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A randomised controlled trial of wax baths as an additive therapy to hand exercises in patients with systemic sclerosis

William J. Gregory [a,b,*], Jack Wilkinson [c], Ariane L. Herrick [b,d]

[a] *Rehabilitation Department, Salford Royal NHS Foundation Trust, UK*
[b] *Division of Musculoskeletal and Dermatological Sciences, The University of Manchester, Salford Royal NHS Foundation Trust, Manchester Academic Health Science Centre, UK*
[c] *Centre for Biostatistics, Faculty of Medicine and Human Sciences, University of Manchester, UK*
[d] *NIHR Manchester Musculoskeletal Biomedical Research Centre, Central Manchester NHS Foundation Trust, Manchester Academic Health Science Centre, UK*

Abstract

Objective The musculoskeletal features of systemic sclerosis (SSc) are a major cause of disability, causing limitations to movement and function. The study aim was to compare the effects of daily hand exercises with or without daily home wax bath hand treatment in patients with SSc.
Design Assessor-blinded randomised controlled trial of parallel group design.
Setting Single participating centre, undertaken in secondary care and in participants homes.
Participants 36 participants with hand skin tightening of SSc, two participants lost to follow up.
Interventions Participants were randomised into wax bath versus no wax bath groups. Both groups in addition performed regular hand exercises as part of standard care. The study period was 9 weeks, with further measures of outcome undertaken at 18 weeks.
Main outcome measures The primary outcome measure was the Hand Mobility in Scleroderma test (HAMIS). Secondary outcomes measures were the Scleroderma Health Assessment Questionnaire, grip and pinch strength and the Cochin Hand Function Scale.
Results Between group comparisons of HAMIS scores showed no evidence of effectiveness of the wax bath treatment at 9-week follow up (adjusted difference in means (95% CI) experimental-control −1.47 (−3.55 to 0.61), $P = 0.16$) or at 18-week follow up (adjusted difference in means (95% CI) experimental-control 1.94 (−1.07 to 4.95), $P = 0.20$). Analysis of secondary outcomes also showed no evidence for effectiveness of the wax bath treatment at either 9 or 18 weeks.
Conclusion Our findings suggest that the addition of regular wax bath treatment confers no additional beneficial effect to standard care with daily home exercises.

Trial registration ISRCTN registry (http://www.isrctn.com) ISRCTN 66736089.

Keywords: Systemic sclerosis; Physical therapy; Rehabilitation; Exercise; Wax baths

Introduction

With the advances in the medical management of systemic sclerosis (SSc) people are living longer with the disease [1,2]. With this trend, there is an increasing need to consider how we can improve quality of life for patients living with SSc; of whom approximately 90% complain of musculoskeletal problems at some stage of the disease [3]. The musculoskeletal symptoms of SSc are a major cause of disability [4], and skin thickening, often with contracture, is frequently a contributory factor. The skin thickening of SSc leads to reduced ability to perform activities of daily living [5]. Skin tightening is often most pronounced in the hands and face [6], and hand

* Corresponding author at: Physiotherapy Department, Rehabilitation Services, Irving Building, Salford Royal Hospitals NHS Foundation Trust, Stott Lane, Salford, M6 8HD, UK.
E-mail address: william.gregory@srft.nhs.uk (W.J. Gregory).

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function limitations are well documented amongst patients with SSc [7,8].

Rehabilitation featured prominently in a recent systematic review of the effectiveness of non-pharmacological treatments in patients with SSc [9]. The authors concluded that there was no good evidence base for any of the included non-pharmacological therapies for SSc. Therefore further research is needed.

Hand rehabilitation interventions, although not underpinned by a strong evidence base, have been the subject of some studies. One hand intervention considered of possible benefit is the wax bath [5,10–13]. The wax bath treatment has traditionally been thought to aid stretches, improve circulation and soften the skin [11]. This treatment was previously reported, in a randomised controlled trial (RCT) in patients with SSc, to improve hand and finger range of movement (ROM) and decrease reported pain levels [11]. These data are supported by two more recent studies [5,13] which also suggest that wax combined with exercises can improve grip and pinch strength.

