A Protocol of Accelerated Rehabilitation following surgery for adolescent Idiopathic Scoliosis (PARIS)

a feasibility study

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Aims

Almost 50% of adolescents who undergo surgery for adolescent idiopathic scoliosis (AIS) do not return to their preoperative levels of physical activity. Considering the potential long-term impacts of surgery, testing postoperative physiotherapy interventions should be a priority in this group. This study aimed to evaluate the feasibility of a future randomized controlled trial (RCT), which compares the effectiveness of an accelerated physiotherapist-led rehabilitation protocol to standard care for patients following surgical correction of AIS.

Methods

A total of 23 participants with AIS were recruited from surgical waiting lists at a single elective orthopaedic hospital. Participants were randomly allocated postoperatively to either a physiotherapist-led intervention of 12 sessions or standard care. Patient-reported outcome measures (PROMs), including Scoliosis Research Society 22-point revised questionnaire, were collected at baseline, six months, and 12 months. Recruitment rate, retention rate, response rate to PROMs, treatment adherence, and safety of the intervention via adverse events were also measured.

Results

Overall, 62% of eligible individuals were consented and there were three withdrawals (surgical delay, unable to travel to appointments). A total of 20 participants remained (intervention n = 9, standard care n = 11). The retention rate was 70% at six months and 65% at 12 months. Overall, treatment adherence was 76%. There were no adverse events related to the intervention.

Conclusion

This feasibility study has indicated that an accelerated physiotherapist-led rehabilitation protocol following surgery for AIS is safe and that patients can be successfully identified, recruited, and randomized to a future RCT. The next iteration of this intervention protocol needs to be developed with relevant stakeholders, including patients and the public, to improve retention rates and treatment adherence.

Take home message

- There are currently no studies that have investigated the implementation of a physiotherapy-led intervention for patients following surgical correction for adolescent idiopathic scoliosis.
- There is, therefore, no current literature to inform postoperative guidelines or pathways.
- This study is the first of its kind to investigate the feasibility of implementing a protocol like this to be evaluated as part of a future randomized controlled trial.

Bone & Joint Open

Introduction

Adolescent idiopathic scoliosis (AIS) is a complex 3D structural disorder affecting the spine and accounts for approximately 80% of scoliosis cases.[1] If left untreated, AIS may lead to severe trunk deformities and reduced pulmonary function, which can affect an individual's ability to exercise, maintain fitness, or work, all factors associated with impaired quality of life.[1,2] The impact of a severe deformity on cosmesis and body image is also significant.[3]

The criteria for a diagnosis of AIS include a Cobb angle of greater than 10° and evidence of vertebral body axial rotation.[4] The majority of AIS can be managed conservatively or with no treatment at all. Bracing treatment aims to prevent curve progression in patients with curves of 25° to 40° and in some cases may even result in curve regression.[5] Surgery is considered the treatment of choice for skeletally immature patients with a Cobb angle of greater than 45° as these patients experience significant reduction in quality of life.[1,6] Around 3.9 to 9.8 per 100,000 population have surgery for AIS.[7,8]

Surgical management of AIS has significantly advanced over the course of a century. Bilateral, multi-segmental, three-column fixation with pedicle screws have become the modern standard, following on from older hook and hybrid models.[9] These newer techniques have been consistently shown to provide better 3D correction, have stronger fixation, and offer lower risk of mid to long-term complications including revision surgery.[10,11] Despite these surgical advances, almost 50% of adolescents who undergo corrective surgery for AIS do not return to their preoperative levels of physical activity.[12] This is despite current evidence that it is safe to return to any level of sport.[13] While overall satisfaction scores following surgical correction of the scoliosis are good, physical functioning and pain are consistently worse postoperatively, negatively effecting overall quality of life.[14] This is a concern given that physical inactivity has been shown to be a highly prevalent risk factor for premature mortality and disease.[15] Long-term follow-up studies have shown that this patient group have significantly lower health-related quality of life (HRQoL) when compared with an age-matched population, and a significant impact on their ability to work.[16] This gives important insight in understanding the long-term outcomes of patients with AIS and may suggest that more monitoring and follow-up is required for these patients than originally thought.[17]

