6)	24 (31.2)	11 (14.3)	2 (2.6)
Exercise diary	9 (11.7)	13 (16.9)	22 (28.6)	18 (23.4)	15 (19.5)
Discharge advice	40 (52)	20 (26)	13 (16.9)	1 (1.3)	3 (3.9)
Continuing exercises long-term	43 (55.8)	19 (24.7)	9 (11.7)	3 (3.9)	3 (3.9)

Table 4: Stage 2 Clinical outcomes

Outcomes	Baseline	N	Baseline (participants providing discharge data)	N	Discharge		Baseline (participants providing follow up data)	N	Follow up	
	Mean [SD] or Median (IQR)		Mean [SD] or Median (IQR)		Mean [SD]) or Median (IQR)	Mean or median change 95% CI	Mean [SD] or Median (IQR)		Mean [SD] or Median (IQR)	Mean or median change 95% CI
Hand function [0-100]	54.3 [19]	96	55.4 [18.4]	75	65.4 [18.1]	10 [6.5 to 13.6]	54.6 [19.2]	93	61.6 [19.5]	7 [3.8 to 10.2]
Hand/wrist pain [0-5]	3 (2 to 3)	97	3 (2 to 4)	73	3 (2 to 3)	0 (-1 to 0)	3 (2 to 3.25)	94	3 (2 to 3)	0 (-1 to 0)
Grip strength – left hand [Kg]	14.3 [9.8]	88	14.3 [9.2]	67	17.8 [11.2]	3.4 (1.1 to 5.8)				
Grip strength – right hand [Kg]	13.9 [8.7]	88	13.9 [8.7]	68	18.2 [10.9]	4.3 (2.2 to 6.3)				

SD: Standard deviation; IQR: Inter-quartile range; CI: Confidence Interval

Figure 1: Patient perceived improvement, usefulness, treatment satisfaction and home exercise adherence at discharge and follow-up



Supplementary Table 1: Training and implementation by NHS organisations

<u>Enrolment in iSARAH training</u>
Therapists from 188 NHS organisations
165 NHS Trusts [England]
7 Health Boards [Wales]
5 Health and Social Care Trusts [Northern Ireland (NI)]
12 NHS Regional Trusts [Scotland]
6 non-NHS organisations providing NHS treatment [England]

<u>Training completers*</u>
Therapists from 145/188 (77%) NHS organisations
124/165 (75%) NHS Trusts [England]
6/7 (86%) Health Boards [Wales]
5/5 (100%) Health and Social Care Trusts [NI]
10/12 (83%) NHS Regional Trust [Scotland]
6/6 (100%) non-NHS organisations providing NHS

<u>Module completers**</u>
Therapists from 85/188 (45%) NHS organisations
73/165 (44%) NHS Trusts [England]
2/7 (29%) Health Boards [Wales]
2/5 (40%) Health and Social Care Trusts [NI]
8/12 (67%) NHS Regional Trust [Scotland]
1/6 (17%) non-NHS organisations providing NHS

<u>Combined (training completers and module completers)</u>
Therapists from 162/188 (86%) NHS organisations
139/165 (84%) NHS Trusts [England]
7/7 (100%) Health Boards [Wales]
5/5 (100%) Health and Social Care Trusts [NI]
11/12 NHS Regional Trust [Scotland]
6/6 (100%) non-NHS organisations providing NHS treatment

<u>Responders to follow up survey</u>
<u>(Sent to training completers only)</u>
Therapists from 70/145 (48%) NHS organisations responded
57/124 (46%) NHS Trust [England]
3/6 (50%) Health Boards [Wales]
3/5 (60%) Health and Social Care Trusts [NI]
7/10 (70%) NHS Regional Trust [Scotland]
2/6 (33%) non-NHS organisations providing NHS treatment

<u>Implementers</u>
At least one person had implemented the SARAH programme within 51/70 (73%) NHS organisations
41/57 (72%) NHS Trust [England]
2/3 (67%) Health Boards [Wales]
2/3 (67%) Health and Social Care Trusts [NI]
6/7 (86%) NHS Regional Trust [Scotland]
0/2 (0%) non-NHS organisations providing NHS treatment

* Therapists who completed all modules, the self-assessment quiz, training evaluation, and downloaded the training certificate were classified as “training completers”

** Therapists who completed all the modules but did not complete the self-assessment quiz or training evaluation so were unable to download the certificate were classified as “module completers”

Supplementary Table 2: Components of SARA programme delivered as part of routine care