The best-practice management of long-term conditions includes the principle of self-management [14], whereby the patient can perform his or her treatments at home as and when needed. One of the previous trials of wax baths used a protocol where patients were given a wax bath to take home for daily use [5]. Results of this study were encouraging: of the 22 patients recruited, clinically significant changes were seen in the majority of participants, with a group-wide statistically significant increase in finger flexion movement [5]. The study examined one month of daily home treatment, and the authors suggested that a longer-term effect should be assessed in future studies. A possible limitation of this study was the absence of any procedure for monitoring compliance, although the authors did state that nothing in their results implied non-compliance. More recent rehabilitation studies in patients with SSc have examined nine weeks of treatment [13,15,16].

The efficacy of hand stretch exercises for patients with SSc is better established than wax bath treatment [12]. Daily home exercises have made up a part of the intervention protocol in many of the previous studies [5,13,15,17–22]. It is generally assumed that daily hand stretches will improve hand movement and function [13,23,24]. An observational study of 45 participants and having no drop outs showed promising results [17]; the exercises used in this study were simple to teach and perform and relatively quick to perform daily. For several years this protocol described by Mugii *et al.* [17] has been part of routine practice for patients with SSc-related hand function limitations attending Salford Royal NHS Foundation Trust.

Aim

Against this background, the main aim of this study was to assess whether the use of a home wax bath in addition to a standard hand exercise programme improves hand function in patients with SSc. A secondary objective was to investigate whether any changes seen at the completion of a 9 week programme, were sustained 9 weeks after the prescribed exercise and wax treatment period had ceased.

Patients and methods

Trial design

This was an RCT of parallel group design conducted at a single tertiary centre for patients with SSc. The study was given ethical approval by the National Research Ethics Service (Committee North West – Greater Manchester East, 13/NW/0773) and was registered in the International Standard Randomised Controlled Trial Number system (ISRCTN66736089). The participants' written consent was obtained according to the Declaration of Helsinki. Outcome measurements were undertaken in the physiotherapy department. All treatment was carried out unsupervised in the participants' own homes or out and about in their day-to-day routine.

Participant selection

Participants were recruited from patient electronic records and from clinic lists.

Inclusion criteria

All patients fulfilled the 2013 American College of Rheumatology/European League Against Rheumatism criteria for SSc [25] and were sub-divided into limited and diffuse cutaneous subtypes on basis of the extent of skin involvement [26]. All had to be over the age of 18, and to be eligible had to have some degree of skin thickening of the hands, measured in this study as a score of at least 1 in the hand and/or fingers of the modified Rodnan Skin Score (mRSS) assessment [27,28] (maximum "hand" mRSS 12: 0 to 3 for each dorsum of hand and 0 to 3 for the fingers of each hand). Finally, patients needed to be able to perform the wax treatment and hand exercises at home, and be willing and able to give informed consent.

Exclusion criteria

Previous hand wax bath treatment, known or suspected allergy to the wax used in the treatment, or any contraindication to the use of the intervention (primarily digital ulcers, but also including neurological or sensory deficits; namely impaired thermal sensation, poorly controlled diabetes and upper limb nerve entrapment).

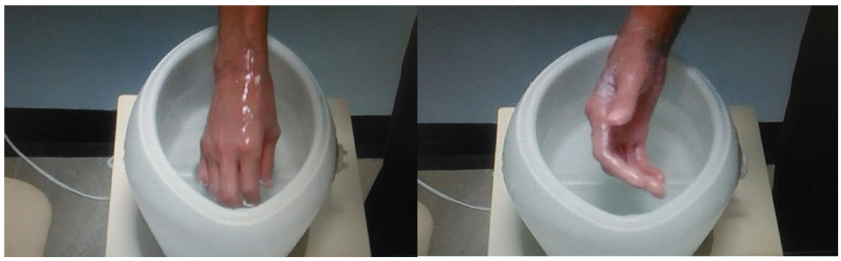

Fig. 1. Wax bath treatment for the hand and wrist.

Interventions

The intervention trialled was the use of a paraffin wax machine for 9 weeks. This machine was provided, with instruction on its use, at the baseline visit for the participants in the intervention group. The exercise-only group received their wax bath at the completion of the 18-week visit. All baths were provided by a member of the physiotherapy support team, ensuring the assessor physiotherapist was kept blind to allocation. To ensure the same potential benefits across groups, all participants were offered a wax bath to keep at completion of the study (new machines for the control group, an offer to keep their machine for the intervention group).