There are currently no studies investigating the impact of physiotherapy interventions for AIS patients following correction surgery. Previous studies that describe the views of spinal deformity surgeons have shown a tendency not to refer to physiotherapy postoperatively with a significant variability in recommendations regarding the timing of return to sport and the types of sports recommended.[18,19] Considering the potential long-term impacts of surgery, testing postoperative physiotherapy interventions, and identifying those who would benefit from them should be a priority for patients undergoing surgical correction of AIS. We therefore aimed to evaluate the feasibility of a future randomized controlled trial (RCT), which compares the effectiveness of an accelerated postoperative course of physiotherapist-led rehabilitation (Protocol of Accelerated Rehabilitation following surgery for adolescent Idiopathic Scoliosis (PARIS)) to standard care for patients following surgical correction of AIS.

Table I. Predefined success criteria for feasibility objectives.

Success criteria	Red (stop)	Amber (amend)	Green (go)
Recruitment rate (% of eligible patients enrolled)	< 20	20 to 29	30 or more
Retention rate (% of returned questionnaire booklets at 12-month follow-up)	< 60	60 to 74	75 or more
Response rate (% of usable SRS-22r for final data analysis)	< 70	70 to 79	80 or more
Treatment adherence (% of physiotherapy-led exercise appointments attended)	< 50	65 to 79	80 or more

SRS-22r, Scoliosis Research Society 22-point revised questionnaire.

Methods

A favourable ethical opinion for this study was granted by the West Midlands – South Birmingham Research Ethics Committee on 21 May 2019 (19/WM/0387).

We conducted a two-arm, single-centre feasibility RCT to assess the feasibility of delivering the PARIS intervention and to evaluate the feasibility of a future fully powered randomized controlled trial. The study is reported according to the CONSORT 2010 statement: extension to randomized pilot and feasibility trials.[20] The screening, recruitment, and follow-up process is reported in Figure 1.

Study setting

Participants were recruited from the spinal deformity outpatient clinics at a single elective orthopaedic hospital (The Royal Orthopaedic Hospital, Birmingham, UK). For those on the study's intervention arm, physiotherapy intervention was conducted in the outpatient physiotherapy department at the same hospital.

Recruitment

Participants were recruited between June 2019 and November 2020. Potentially eligible participants were identified from spinal deformity surgical waiting lists, screened in relation to the eligibility criteria, and sent the study information. If participants were aged under 16 years, informed consent was sought from the parent/guardian with assent from the participant. For participants aged 16 years or more, informed consent was obtained from the participants themselves.

Randomization

Participants were randomized while an inpatient in the hospital, following their surgery, to ensure that there were no significant postoperative complications that would preclude enrolment and that they still met the eligibility criteria. Randomization was conducted via an online randomization service (Sealed Envelope, UK). Randomization via this method uses an allocation ratio of 1:1 and is blocked (using random permuted blocks) to ensure the groups are balanced periodically throughout the period of enrolment to the study.