Face-to-face sessions as delivered*	No. of patients attended	Therapist reports available for N patients
Baseline session	N=95	N=93
Joint protection and /or splinting advice		71 (76)
Taught all SARA exercises		90 (97)
Goal setting and exercise planning strategies		66 (70)
Review appointment 1	N=73	N=68
Progression/Regression of exercises		62 (91.2)
Goal setting and exercise planning strategies		43 (64.7)
Patient progress reviewed using exercise diary		52 (76.5)
Review appointment 2	N=49	N=48
Progression/Regression of exercises		45 (94)
Goal setting and exercise planning strategies		30 (63)
Patient progress reviewed using exercise diary		38 (78)
Review appointment 3	N=29	N=24
Progression/Regression of exercises		24 (100)
Goal setting and exercise planning strategies		13 (56)
Patient progress reviewed using exercise diary		20 (80)
Review appointment 4	N=18	N=14
Progression/Regression of exercises		11 (80)
Goal setting and exercise planning strategies		10 (73)
Patient progress reviewed using exercise diary		12 (80)
Discharge session	N=58	N=57
Patient progress reviewed using exercise diary		41 (72)
Discharge advice provided		48(84.5)
Advised to continue the SARA programme long-term		55 (98)

*As the SARA programme was not delivered over a set number of sessions, the actual session classified as the discharge session varied between participants (for example, if participants had 2 sessions then session 2 was the discharge session).

Supplementary Table 3: SARAH service evaluation vs SARAH trial: Demographics and clinical outcomes

Variables	Service evaluation	SARAH trial
No. of participants (n)	97	246
Age, Mean [SD] years	61.6 [13.6]	61.3 [12]
Gender (%)	Male/Female :19.6/80.4	Male/Female: 24/76
Duration since RA diagnosis, Median (IQR) years	6 (1 to 17.1)	10 (4 to 21)
Baseline hand function, Mean [SD]	54.6 [19.2]	52.1 [15.2]
Follow-up at 4 months, Mean [SD]	61.6 [19.5]	61.1 [16]
Baseline grip strength, Mean [SD] kgs	13.9 [8.7]	13.7 [8.5]
Follow-up grip strength, Mean [SD] kgs	18.2 [10.9] *	15.6 [8.9] **
Self -rated improvement		
Slightly worsened (%)	9	14
No change (%)	16	28
Slightly improved (%)	43	33
Much improved (%)	31	18.5
Treatment satisfaction		
Neither satisfied nor dissatisfied (%)	0	6.5
Somewhat satisfied (%)	23	11
Very satisfied (%)	76	44
Home exercise adherence		
Yes (%)	90.4	88
No (%)	9.6	12
Number of SARAH sessions, Median (IQR)	4 (2 to 5)	6
Follow-up rate at 4 months (%)	95	91
Time from enrolment to follow-up, Median (IQR) days	147 (130 to 202)	127 days (121 to 146)

SARAH: Strengthening And stretching for Rheumatoid Arthritis of the Hand; SD: Standard deviation
IQR: Inter-quartile range

*Grip strength of right hand collected during treatment discharge

** Average grip strength of both hands collected at 4-month follow-up.

Reviewer comments to be addressed

Associate Editor(s)' Comments

Please ensure the abstract is structured using the journal guidelines and subheadings

Response: We have ensured this is the case.

Although reviewer 1 recommends extending the background I suggest this is not necessary as most of the background material is referenced. Please note the 'background' subheading should be 'Introduction'

Response: I have judiciously expanded a couple of points in the background but also removed some text. I changed heading to "Introduction". I have tried to contain the word count even with the extensive changes requested by reviewer 1 including editing the discussion to focus on points raised by both reviewers. I hope this is acceptable.

Reviewer: 1

Title: Line 5: The term hybrid implementation study isn't typically used, rather these studies are termed effectiveness-implementation hybrid designs, as they are a hybrid between both effectiveness and implementation designs (see comment below about different types of effectiveness-implementation hybrid designs).

Response: We have changed the title of the paper based on your recommendations.

Abstract: Line 15: I suggest removing the term "implementation strategy". This is a widely used term in the implementation science field, but needs to be accompanied with a definition when used for a broader readership. I would be more specific, and say you adapted face-to-face training into an online format, with benefits of costs and scalability, and evaluated its impact on educational, implementation and clinical outcomes.

Response: We have modified the abstract based on your comments.

Line 21: "A hybrid implementation study evaluated training, implementation and clinical outcomes". This sentence is confusing. Suggest re-wording ... "evaluated the impact of online training using educational, implementation and clinical outcomes.