The wax bath is heated to 45 to 55° C participants place their hands into the wax, up to the wrist level and then remove within a few seconds (Fig. 1). This dipping into the wax is repeated 5 to 6 times. The hand is then wrapped in a plastic bag and then a towel to prolong the heating period. The wax layering, bag and towel are then left on for 10 minutes. Participants were asked to perform wax bath treatment to each hand no less than 4 times per week.

Both groups in the RCT also performed a set of three finger exercises [17]. The hand exercises involved 10 seconds holds of auto-assisted finger stretches, from the Mugii *et al.* [17] protocol. The three stretches involved (i) push in to full finger flexion, (ii) push in to full finger extension and (iii) a push into proximal interphalangeal joint extension whilst maintaining distal interphalangeal and metacarpo-phalangeal joint flexion. Participants were asked to perform these stretch exercises 3 to 10 times per day. The participants in the wax bath/intervention group were asked to perform at least one of these exercise repetitions immediately after their wax bath treatment. All participants were asked to be on the alert for, and to report to the study team any aching, local inflammation or ulcer formation.

Randomisation and blinding

Following informed consent and baseline assessment, participants were randomised into the intervention (exercise and wax bath) or control (exercise only) groups. Blocking within strata was used, with limited/diffuse cutaneous subtype as the stratification variable and random block sizes between 4 and 8. A list was provided by a statistician and embedded into a Microsoft Access file.

The allocation reveal and provision of treatment to the participant was undertaken by a member of the care team other than the assessor physiotherapist. It was not deemed possible to keep the participant blind to their allocation based on the nature of the treatments. The assessor physiotherapist was kept blind to each participant's group until after the last participant completed their 18 week assessment.

Sample size

The primary outcome measure was the Hand Mobility in Scleroderma (HAMIS) [29]. The HAMIS has been reported to have a standard deviation of 6.64 [30]. To detect a difference in means of the same magnitude with 80% power at 5% significance level it was calculated there would need to be 16 participants per group. Allowing for up to 10% drop-out from the study, 36 participants were recruited to allow analysis of, at minimum, the required 32 across the two groups.

Outcome measurements

Six measures for treatment effect were assessed at baseline, end of treatment (after 9 weeks ± 14 days) and at end of study (18 weeks ± 14 days). These were the HAMIS [29], the Scleroderma Health Assessment Questionnaire (SHAQ) [31] (including a visual analogue scale (VAS) for pain), grip and pinch strength using a Jamar© grip meter and a Jamar© pinch meter [32], the Cochin Hand Function Scale [33] and the mRSS [27,28].

The HAMIS is a reliable, validated performance index developed for patients with SSc [29]; it includes nine functional task assessments scoring the patient for their ability to use their hand in daily activities and also detecting limitations in ROM of the fingers and wrist. Each task is scored 0 to 3; giving a total potential maximum score of 27. A higher score indicates a greater limitation to hand mobility.

In addition participants completed a diary through the 9 week treatment period to record compliance with the wax bath and hand exercise protocols (minimum 4 times per week per hand for the wax bath; minimum 7 times per week for the hand exercises). They were also able to record any changes in