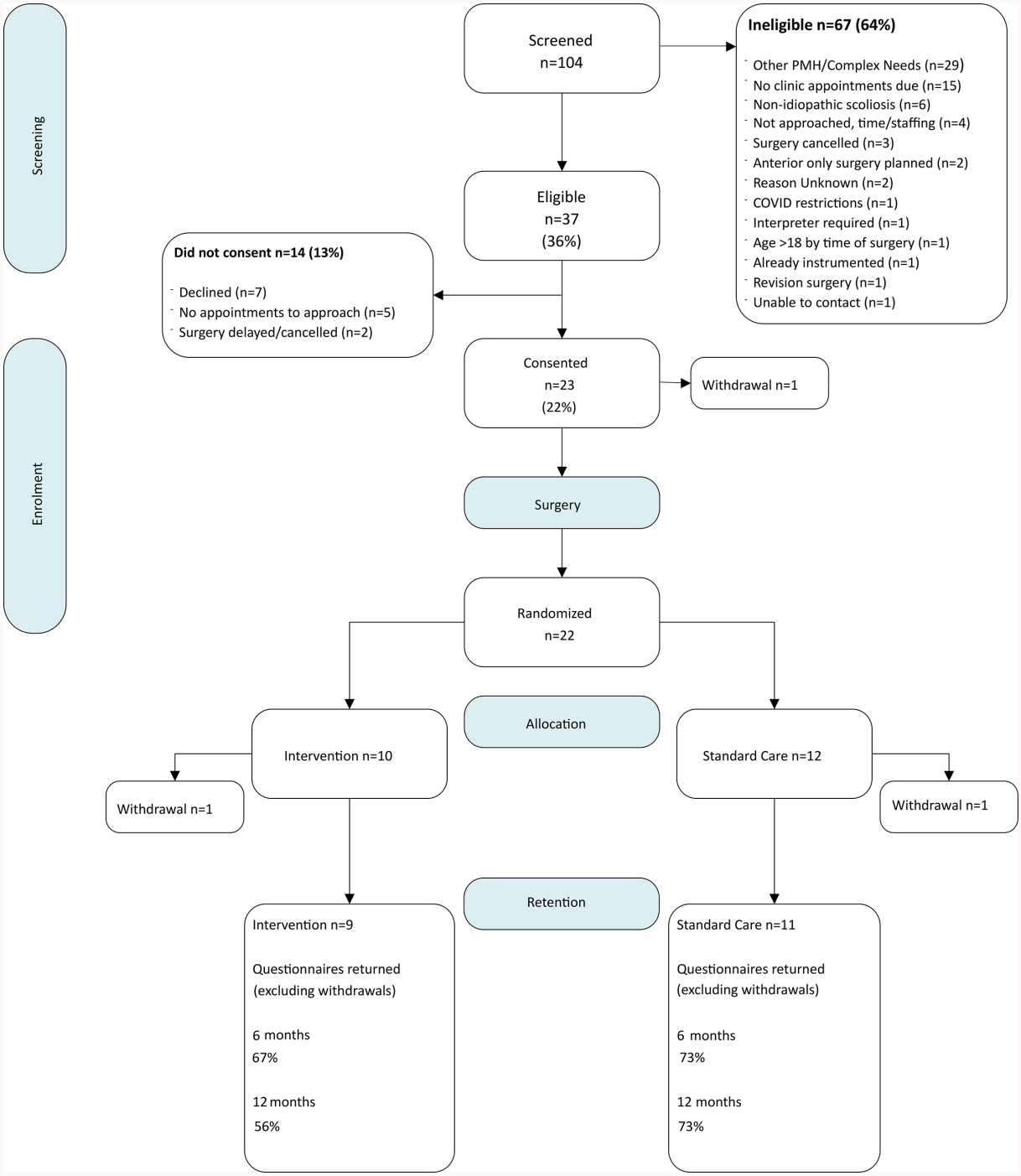

Fig. 1
CONSORT recruitment and screening flow diagram. PMH, past medical history.

Blinding

It was not possible to blind the participants themselves to the treatment they were receiving, or the clinicians who were delivering the treatment, as it was being delivered in addition to standard care. The assessors who collected the follow-up data from the participants were blind to the treatment allocation.

Aims

To evaluate whether it is feasible to deliver a future, statistically powered RCT comparing an accelerated physiotherapist-led exercise programme (PARIS) to standard care, for patients undergoing surgical correction and fusion surgery for AIS.

Objectives

The feasibility objectives of this study are as follows:

1. To determine the rate of recruitment via the number of eligible patients enrolled onto the study and randomized as a percentage of those eligible.
2. To determine the retention rate via the number of participants returning self-reported questionnaires at 12 months.

Table II. Baseline characteristics, Scoliosis Research Society 22-point revised questionnaire (SRS-22r) scores, and follow-up rate of each group.

Variable	All (n = 22)	Intervention (n = 10)	Standard care (n = 12)
Sex, n			
Male	4	3	1
Female	18	7	11
Mean age, yrs (SD; range)	15.9 (1.50; 13 to 18)	16.5 (0.97; 13 to 18)	15.4 (1.73; 15 to 18)
Baseline SRS-22r total score	3.56	3.68	3.45
Six-month booklet returned, n	14	6	8
Overall FU rate, %	64	60	67
Excluding withdrawals, %	70	67	72
12-month booklet returned, n	13	5	8
Overall FU rate, %	59	50	67
Excluding withdrawals, %	65	56	72

FU, follow-up; SRS-22r, Scoliosis Research Society 22-point revised questionnaire.

