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ORIGINAL ARTICLE

Effects of 6 months of regular passive movements on ankle joint mobility in people with spinal cord injury: a randomized controlled trial

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Study design: Assessor-blinded within-subject randomized controlled trial.
Objective: To determine the effects of 6 months of regular passive movements on ankle joint mobility in people with spinal cord injury.
Setting: Community, Australia.
Methods: A total of 20 people with tetraplegia living in the community had one ankle randomized to a control group and the other to an experimental group. Carers administered passive movements to participants' experimental ankles for 10 min, 10 times a week for 6 months. The control ankles were left untreated. The primary outcome was passive ankle dorsiflexion range of motion.
Results: Adherence was high (mean adherence rate of 96%). Ankle dorsiflexion range of motion decreased by a mean (s.d.) of 2° (4) in control ankles and increased by 2° (4) in experimental ankles. The mean (95% confidence interval, CI) effect on ankle dorsiflexion range of motion was 4° (95% CI, 2–6°).
Conclusion: Regular passive movements have small effects on ankle joint mobility. It is unclear if these effects are clinically worthwhile.
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Keywords: ankle; stiffness; spinal cord injury; rehabilitation

Introduction

Contractures are a disfiguring and disabling complication of spinal cord injury (SCI).[1] They prevent the performance of motor tasks and result in unsightly deformities. They also predispose individuals to pain and sleep disturbances.[1] Contractures are caused by structural adaptation of muscles and soft tissues spanning joints, and are frequently accompanied by spasticity.[2,3]

A range of interventions are used to treat and prevent contractures.[4] Perhaps the most widely used intervention is the application of passive movements. Passive movements involve manually and repeatedly moving joints through range. Typically a carer or physiotherapist applies a total of 20–30 min of regular passive movements to all joints affected by paralysis. This often equates to a couple of minutes per joint for a person with tetraplegia. These interventions are typically administered every day throughout a person's life. This places a significant burden on people with SCI as well as their carers.

It is widely believed that passive movements are an essential part of the ongoing physical care of people with SCI. They are primarily justified by the deleterious effects of paralysis on joint mobility and by anecdotal observations regarding the benefits of regular passive movements. However, the effectiveness of passive movements has never been confirmed with a clinical trial and the results of the few high quality studies in non-disabled populations have not demonstrated improvements in passive range of motion from regular passive movements.[5–8] Therefore, the purpose of this trial was to determine the effectiveness of passive movements administered over a 6-month period to the ankles of people with SCI. An intensive treatment was selected (that is, 20 min of passive movements five times a week) because we wanted to maximize the likelihood of finding a treatment effect. Subsequent trials can address questions about the relative effectiveness of different dosages. This is a more efficient way of answering questions about treatment effectiveness than starting with smaller dosages, running the risk of finding no treatment effect, and

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therefore needing to repeat the same trial with larger dosages.

Materials and methods

Participants

A total of 20 people with tetraplegia living in the community were invited to participate in the trial. Participants were included if they were wheelchair dependent, had mild to moderate ankle stiffness (less than 101° dorsiflexion with a 12 Nm torque applied to the ankle[9] but an arc of at least 15° motion), had paralysis around both knees and ankles and had carers able to provide the intervention.

A power analysis indicated that 20 participants (that is, 20 pairs of ankles) would provide a 95% probability of detecting a treatment effect of 5°, assuming an α of 0.05, a standard deviation (s.d.) of the treatment effect of 5° and loss to follow-up of 15%. It was decided prior to the conduct of the trial that the smallest clinically worthwhile effect would be 5°. This figure was nominated after considering the time, cost and effort associated with the intervention and the implications of loss of ankle mobility on the lives of people with SCI.

All applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. The trial was registered prior to commencement with the Australian New Zealand Clinical Trial Register (ACTRN12607000220460).

Intervention

Prior to commencement of the trial, a computer-generated random number sequence was created by a person not involved in recruitment to determine the allocation schedule. Each participant's allocation was placed in a sealed, opaque, sequentially numbered envelope to ensure concealment. The envelopes were not opened until after the participant had completed all pre-trial assessments. A participant was considered to have entered the trial once his/her envelope was opened.

The experimental ankles of participants were passively moved by participants' carers for 10 min in the morning and 10 min in the evening, 5 days a week for 6 months. Carers were given written instructions and training on how to administer the passive movements. Participants and carers were also visited regularly to ensure the passive movements were performed correctly. Participants or carers were required to record when and for how long the passive movements were administered in a diary. In addition, participants were contacted at least every second week and often every week. At this time, recordings from the diaries were noted. The control ankles did not receive passive movements or stretches for the duration of the trial.