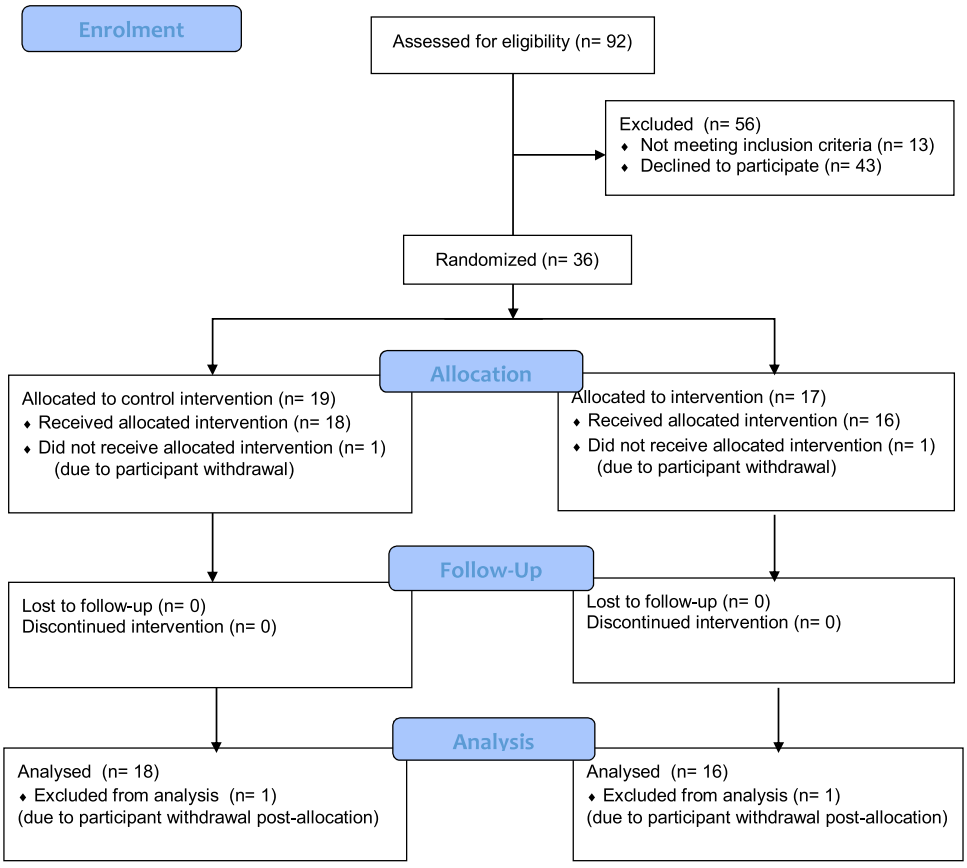

Fig. 2. CONSORT (2010) flow diagram.

their pain medication use as a further assessment for detecting changes in pain levels.

Statistical methods

Analysis of covariance was used to compare groups with adjustment for baseline value of the relevant outcome assessment.

Results

Recruitment

Eligibility screening commenced on 24th January 2014. A total of 92 potential participants were assessed for eligibility (Fig. 2). Thirteen were excluded for not meeting the inclusion criteria (six had had previous hand wax treatment, two did not have the required finger/hand skin involvement and five had digital ulcers). Forty-three declined to participate. Of the 36 patients who entered the study, 17 were randomised to wax bath treatment.

Baseline visits for the 36 participants took place between 31st March 2014 and 12th January 2015. The final participant completed the 18-week trial period on 8th May 2015.

Participant losses

In each group there was one participant lost to follow up testing; each opted not to commit to the daily exercise regime once they had been taught it.

Baseline characteristics and comparability

There was no difference in baseline characteristics in the experimental (wax bath) and control groups (see Table 1 for details).

Primary outcome (HAMIS)

Between group comparisons showed no evidence of effectiveness of the wax bath treatment at 9-week follow up (adjusted difference in means (95% CI) experimental-control −1.5 (−3.6 to 0.6), $P = 0.16$) or at 18-week follow up (adjusted difference in means (95% CI) experimental-control 1.9 (−1.1 to 5.0), $P = 0.20$), although most participants in both groups showed improvement over the study period (see Fig. 3). Outcomes were more variable in the experimental group. The confidence intervals appear to rule out large effects or disadvantages of treatment.

Table 1
Baseline characteristics of the sample. N (%) for categorical variables. Median and interquartile range for continuous variables.