3. To determine the response rates via the number of participants who returned primary outcomes measures at 12 months that were completed sufficiently for analysis.
4. To determine adherence with the PARIS intervention through attendance rates to physiotherapy-led appointments.
5. To determine the safety of the intervention via monitoring and reporting of serious adverse events (SAEs).

Participants

Patients were included if they met the following criteria:

1. They have a diagnosis of AIS confirmed by their treating clinician.
2. They are on the waiting list for a posterior only scoliosis correction procedure.

Patients were excluded if they met any of the following criteria:

1. Non-idiopathic scoliosis diagnosis.
2. Any impairment affecting their ability to understand verbal instructions or written information.
3. Language barrier affecting their ability to understand verbal instructions or written information given in English that could not be resolved via an interpreter.
4. Underwent any form of surgery other than a posterior only correction procedure (such as an anterior release or anterior correction procedure).

Intervention development

The development of the PARIS intervention was through several stages. First, physiotherapy departments in seven spinal orthopaedic centres performing AIS surgery (32% of all spinal centres performing surgery for AIS in the UK) were contacted to understand standard postoperative care, offered across the UK. None of the centres contacted routinely referred patients postoperatively to physiotherapy on discharge, and none had a postoperative rehabilitation protocol beyond discharge home postoperatively.

A team of clinicians with relevant expertise was then formed to plan the postoperative rehabilitation intervention (PARIS), review the published evidence, and draw on existing theories to begin the development process, in line with intervention development guidelines.[21] This included physiotherapists (n = 3), consultant spinal surgeons (n = 5; including AG), and an occupational therapist (n = 1) (see Acknowledgements) working at a single elective orthopaedic hospital with spinal deformity speciality. Decisions were made during meetings by the clinical team via majority vote. This included suitable exercises and time frames in which participants could progress through the stages of exercises.

Study intervention

Participants in both groups had the same physiotherapy care while an inpatient in the hospital in line with standard care (Supplementary material ii). Following discharge from the hospital, the control group did not have any other physiotherapy follow-up organized, in line with standard care. However, being in the standard care group did not exclude them from being referred on for further physiotherapy if required. The intervention group had up to 12 follow-up sessions offered as an outpatient, which were booked on discharge from hospital. They were scheduled to start at six weeks postoperatively, and finish by approximately six months postoperatively. All intervention sessions were conducted by a qualified physiotherapist trained to deliver the PARIS intervention. Training to deliver the PARIS intervention was delivered to three therapists over a one-hour training session. The progression through stages of the PARIS intervention were milestone driven, but there were some timeframe constraints added to specific exercises following agreement between the expert clinicians (Supplementary material i).

Participants were discharged from physiotherapy after their 12th session, unless they had specific requirements for continuing care. If patients felt they did not require all 12 sessions, they were able to be discharged sooner at their request.

Success criteria

To determine the feasibility of progressing to a pilot RCT, we outlined several success criteria. These criteria are reported in Table I with respective (red/amber/green) thresholds.

Patient-reported outcome measures

Validated patient-reported outcome measures (PROMs) were used to measure health-related quality of life (HRQoL), child and parent self-efficacy, and global rating of change.

The Scoliosis Research Society 22-point revised questionnaire (SRS-22r)[22] was chosen as the primary outcome measure as it is disease-specific, well validated in the AIS population, and is included in the core outcome set for adolescents with spinal deformity.[23]

Secondary PROMs were the short-form 36-point questionnaire (SF-36),[24] the Child and Parent Self-Efficacy

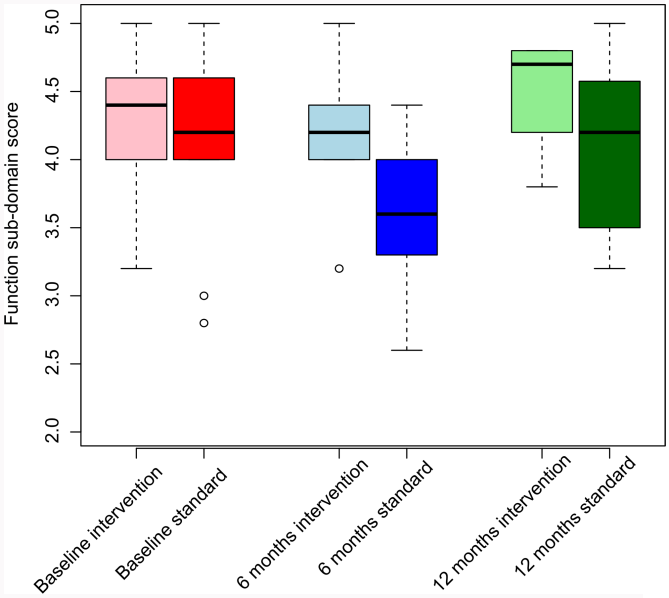

Fig. 2
Function sub-domain Soliosis Research Society 22-point revised questionnaire (SRS-22r) scores.