Measurement

Participants were assessed at baseline and then 1 day after the 6-month intervention period. No passive movements or stretches were administered in the 24 h prior to either assessment. One assessor performed all but two assessments. All assessors were blinded to group allocation.

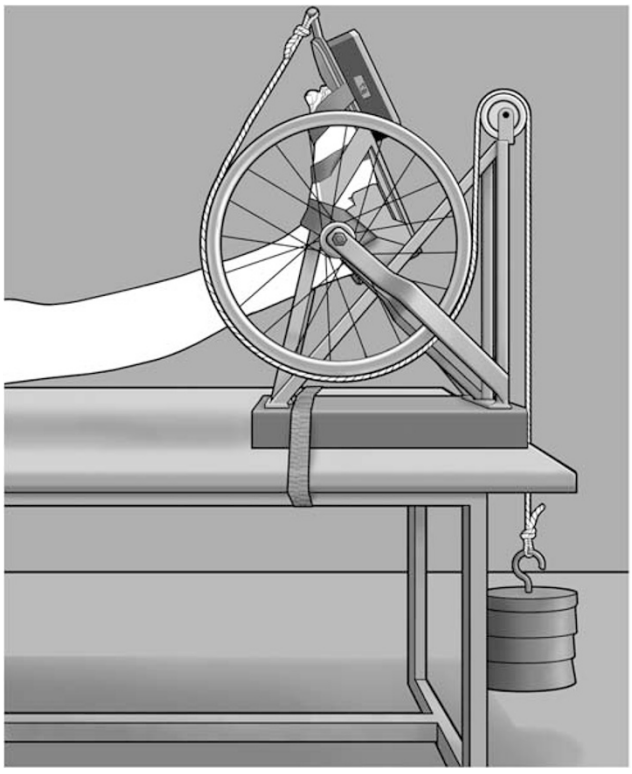

Figure 1 The testing device. Image used with permission from www.physiotherapyexercises.com.

The primary outcome was passive ankle dorsiflexion range of motion with the application of a 12 Nm torque. This torque was less than that specified in the original protocol (i.e., 17 Nm). It was changed soon after commencing the trial because of concerns about the integrity of participants' plantarflexor muscles. Passive ankle dorsiflexion was also measured with the application of six smaller torques (2, 3, 5, 7, 8 and 10 Nm). Measurements were made with a custom-built device.[10] The device consisted of a footplate attached to a wheel (Figure 1). The foot was firmly secured to the footplate. Both the foot and footplate rotated in response to a weight hung from a rope looped around the rim of the wheel. Dorsiflexion angle was derived from the difference in inclination of the footplate and tibia measured with a digital inclinometer.

Testing always followed the same format. Participants lay in a supine position. The right ankle was tested before the left ankle. Initially a 12 Nm torque was applied for 3 min to precondition the ankle. Dorsiflexion was then measured with the application of six progressively larger torques, starting with 2 Nm and finishing with 12 Nm torques. Each torque was applied for approximately 20 s before measuring ankle angle. The reliability of this procedure is high (intraclass correlation coefficient of 0.95; 95% confidence interval (CI), 0.92–0.98).[10]

The secondary outcomes were spasticity in ankle plantarflexor and knee hamstring muscles and a measure of participants' perception of change. Spasticity in ankle plantarflexor and knee hamstring muscles was measured

with the six-point modified Ashworth scale.[11,12] This test has limited reliability in people with SCI (mean $\kappa = 0.37$)[12] but is widely used as a clinical test of spasticity in the community setting.[13] At the completion of the trial, participants were asked to rate perceived Global Impression of Change in both the treated and untreated ankle using a 15-point Likert scale where −7 indicates 'very great deal worse', 0 indicates 'no change' and +7 indicates 'very great deal better'.[14] In addition, participants were asked to rate the convenience or inconvenience of the intervention on a 10 cm visual analogue scale. At one end of the 10 cm scale were the words 'very inconvenient' and at the other end were the word 'not at all inconvenient'. A higher score indicated less inconvenience.

Data analysis

The *t*-distribution was used to estimate 95% CI for between-group (that is, between-leg) differences in change scores for ankle angle (posttest score minus pretest score). Paired *t*-tests were used to test for significant differences. Probabilities of less than 0.05 were considered significant. The 'centile' routine in Stata (v9.2; Statacorp, TX, USA) was used to derive the 95% CIs for median between-group differences for the modified Ashworth and Global Impression of Change data. This method does not make assumptions about the distribution of the data. All data were analyzed according to the intention-to-treat principle.