Characteristic	Control ($n = 19$)	Experimental ($n = 17$)
Sex (F)	12 (63%)	13 (76%)
Age (years)	64.4 (53.3 to 67.3)	66.4 (56.3 to 71.7)
Disease subtype (limited)	11 (58%)	10 (59%)
Time since first non-Raynauds symptom (yrs)	9.9 (4.9 to 20.8)	5.8 (3.2 to 18.8)
HAMIS total	15.0 (9.5 to 19.0)	14.0 (4.0 to 19.0)
HAQ-DI	1.0 (0.3 to 1.6)	1.1 (0.8 to 1.5)
SHAQ VAS pain	0.96 (0.40 to 1.91)	1.18 (0.49 to 1.56)
SHAQ VAS vascular	0.96 (0.26 to 1.25)	0.93 (0.14 to 1.56)
SHAQ VAS overall	1.21 (0.69 to 1.61)	1.15 (0.54 to 1.50)
Grip left (kg)	14.0 (8.0 to 21.5)	14.0 (7.0 to 26.0)
Grip right (kg)	12.5 (10.25 to 17.0)	14.3 (7.0 to 26.0)
Pinch left (kg)	6.3 (4.5 to 7.5)	5.9 (3.7 to 9.0)
Pinch right (kg)	5.7 (4.5 to 7.2)	5.0 (3.5 to 9.0)
Cochin Hand Function Scale	14.0 (8.0 to 22.0)	8.0(3.0 to 16.0)
mRSS (0 to 51)	8 (6 to 20)	10 (7 to 17)
Hand mRSS (0 to 12)	6 (6 to 10)	6 (6 to 8)

Key: HAMIS = Hand Mobility in Scleroderma; HAQ-DI = Health Assessment Questionnaire-Disability Index; SHAQ = Scleroderma Health Assessment Questionnaire; VAS = Visual Analogue Scale; mRSS = modified Rodnan Skin Score.

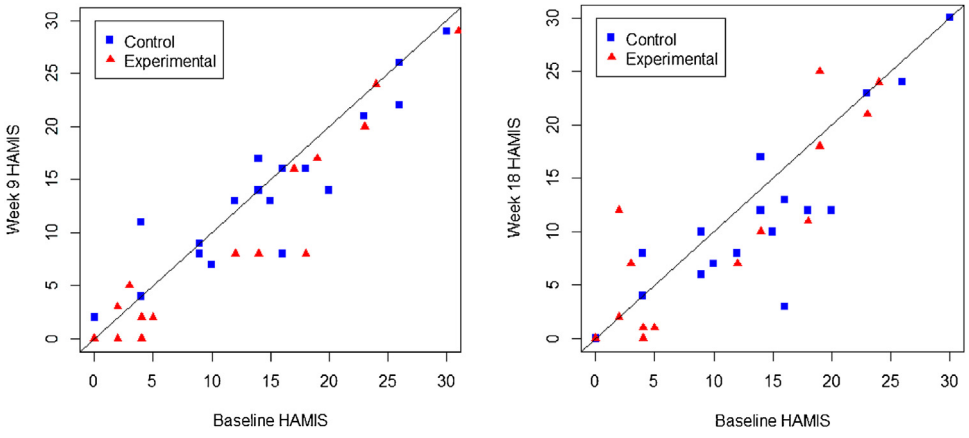

Fig. 3. Plot of primary outcome measure (HAMIS) comparing baseline to (a) 9 and (b) 18 week data in control and experimental groups.

Table 2
Secondary outcomes (all tested by ANCOVA, adjusted for baseline values).

Secondary outcome	Week 9				Week 18			
	Mean Outcome Scores		Adjusted difference in means (95% CI): experimental – control	*P*-value	Mean Outcome Scores		Adjusted difference in means (95% CI): experimental – control	*P*-value
	Experimental	Control			Experimental	Control		
HAQ-DI	1.00	1.13	−0.13 (−0.34 to 0.08)	0.22	1.00	1.44	−0.18 (−0.36 to 0.01)	0.06
VAS pain (cm)	1.11	1.28	−0.07 (−0.39 to 0.97)	0.65	0.90	1.36	−0.10 (−0.53 to 0.32)	0.62
VAS vascular (cm)	0.97	0.57	0.01 (−0.38 to 0.40	0.97	0.65	0.72	−0.02 (−0.42 to 0.39)	0.93
VAS overall (cm)	1.04	1.29	−0.08 (−0.44 to 0.27)	0.64	0.84	1.44	−0.15 (−0.53 to 0.22)	0.41
Grip left (kg)	14.8	16.0	2.2 (−0.6 to 5.0)	0.12	12.0	15.2	2.4 (−0.8 to 5.7)	0.14
Grip right (kg)	12.5	12.9	0.8 (−2.2 to 3.7)	0.60	14.6	14.0	1.2 (−1.9 to 4.2)	0.44
Pinch left (kg)	6.0	6.6	−0.1 (−1.0 to 0.8)	0.88	5.2	7.2	0.2 (−0.3 to 0.7)	0.46
Pinch right (kg)	5.5	6.2	0.1 (−0.9 to 1.0)	0.91	6.4	7.0	0.3 (−0.6 to 1.1)	0.28
Cochin HFS	9.0	16.0	−0.5 (−6.8 to 5.7)	0.86	11.0	17.0	2.3 (−3.8 to 8.3)	0.45
Hand mRSS	6.0	6.0	−0.12 (−0.40 to 0.16)	0.40	6.0	6.0	0.47 (−0.10 to 1.04)	0.10