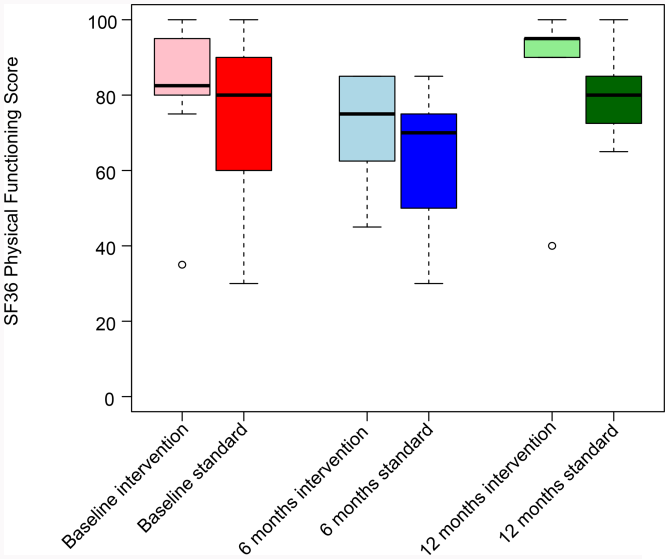

Fig. 3
Physical functioning domain scores of the short-form 36-point questionnaire (SF-36).

Scales (CSES),[25] and the Global Rating of Change Scale (GROC).[26]

The secondary outcome measures were also chosen because of their validated use in adolescent populations and included the SF-36 that measures eight health-related domains. The CSES was included to evaluate child and parent self-efficacy related to activities and the GROC to measure the participant's perceived overall change.

PROMs were completed at baseline, and at six and at 12 months postoperatively. Baseline responses were completed face to face at the same time as consent. The six- and 12-month responses were collected via postal questionnaires.

Sample size

This feasibility study aimed to evaluate whether participants could be recruited, randomized, and retained within a future, fully powered RCT. Importantly, it also aimed to assess the safety of the accelerated rehabilitation programme given the conservative approach of current standard care. In this context, a sample of 20 participants was deemed suitable to provide provisional data on the feasibility of delivering a future fully powered multicentre RCT with integrated pilot, but also the safety of the PARIS intervention.

Recruitment

A total of 104 individuals were screened; of those, 37 (36%) were deemed eligible and were approached. The most common reasons for ineligibility were related to other complex health needs/non-AIS diagnoses, and being out of area (Figure 1). Of the eligible individuals, 62% (23/37) were consented to the study (22% of the overall number screened). This was in line with the green zone of our success criteria. The reasons for non-consent were patient choice to decline, no scheduled appointments to approach, and surgery delay or cancellation.

There were three withdrawals. One occurred after consent but before surgery and therefore they were not randomized. This participant was withdrawn due to a delay in surgery. There were therefore 22 participants randomized to the trial. There were two further withdrawals following randomization, one from each arm of the trial. One participant withdrew because they were unable to commit to intervention appointments and the other participant did not reveal the reason behind withdrawal. Therefore, 20 participants remained in the trial. Of these, 11 were randomized to standard care and nine were randomized to the intervention arm. The baseline characteristics, follow-up rate, and baseline SRS-22r scores of participants are described in Table II.

Statistical analysis

As this was a feasibility RCT, formal powered statistical analysis was not possible. All data are thus described as means or medians with SDs or IQR and total range. PROMs data are displayed as box and whisker plots and bar charts as appropriate for the data type.