Results

Participants had American Spinal Injury Association (ASIA) neurological levels ranging from C2 to C7. Eleven participants had ASIA A lesions and nine participants had ASIA B lesions. The median (interquartile) age and time since injury were 39 (34–44) and 8 years (4–14), respectively. Three participants were women and seventeen were men.

The flow of participants through the trial is given in Figure 2. There was no loss to follow-up and complete data sets were obtained from all participants.

The protocol dictated that each participant receive 260 10-min treatments over a 6-month period. In practice participants received on average (s.d.) 250 treatments (70) over a 6-month period (equivalent to an average adherence of 96%). The reasons given for nonadherence included hospital visits, pressure areas and lack of time. One participant sustained an ankle fracture within a week of commencing the trial. This was unrelated to participation in the trial but required cessation of passive movements for 14 weeks.

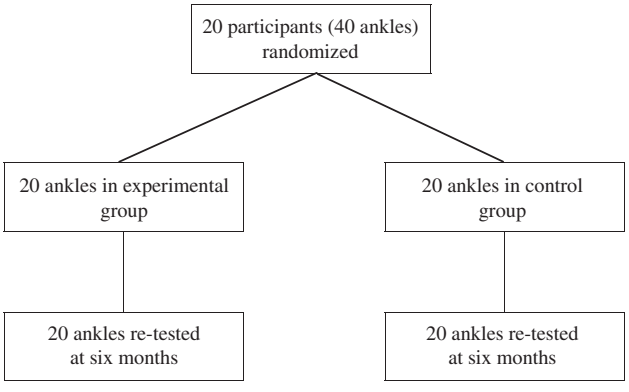

Figure 2 Flow of participants through the trial.

Three participants spent the majority of the 6-month period in bed. The other participants mobilized in a wheelchair with their feet supported on footplates. Twelve participants slept at night on their sides with their feet unsupported and eight slept supine with both feet supported at 90°. No participant used stationary bicycles or electrical stimulation but one participant regularly stood with standing equipment. None of these co-interventions or any other unidentified co-interventions were likely to affect one ankle more than the other.

Passive dorsiflexion of the experimental ankles increased slightly over the 6-month period from a mean (s.d.) of 88 (9) to 91° (10) when measured with the application of 12 Nm torque. The corresponding angle in control ankles decreased slightly over the same period from a mean (s.d.) of 89 (8) to 87° (9). Thus, the overall between-group mean difference was 4° (95% CI, 2–6, $P = 0.002$). Between-group differences for passive dorsiflexion with the other five torques were similar (Table 1). Removal of the three least compliant participants' data from the analyses had little effect on the results (mean treatment effect with 12 Nm was 5°, 95% CI, 3–7).

The overall between-group difference in median scores for the modified Ashworth score of the hamstring and plantarflexor muscles were 0 (95% CI, 0–0) and 0 (95% CI, 0–1), respectively (Table 2). These results were not statistically significant.

Participants reported a median (interquartile) Global Impression of Change of three points (2–4) on the 15-point scale in the treated ankle and 0 points (0–0) in the untreated ankle. The overall between-group difference in median scores was two points (95% CI, 2–3). Some participants reported that the passive movements reduced ankle stiffness, spasticity and edema.

Participants did not find the passive movements inconvenient. The median (interquartile) rating of inconvenience associated with the provision of passive movements was 8 points (6–8) where 10 is 'not at all inconvenient'.

Discussion

This is the first randomized controlled trial to examine the effects of passive movements on joint mobility in people with SCI. It is important because passive movements are commonly administered to people with SCI on a regular basis for the treatment and prevention of contractures.

There was a small but statistically significant effect of passive movements on ankle mobility: on average the effect of 260 10-min treatments of passive movements administered over a 6-month period was 4° (95% CI, 2–6). At issue is whether this effect is large enough to justify the widespread and ongoing administration of passive movements for the treatment and prevention of contractures. Prior to the start

Table 1 Mean (s.d.) passive ankle dorsiflexion (degrees) of experimental and control legs at the beginning and end of the 6-month period