Response: We have modified the abstract based on your comments.

Line 25: "At 6 months, we measured implementation". The term implementation can encompass several outcomes (such as feasibility, acceptability, adoption, reach, fidelity, sustainability etc). Can you add the implementation outcomes that you assessed (e.g. intention to adopt, adoption, barriers to implementation etc). For definitions of implementation outcomes see

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068522/>

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Response: We have modified the abstract based on your comments although the word limit has meant that we were unable to include all of your suggestions. We have included as many as the word limit allowed in the main text of the paper.

Line 49: Your conclusion that the findings indicate successful implementation into routine NHS care needs rephrasing. Routine care suggests long-term implementation and you only assess short-term outcomes. Perhaps this could be rephased – you have provided preliminary evidence..., which needs to be assessed over a longer-term basis. Also, you compare clinical outcomes with trial, but this should come with the caveat of your study design and response rate.

Response: We have modified the abstract based on your comments.

Background: General: The Background is currently lacking. The first paragraph would benefit from a discussion of the effectiveness of treatment approaches more broadly (before going straight into an explanation of the SARAH programme). As the focus of this study is on the impact of training, further detail of the face-to-face training programme used in the trial is needed. This should be followed by a more detailed justification for adapting the training for an online format, e.g. cost, scalability etc. The literature on the use / impact of online training as an implementation strategy should be referred to.

Response: We have added some further detail as suggested but have also had to keep in mind the editor's comments that adequate references had been provided.

Line 19: "We, therefore, proposed an implementation strategy using online training" – I would delete this. Otherwise, you need to explain the meaning of the term "implementation strategy". Again, I would just be more specific, e.g. we therefore adapted the face-to-face training to an online format.

Response: We have modified the introduction based on your comments.

Line 23: "We followed the ADDIE (Analysis, Design, Development, Implementation, and Evaluation) model to guide the SARAH implementation project [12]. The analysis, design and development stages are published elsewhere [11]." - this should be under Methods. The ADDIE model may need some explanation. You mention that analysis, design and development are published elsewhere – isn't evaluation also published in the form of the trial? This is a bit confusing.

Response: To make this clearer we have removed reference to the ADDIE model in the Introduction. We were mindful of the editors comments regarding extending the Introduction so we direct readers to the development paper which provides a full description of the development of the online training.

Line 31: "The overall aim of this study was to evaluate implementation of the SARAH

programme into routine NHS care using an online training programme for therapists". The aim does not account for the hybrid design.

Response: We have clarified the aim of the study based on your feedback.

Methods

General: What is a hybrid design and why are you using one?

The readership of this journal will not be familiar with hybrid study designs, so a few sentences on what they are, when they should be used, and why you are using one is needed. Effectiveness-implementation hybrid designs are typically defined as either type 1, 2 or 3 (although there may be more of a spectrum). The paragraph below comes from your citation number 13.

"... hybrid designs which combine traditional effectiveness research with implementation research. Hybrid models 1 through 3 are defined based on the emphasis of the project on effectiveness or implementation. Hybrid 1 models focus on effectiveness, but also collect process evaluation information during the clinical trial to inform future implementation. Hybrid 2 designs focus equally on testing a potential implementation strategy and testing the effectiveness of the intervention. Finally, Hybrid 3 designs focus primarily on testing an implementation strategy, but also collect effectiveness information on the population/setting of interest" <https://www.queri.research.va.gov/implementation/ImplementationGuide.pdf>

With this in mind, could you provide further detail of the type of hybrid design you are using in this study.

Response: We have modified the methods based on your comments.

Methods / Recruitment / Stage 2

Line 4: Therapists invited patients they deemed suitable for the Sarah programme to take part in stage 2. There is potential for selection bias here. This needs highlighting in the Discussion.

Response: Thank you. We have now added this point to the discussion.

Line 15: I appreciate you have published details of the training programme elsewhere, but a more detailed description of the online training programme is needed, given it is the implementation strategy that is being evaluated, maybe in an Appendix.

Response: More detail has been added to the text as requested. The link to the training is also included in this section where the training can be viewed and is freely available to all. We would like to encourage use of this free access through the paper.

Line 42: The following data were collected: 1) educational outcomes: confidence and capability; 2) implementation outcomes: intention to implement (or intention to adopt), satisfaction with training and barriers and facilitators with training. I would specify these outcomes in the objectives.