All analysis was performed using R v. 4.3.2 (R Foundation for Statistical Computing, Austria).[27]

Results

Surgery for all 20 participants was performed under general anaesthesia with multi-modal spinal cord monitoring. An open posterior approach to the spine was performed. The upper and lower instrumented levels were assessed preoperatively based on the upright standing and supine maximal side bending radiographs. The instrumentation was performed using multi-level pedicle screw fixation and the reduction of deformity was tailored for the best result on an individual patient-specific basis. Posterior spinal decortication and fusion were performed in all cases.

Retention

In the intervention group, the retention rate was 60% at six months and 50% at 12 months. In the standard care group, it was 67% at both six months and 12 months. Excluding withdrawals, the retention rate in the intervention group was 67% at six months and 56% at 12 months. The six-month retention rate is in line with our amber success criteria. However, the 12-month retention rate falls into the red zone. Excluding withdrawals, the retention rate in the standard care group was 72% at both time intervals, in line with the amber zone (Table I).

Response rates

At baseline, all 23 of the patient questionnaires were fully completed. At the six-month follow-up, 14 booklets were returned (70%). There was 100% completion of the SRS-22r with no missing data. This falls in the green zone of the set success criteria. There was also 100% completion of the SF-36 and the GROC, and 85% completion of the CSES.

At the 12-month follow-up point, 12 questionnaires were available for analysis. Out of these 12 questionnaires there was 100% completion of the SRS-22r, again in line with the green zone of the success criteria. There was also 100% response rate of the SF-36 and the GROC, and 83% completion of the CSES.

Treatment adherence in the intervention arm

There were three/nine participants (34%) who attended 100% of their scheduled appointments. There were six/nine participants (67%) who partially attended their booked sessions. Overall, 44% of participants attended more than 75% of booked sessions; 44% of participants attended between 50% and 75% of booked appointments; only one participant (11%) attended less than 50% of their booked appointments and was therefore deemed non-adherent to the intervention. The mean attendance rate for booked appointments across the intervention was 76%, which is in line with the amber zone of our success criteria.

Safety

There were two complications of surgery deemed as SAEs with early postoperative infection managed with surgical debridement and retention of metalwork. Both individuals were in the standard care group. There was one adverse event (AE) reported in the intervention group due to a reporting of persistent pain, which required referral to a pain management team. This individual reported that persistent pain had been present prior to surgery and had not changed since surgery or starting the intervention. It was therefore deemed reasonable to presume that none of the AEs were related to the intervention protocol or standard care interventions.

PROMs

While this study was underpowered to detect statistically significant differences between groups in terms of PROMs, there were points of interest in the data displayed. For example, when looking at the 'function' domain of the SRS-22r, baseline scores are slightly higher (associated with high HRQoL) in the intervention group compared to the standard care group. Postoperatively, this gap widens at six months, with the standard care groups reported 'function' decreasing from baseline. At 12-month follow-up, the standard care group scores begin to return to baseline levels, while the intervention group scores exceed baseline levels. The equivalent SF-36 domain of 'physical functioning' shows a similar trend across the groups. These 'function' domain box and whisker plots are displayed in Figures 2 and 3.

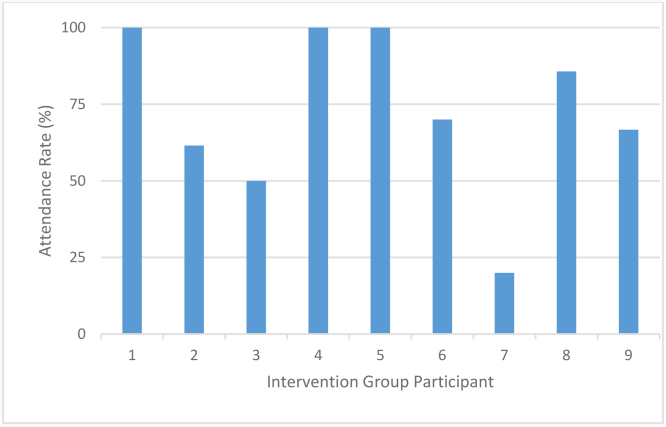

Fig. 4
Attendance rates of each participant in the intervention group, used to measure treatment adherence.

Discussion

There is no evidence to date that guides clinicians on how to rehabilitate patients following correction surgery for AIS. The results of this study indicate that a RCT comparing an accelerated intervention protocol to standard care would be feasible and safe, with amendments to the research design.

Overall, 62% of eligible individuals were enrolled, which was in line with the green zone of our success criteria and was therefore considered a proficient level of uptake to the trial.

