**Implementing the Strengthening and Stretching for Rheumatoid Arthritis of the Hand (SARAH) programme using online training: a hybrid implementation study**

**Short title**

Hand exercises for patients with RA

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Guarantor: EW

Contributorship: SL and EW conceived and secured funding for the study. EW led the study team. SL was senior author. CS was responsible for the development of the online training, gaining the necessary approvals to conduct the study, hand therapist and patient recruitment, and data collection and analysis. LA provided programming and technical support for the online training. JT and ET assisted with the service evaluation data collection, data entry and analysis. JA was involved in protocol development and assisted in developing the online training. EW and CS drafted this manuscript. All authors reviewed and edited the manuscript, and, approved the final version of the manuscript.

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*Abstract (249/250)*

Introduction

The SARAH (Strengthening and Stretching for Rheumatoid Arthritis of the Hand) programme is a hand exercise programme for people with rheumatoid arthritis. A large clinical trial demonstrated it was clinically and cost-effective. We developed an implementation strategy, using online training. The study aim was to evaluate this strategy.

Methods

A hybrid implementation study evaluated training, implementation and clinical outcomes. National Health Service (NHS) therapists completed the training. Training outcomes included; confidence and capability to deliver the SARAH programme, and implementation intention. At 6 months, we measured implementation. Patients receiving the SARAH programme provided clinical data at baseline, treatment discharge and 4 months follow up, including hand function (Michigan Hand Questionnaire (MHQ) function scale), grip strength and pain.

Results

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. They reported being confident (447/448, 99.8%) and capable (443/488, 99%) to deliver the programme and 78% intended to implement it (379/488). 116/448 (26%) therapists provided follow-up data. Two-thirds (77/116) had implemented the programme across 51 NHS organisations.

118 patients (15 NHS Trusts) participated. Patients reported improved hand 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 improved by 24.6% (left) and 22.6% (right). Pain was stable.

Discussion

Online training was an effective way to train therapists. Clinical outcomes were similar to the clinical trial indicating successful implementation of the SARAH programme into routine NHS care.

*Keywords*
Implementation, hand exercises, rheumatoid arthritis, online training

## Background

Rheumatoid Arthritis (RA) is the most common form of inflammatory arthritis. It affects 1% of the UK general population [1] and 2% of those over 65 years [2]. 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 [3-7].

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 [8]. 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 [9,10]. In the trial, therapists received face-to-face training to deliver the SARAH programme but it was unfeasible to provide this training to facilitate implementation. We, therefore, proposed an implementation strategy using online training. Free, online training (iSARAH <https://isarah.octru.ox.ac.uk/>) was developed 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 [11]. 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].

We launched iSARAH in April 2017. This paper describes the implementation and evaluation phases of the ADDIE model. 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 objectives were:

1. To evaluate the training outcomes and implementation 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.

## Methods

Study design

We used a hybrid implementation design as recommended by the USA Department of Veterans Health Administration [13] evaluating training and implementation in Stage 1 and clinical outcomes in Stage 2.

Recruitment

*Stage 1*

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 [11]. The training takes 2 to 3 hours. After completing the modules and training evaluation, therapists downloaded their training certificates.

*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 [8].

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, NHS trust, age, experience in treating people with RA, and the average number of RA patients they treated each month. On training completion, the therapists completed a questionnaire to rate their confidence and capability to deliver the SARAH programme in clinical practice and if they intended to implement it, satisfaction with the training and any potential barriers to implementation (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 (Table 1). We sent reminder emails to non-responders 2 and 4 weeks later. We asked if therapists had implemented the SARAH programme and if so, the number of patients prescribed the programme in the past six months. We collected ratings on clinical usefulness, patient satisfaction and future intended use. Therapists were asked details of programme delivery and to identify aspects of the SARAH programme that were helpful or unhelpful in its implementation. Respondents who reported they had not implemented the programme were asked to describe barriers to implementation.

*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 [14]. 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 weeks, then the patient was contacted by telephone and follow-up was completed over the phone where possible to minimise the amount of missing data.

Sample size

*Stage 1*

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

*Stage 2*

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

Analysis

*Stage 1*

We summarized the post-training evaluation responses from the therapists. Ratings of capacity and capability to deliver the SARAH programme, satisfaction with training and intention to implement were categorised as described in Table 1. Barriers to implementation were grouped into categories (by CS and checked by EW), and their frequency summarised. We compared characteristics of those completing the training with those who did not using a Mann Whitney test.

Similarly, we summarised the 6-month follow-up data as described in Table 1. Helpful and unhelpful aspects of the programme and barriers to implementation were grouped into categories (by CS and checked by EW), and their frequency summarised. We compared the characteristics of implementers and non-implementers, and, those who completed follow-up and did not complete follow-up using a Chi-square test.

Stage 2

The MHQ overall hand function scale and pain ratings were collected at session 1, final session and follow-up (4 months). We anticipated that patients would complete their final session before the 4-month follow-up. However, if patients attended the therapy sessions over a longer time frame than anticipated, we analysed the MHQ and pain rating in chronological order for those patients based on the date of data collection. We estimated changes in hand function, pain and grip strength between baseline and each follow-up point as mean or median difference (95% confidence interval, CI) using a paired t-test or Wilcoxon signed-rank test as appropriate. We also calculated Cohen’s d in order to estimate an effect size which were interpreted as as small (0.2), medium (0.5) and large (0.8) [15].

We summarised the number of hand therapy sessions provided, the core components delivered during the sessions and the number and proportion of participants in each response category for self-rated improvement, usefulness and satisfaction with the programme, home exercise adherence, and frequency of home exercise sessions.

For all analyses, we used all available data, and as missingness varied, the contributors are not the same in all analyses.

## 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 (443/488, 99%) to deliver the SARAH programme and were satisfied (443/448, 98.8%)) with the training. Nearly 85% (379/488) of training completers intended to use the programme, but 70% (314/488) 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 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%). 99% of patients 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**

There is a drive to provide evidence-based interventions to improve patient outcomes. 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. There is growing evidence that online training programmes are a feasible, acceptable and cost-effective to reach large numbers of health professionals [17, 18] and are an effective way to influence their behavior and patient outcomes [12]. Our findings add further evidence that online training is a feasible, acceptable and effective option to educate health professionals. 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 courses [17], 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. Registrants who reported seeing more patients with RA were more likely to complete the training. A possible explanation is probably more motivated due to the potential impact on their clinical caseload.

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 implementation. 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. Therapists were more likely to implement the programme if they reported seeing more patients with RA, once again, potentially reflecting the training was more applicable to their caseload and worthwhile putting into practice even if they reported facing barriers to implementation.

In both stages, 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 [19]. 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 [20, 21]. We identified facilitators related to the SARAH implementation at four levels: intervention, patient, therapist and organisation [21, 22]. 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 [9].

*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 [11, 23]. 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 any fidelity assessments to evaluate therapists’ competence while delivering SARAH programme. 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.

**Conclusion**

Online training was an effective way to train therapists. Clinical outcomes were similar to the clinical trial indicating successful implementation of the SARAH programme into routine NHS care.

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