	Control		*Experimental*		*Between-group difference*
Stretch torque (Nm)	*Pre*	*Post*	*Pre*	*Post*	
2	81 (7)	78 (9)	81 (9)	81 (10)	3 (95% CI, 1–6)
3	81 (7)	80 (9)	81 (9)	83 (9)	3 (95% CI, 1–5)
5	82 (10)	81 (9)	83 (9)	84 (9)	2 (95% CI, -1–4)
7	85 (7)	83 (9)	85 (9)	86 (10)	3 (95% CI, 1–5)
8	86 (7)	84 (9)	86 (9)	88 (10)	4 (95% CI, 1–6)
10	87 (7)	85 (9)	87 (9)	89 (10)	4 (95% CI, 2–6)
12	89 (8)	87 (9)	88 (9)	91 (10)	4 (95% CI, 2–6)

Passive ankle dorsiflexion was measured with the application of 2, 3, 5, 7, 8, 10 and 12 Nm. The overall mean (95% CI) between-group differences are also shown. Data reflect both feet of all participants.

Table 2 Median (interquartile) modified Ashworth scores for the hamstring and plantarflexor muscles of experimental and control legs at the beginning and end of the 6-month period

Muscle	*Control*		*Experimental*		*Between-group difference*
	Pre	*Post*	*Pre*	*Post*	
Hamstring	1 (0–2)	0 (0–1)	1 (0–2)	1 (0–1)	0 (0–0)
Plantarflexor	1 (0–2)	1 (0–2)	1 (0–2)	1 (0–1)	0 (0–1)

The overall between-group differences (95% CI) in median scores are also shown. Data reflect both feet of all participants.

of the trial we articulated a belief that passive movements administered for 6 months needed to have an effect on ankle range of motion of at least 5° to be clinically worthwhile. This is conservative as others set the clinically worthwhile criterion at 10°.[15] Our point estimate of 4° therefore suggests a treatment effect that is too small to be worthwhile.

Few would dispute the claim that 4° of ankle range of motion is of little functional importance on its own. However, it is possible that the therapeutic effects of passive movements accumulate over time. That is, it is possible that 20 min of passive movements could prevent a loss of 4° every 6 months, equivalent to a loss of 80° every 10 years. An effect of this magnitude would justify the routine provision of passive movements over an extended period of time. However, it is not known whether the therapeutic effects of passive movements are cumulative or not. Nor is it feasible to conduct a randomized trial over a 10-year period to clarify the issue.

The passive movements administered in this trial were very intensive. In most contexts it would be difficult to apply 20 min of passive movements to any one joint on a long-term basis, and it would be nearly impossible to apply 20 min of passive movements to all the joints affected by tetraplegia. Data on the relationship between dose of passive movements and effects are not available but it would seem reasonable to expect that the size of the treatment effect is positively related to dose. If this is the case, 2–3 min of passive movements to a joint each day, as typically provided in the community setting, would be expected to have smaller treatment effects than demonstrated in this trial. It is not clear just how small the treatment effects would be.

With any intervention there is always the possibility that a particular subgroup of patients respond better to the intervention than the majority. If these patients could be identified, they could be specifically targeted for therapeutic attention. For example, it could be that those with recent SCI benefit more from regular passive movements than those with long-standing SCI, or that those with early contracture benefit more than those with more established contracture. Although these hypotheses sound plausible they are not supported by the data. There was little person-to-person variation in the size of the treatment effect (the s.d. of the treatment effect was just 5°). That is, there was no evidence that some individuals responded substantially more to passive movements than others.

The results of this study are consistent with three randomized controlled trials in people with SCI and two in people with other neurological conditions indicating that sustained stretch, as typically applied in the clinical setting, is not effective for the treatment and prevention of contractures.[16–20] Although passive movements confer a slightly different mechanical stimulus to that provided by sustained stretch, the two interventions are similar. The main difference is that passive movements involve the administration of repetitive short-duration stretches. The results of this trial add to the mounting evidence indicating that stretch is not the potent stimulus it is assumed to be, regardless of whether it is applied in a cyclic repetitive manner or in a sustained way.

Interestingly, although the effects of passive movements on ankle range of motion were small, nearly all participants felt the passive movements were worthwhile. They commonly stated that the passive movements decreased spasticity and ankle stiffness even though these claims were not substantiated in the data collected by blinded assessors. Participants did not find the intervention particularly inconvenient.

In conclusion, this randomized trial indicates that an intensive 6-month program of passive movements increases range of motion by 4°. This treatment effect is too small to be intrinsically worthwhile. However, if the same effect can be attained with 2–3 min of passive movements and if the effects accumulate with time, passive movements may be effective for the treatment and prevention of contractures when provided on a routine and long-term basis.

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