We note that the mean age in the intervention group is approximately one year higher than that in the standard care group. We believe this is due to the small sample size of this work which was designed to create and test the intervention for safety rather than to be powered for a definitive answer. As such, a small sample size increases the likelihood that parameters within the groups will not be entirely normally distributed, explaining the difference in ages seen. We expect this not to occur when the definitive, fully powered RCT is undertaken in the future.

While the retention rate in terms of returned follow-up questionnaires was satisfactory in the standard care group and at the six-month follow-up in the intervention group, it was 56% at 12 months in the intervention group. This falls into the red zone of our success criteria, indicating a need for substantial amendments to the research design. A future RCT would need to involve patients and the public in its design to optimize retention rates.

The response rate of each outcome measure in the returned booklets was very high, with 100% full datasets for the SRS-22r and the SF-36 out of the returned forms, suggesting that they are usable for participants and provide adequate data. There was a slight reduction in complete data for the CSES, although still high at 85%. However, while this outcome measure was developed for children, it has not been specifically validated in the AIS population and has not been widely

adopted in studies including adolescent participants and is therefore less likely to be suitable to use in a future RCT.

Adherence to the intervention was good, with only one participant from the intervention group recorded as non-compliant, due to lack of attendance. Only three participants (34%) attended all 12 sessions offered. There was a 76% overall attendance rate, and 88% attended more than 50% of sessions. Overall adherence aligned with the amber zone of the success criteria indicating minor amendments to the methodology around compliance and attendance are required. Travel requirements to appointments and the number of sessions provided could be reviewed with patient and public involvement and engagement members to inform the development of a future pilot RCT.

Regarding safety, no SAEs or AEs were associated with the PARIS intervention. The SAEs relating to early postoperative infection were not related to the study interventions. These outcomes are encouraging, although due to the number of participants in this study being at the lower end of the recommended number of participants in feasibility and pilot RCTs,[28] they are not definitive. Safety of the intervention would be monitored in any future RCT. While there are no definitive guidelines on sample sizes for pilot and feasibility studies, this study was compliant with the smallest recommended sample size[29] and within the IQR (n = 20 to 43) of recent UK pilot and feasibility studies with continuous outcomes on the International Standard Randomized Controlled Trial Number (ISRCTN) registry.[28] However, this study does not meet more recent recommendations, which suggest a sample size of 70.[30] These recommendations would need to be considered alongside the findings from this study to determine the required sample size for a future RCT.

While the number of participants in this study was too low to detect a minimum clinically important difference between the groups, the distribution of the data is nevertheless interesting. Examples of sub-domain scores for the SRS-22r and SF-36 (Figures 2 and 4) show a trend of higher scores in the intervention group (in these measures higher scores correlate with improved quality of life) compared to standard care in the domains relating to function. There is also some indication of deterioration in these scores within the standard care group compared to their baseline scores, which are maintained at 12 months. The trends of higher scores for the intervention group are more pronounced at the six-month follow-up and then level out slightly by 12 months. These results may signal positive health and quality of life benefits in those patients who had the intervention, although it is not clinically meaningful or statistically significant due to the small number of participants in this study.

There are no previous studies to compare our results to. However, the findings of this study indicate that taking part in the intervention is safe. Considering this in the context of the robustness of current surgical techniques[10,11] and the potential long-term negative impact of the surgery on quality of life[31] a platform is provided to conduct a RCT that can compare accelerated rehabilitation to standard care in patients following surgical correction of AIS.

There is a need to evaluate rehabilitation programmes for patients following surgical correction of AIS in a future RCT to improve function, activity levels, and quality of life postoperatively. This feasibility study has indicated that the PARIS intervention is importantly, safe and that patients can be successfully identified, recruited, and randomized to a future RCT, with some amendments to the research design to improve compliance with the intervention and retention at 12 months. A future iteration of the PARIS intervention needs to be developed with relevant stakeholders, including patients and members of the public, to optimize compliance. The PARIS intervention then requires evaluating as part of a fully powered multicentre RCT with internal pilot.

Social media

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Supplementary material

Details of the rehabilitation protocol followed by the intervention group as part of the study, and the inpatient postoperative physiotherapy protocol.

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Data sharing

The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

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