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Response: The objectives have been modified. We have not listed the individual outcomes as part of the objectives to avoid repetition. We have listed these in Table 1.

Line 51: Refers to implementation / adoption as “the number of patients prescribed the programme in the past six months.” This refers to actual adoption, rather than intention to adopt. It looks like you are assessing both, in which case this also needs to be clarified in your objectives.

Response: We are assessing both and we have now clarified this to be more immediately obvious for the reader in the text and in Table 1.

Further, this section does not mention how you developed your questionnaire. Did you use validated measures to assess confidence, capability, barriers and enablers etc. If not, the limitations of this need mentioning in the Discussion.

Response: Thank you for these observations. We have addressed these concerns by; adding a reference for the Perceived Confidence Scale that was that missing from the text and by describing the barriers and enablers to data collection methods in Table 1. We hope this will suffice as needed to prioritise adding further detail and text within the word count limit.

Results

General: How representative is your sample compared with the entire sampling frame?

Response: We have now addressed this issue adding further commentary in the discussion.

Discussion

General: The Discussion typically starts with a summary of your findings. I would suggest removing any discursive points, and providing the key findings from your educational, implementation and clinical findings.

Response: Thank you. We have now removed these discursive points and the key findings have now been clearly presented.

Line 45: “There is a drive to provide evidence-based interventions to improve patient outcomes”. I would delete this. A drive sounds like it’s a recent occurrence. Also, I’m not sure how the second sentence follows this “However, the provision of detailed descriptions of effective interventions as recommended by the Template for Intervention Description and Replication (TIDieR) guidelines [16] does not necessarily translate into changes in clinical practice.” TIDieR guidelines are to enable replication and to build the knowledge base. They are not intended to implement change.

Response: As requested, we have now removed these sentences from the text.

Line 51: You mention feasibility, acceptability and reach for the first time in the Discussion – these implementation outcomes are not mentioned in your aims. Much greater clarity is needed on the implementation outcomes you assessed. I strongly suggest using a

recognised framework to define these terms (see link below), and being consistent with your terminology throughout the objectives, methods, results and discussion.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068522/>

Response: Thank you for the useful reference. We have now modified our descriptions of the outcomes and made them consistent throughout the paper.

Discussion / strengths and weaknesses

There should be some recognition that this is a quasi-experimental study and therefore comparison with the trial findings is tentative. This should also be reflected in the Conclusion.

Response: We have made modifications to the text in the methods and expanded the strengths and weakness section as suggested.

Reviewer: 2

Page 2; lines 5/6 - Recent evidence is contrary to the statement as to RA is the most common form of inflammatory arthritis (IA). Please rephrase this statement accordingly.

Response: Thank you for pointing this out. We have now modified the text in line with your suggestion.

Page 10; lines 11/12 - Authors should consider the methodological limitations highlighted when reporting conclusions, and put forward that "Clinical outcomes were similar to the clinical trial indicating successful implementation of the SARAH programme into routine NHS care" and what this means for the implementation of the iSARAH. What are the impact of these limitations with regards to the small sample size and lack of fidelity assessments to evaluate therapists' competence while delivering iSARAH programme?

Response: We have added this point to the limitations section along with points raised by reviewer 1.

Page 8; line 36/37 - Re-consider writing the percentage in full at the start of the sentence (99%). Please check similar grammatical/ formatting accuracies across the paper.

Response: We have changed this and checked the paper throughout for consistency.

Introduction: This is a well written introduction, setting the backdrop and the rationale for the study. However, the opening sentence is that RA is the most common form of IA, with a reference dating back to 2002. To my knowledge, recent studies with CPRD data has shown that Gout is now the most common form of IA. Please see paper by Kuo et al. 2014 (Rising burden of gout in the UK but continuing suboptimal management: a nationwide population study). I would recommend that the authors reconsider this sentence, perhaps rephrasing it is as such to put forward that RA is one of the most common forms of IA, but not 'the most common' type.

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Response: Thank you for pointing this out. We have modified the text as suggested.

I would also recommend that authors revisit some of the older references in this section to ensure these are supported by more recent research evidence to ensure that the latest evidence base is utilised and promoted.

Response: References have been checked and updated as recommended.

Discussion: Although this section follows a clear, critical and logical format, some of the methodological limitations highlighted should be taken into the conclusions, when authors put forward that "Clinical outcomes were similar to the clinical trial indicating successful implementation of the SARAH programme into routine NHS care" and what this means for the implementation of the iSARAH.

Response: We have now added this consideration to the discussion.

For Peer Review