Key: HAQ-DI, Health Assessment Questionaire-Disability Index; VAS, Visual Analogue Scale; Cochin HFS, Cochin Hand Function Scale; mRSS, Modified Rodnan Skin Score.

Secondary outcomes

Analysis of secondary outcomes showed no evidence for effectiveness of the wax bath treatment at either 9 or 18 weeks (see Table 2). There was no significant improvement in disease status for the wax bath group compared to the control group by analysis of SHAQ, pain, vascular or overall VAS, grip and pinch strength, Cochin Hand Function Scale, mRSS or use of analgesics. Analgesic use was no different between the two groups and there was no significant change in use through time in either group. Owing to the large number of comparisons performed, p-values for these analyses should not be given much weight.

Compliance

Patient reported compliance to the treatment protocol was very high: participant diaries showed 100% compliance for the wax bath in the intervention group and 100% compliance to the finger stretches protocol in both groups.

Harms

Three participants reported a transient ache after the stretches. One participant ceased her home exercises due to discomfort on performing these exercises; she was reviewed and advised to persist with the exercises but less strongly, there were no issues with these exercises after this intervention.

No other harms were identified.

Discussion

Very few RCTs have been carried out in SSc rehabilitation. This study adds to this thin body of research. As standard care, daily home exercises for the hands have been shown to aid hand movement and function [12,15,17,18]. The addition of a wax bath home daily treatment has been shown in this study to have no additional beneficial effect. We are, however, unable to exclude the possibility that certain subgroups of patients, such as those with early disease, might benefit from the wax bath protocol. The numbers recruited in this study were guided by previous research, and appropriately decided upon from a power calculation with the primary outcome measure. However, numbers were too small for any meaningful subgroup analyses to be performed. Importantly in the planning of future studies aimed at studying specific subgroups, we have shown this protocol of home use wax baths and hand exercise to be tolerable for a representative cohort of patients with SSc. Only one participant temporarily ceased the treatment due to discomfort.

The composition of the two participant groups was characteristic of the SSc population as a whole; with male: female ratios and median age range well matched to epidemiological data [2,34]. Both early and late disease stages were represented, with a wide range of disease duration. A strength of the study was that the same physiotherapist performed all assessments through the baseline, 9- and 18- week visits.

The results of this study appear in line with previous wax bath SSc research. Whilst a published collection of case studies showed some significant improvements in some outcome measures [12], all three of the previous controlled trials showed short term benefit, and improvement in certain outcome measures, but overall no convincing clinically important sustained changes. Two of the previous studies were from over 25 years ago and studied shorter periods of treatment [10,11]. Askew *et al.* in 1983 [10] assessed the effect of a 'one-off' physiotherapy intervention for patients with SSc. Pils *et al.* in 1991 [11] looked specifically at the effect of a series of paraffin wax hand treatments on joint motion. The Askew *et al.* [10] intervention involved hand and forearm wax bath, friction massages and then active ROM exercises. There were ten participants in the intervention group and seven controls. There is no mention of how well matched the two groups were. The study reported statistically significant improvements for hand ROM; there were improvements in hand dexterity, strength and skin score, but these were all below the level of statistical significance. The post intervention measures were taken two hours after physiotherapy treatment was completed, so longer term impact of this brief physiotherapy treatment cannot be implied [10]. Furthermore when relating the results of this study to our current RCT one could postulate that the improvements may have been due to the hand exercises rather than the wax baths.

The Pils *et al.* [11] study recruited sixteen participants who had daily paraffin wax hand treatment for twelve days. Immediately after the twelve treatments, there was a significant decrease in joint contractures and significant increase in finger ROM, as well as decrease in reported pain levels. The researchers then randomly selected eight of these participants to discontinue wax treatment, whilst the other eight continued with daily treatment. We do not know how well matched these two groups were. During the three months that the control group received no treatment their ROM decreased to pre-intervention levels; whilst the eight patients continuing to receive daily wax treatment maintained their beneficial changes at three month review [11].

The third paraffin wax treatment RCT carried out in 2004 found clinically significant changes in a number of patients in a variety of outcome measures assessed, but a statistically significant change for the group as a whole was only achieved for the finger flexion component of the HAMIS [5]. No statistically significant changes were reported in pain levels, stiffness and elasticity, or grip force. The authors suggested that the HAMIS does not have sufficient sensitivity to identify small changes in ROM [5]. This appears a valid argument as scoring the HAMIS requires a grading of the participant's abilities on a scale of zero to three for each of the nine items. Thus a participant could have improved ROM yet still score the same number in the HAMIS assessment. The use of graded outcome measures in the HAMIS does

limit the sensitivity to change, with only four options for the participant's performance: smaller changes within these four options would not be shown in the results. This limitation applied also in this current study given that the HAMIS was the primary outcome measure. The justification for choosing the HAMIS was that it is a well established outcome measure used in much of the SSc rehabilitation research to date, and that using it would therefore allow appropriate comparison to other studies. The measurement of individual joint ROM or delta finger-to-palm may have given a better chance of detecting change, but it was felt at study design that having a measure that was not included in previous studies of wax for SSc would have been inappropriate because this would have made comparison with other studies difficult. It has been stated that measuring individual joint ROM is time consuming [35] and one can assume this is a strong reason why it is not usually assessed in clinical trials. Delta finger-to-palm was first proposed in the literature in 2010 [35] and therefore was a fairly new measure when the study protocol for this paper was written and had yet to achieve universal uptake.

Our study had limitations. The study protocol was devised to be 'user friendly' in terms of clinician time and participant visits. It was devised in this way to replicate NHS provision and to enhance participant adherence. With participants often travelling considerable distances to secondary care it is appropriate to look at self-management treatment strategies. We were keen to produce a cost effective programme and the heavy reliance on self-treatment at home and minimal amounts of clinician input have enabled this. However this low level of clinician input is deviant from some of the other RCTs undertaken in rehabilitation for SSc, where a lot more clinician time was utilised [13,15,16,19].

It is well established that the majority of rehabilitation-type interventions cannot be double-blinded by their very nature [36]. The design of this study was single-blinded as it was clear that potential bias of the participant being aware of their intervention allocation could not be avoided. However, we would expect such performance bias to exaggerate the effect of the wax bath, which has not been observed.

A post study analysis of the 43 potential participants who declined the study showed no significant differences in demographic or disease data between those included and those who declined to participate. The proportion of potential participants who declined was anticipated (given the long distances some travelled to the clinic) and was similar to previously reported wax SSc study recruitment [5].

Although not limitations for the study per se, it is worth highlighting firstly that the inclusion criterion for mRSS-identified hand and finger skin involvement meant that our cohort was possibly more disabled in their hand movement and function than those studied in other SSc rehabilitation studies. Secondly, the treatment intervention trialled was quite single-faceted yet SSc is a multi-faceted condition. In a systematic review of SSc non-pharmacological interventions the authors noted that multimodal interventions targeting a range of symptoms were used in some studies [9]. The exercise protocol was based on a previous study that showed effect [17], but could be criticised for not including strengthening or functional rehabilitation exercise components; however it was felt preferable to replicate a previously effective exercise programme.

In conclusion, daily home exercises for the hands are well accepted as standard care in patients with SSc. The addition of a wax bath home daily treatment has been shown in this study to have no additional beneficial effect. However, our findings do not exclude the possibility that some subgroups of patients might benefit.

Key messages

- The musculoskeletal symptoms of SSc are a major cause of disability
- Very few RCTs have been carried out in SSc rehabilitation
- Wax bath home daily treatment confers no additional beneficial effect to hand exercises alone

Ethical approval: By the National Research Ethics Service (Committee North West – Greater Manchester East, 13/NW/0773).

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Conflicts of interest: None declared.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.physio.2018.08.008.

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