Journal of Physiotherapy 60 (2014) 201–208

Journal of PHYSIOTHERAPY

journal homepage: www.elsevier.com/locate/jphys

Research

Standing with electrical stimulation and splinting is no better than standing alone for management of ankle plantarflexion contractures in people with traumatic brain injury: a randomised trial

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KEY WORDS

Traumatic brain injury
Contracture
Splinting
Electrical stimulation
Stretch

ABSTRACT

Question: Is a combination of standing, electrical stimulation and splinting more effective than standing alone for the management of ankle contractures after severe brain injury? **Design:** A multi-centre randomised trial with concealed allocation, assessor blinding and intention-to-treat analysis. **Participants:** Thirty-six adults with severe traumatic brain injury and ankle plantarflexion contractures. **Intervention:** All participants underwent a 6-week program. The experimental group received tilt table standing, electrical stimulation and ankle splinting. The control group received tilt table standing alone. **Outcome measures:** The primary outcome was passive ankle dorsiflexion with a 12 Nm torque. Secondary outcomes included: passive dorsiflexion with lower torques (3, 5, 7 and 9 Nm); spasticity; the walking item of the Functional Independence Measure; walking speed; global perceived effect of treatment; and perceived treatment credibility. Outcome measures were taken at baseline (Week 0), end of intervention (Week 6), and follow-up (Week 10). **Results:** The mean between-group differences (95% CI) for passive ankle dorsiflexion at Week 6 and Week 10 were –3 degrees (–8 to 2) and –1 degrees (–6 to 4), respectively, in favour of the control group. There was a small mean reduction of 1 point in spasticity at Week 6 (95% CI 0.1 to 1.8) in favour of the experimental group, but this effect disappeared at Week 10. There were no differences for other secondary outcome measures except the physiotherapists' perceived treatment credibility. **Conclusion:** Tilt table standing with electrical stimulation and splinting is not better than tilt table standing alone for the management of ankle contractures after severe brain injury. **Trial registration:** ACTRN12608000637347. **[Leung J, Harvey LA, Moseley AM, Whiteside B, Simpson M, Stroud K (2014) Standing with electrical stimulation and splinting is no better than standing alone for management of ankle plantarflexion contractures in people with traumatic brain injury: a randomised trial. *Journal of Physiotherapy* 60: 201–208]**

Introduction

Contractures are a common secondary problem after acquired brain injury.[1,2] Traditional treatment for contractures has primarily involved passive stretch. However, a systematic review found that commonly-used passive stretch interventions do not produce clinically worthwhile effects.[3] Two reasons may explain this finding. Firstly, the dose of passive stretch used in the included trials may be insufficient (median dose: 6 hours a day over 30 days). In a randomised controlled trial, 24 hours a day of passive stretch produced a greater effect on joint range than an hour a day of passive stretch (between-group difference of 22 deg, 95% CI 13 to 31), and when the dose of passive stretch was reduced its effect diminished.[4] Secondly, passive stretch focuses primarily on increasing the length of soft tissues but does not address the factors that are believed to contribute to contractures, such as muscle weakness and spasticity. The continuous presence of factors such as muscle weakness and spasticity[1,5] may explain why passive stretch fails to produce a large or sustained effect.

Effective management of contractures may therefore require a combination of a high dose of passive stretch with treatments that address the underlying causes of contracture. A case report has described an intensive program of a high dose of passive stretch combined with motor training for the correction of chronic knee contractures.[6] However, case reports only provide weak evidence. High-quality evidence is needed to verify the effectiveness of this approach.

The purpose of this study was to compare a multimodal treatment program (combining tilt table standing, splinting and electrical stimulation) with a single modality treatment program (tilt table standing alone). People with severe traumatic brain injury were targeted because contractures are common in this clinical population. Tilt table standing and splinting were investigated because both are commonly used, and together they

http://dx.doi.org/10.1016/j.jphys.2014.09.007

increase total stretch dose. Electrical stimulation was used because of its potential therapeutic effects on muscle weakness and spasticity – the two known contributors to contractures. A systematic review[7] and a randomised controlled trial[8] have suggested that electrical stimulation increases strength after acquired brain injury. Five randomised controlled trials have also reported a decrease in spasticity with electrical stimulation.[9–13] In addition, people with contractures often have severe motor impairments and therefore very limited ability to participate in active treatment. Electrical stimulation can elicit muscle contractions in people with little or no ability to voluntarily contract muscles.[14] Hence, it seems to be an appropriate adjunct treatment for contractures in the target population. Therefore, the research question for this study was:

Is a combination of tilt table standing, electrical stimulation and ankle splinting more effective than tilt table standing alone in the treatment of ankle contractures following severe traumatic brain injury?

Method

Design

A multi-centre, assessor-blinded, randomised controlled study was undertaken. All participants were randomly allocated to one of two groups using a blocked randomisation schedule: experimental group (tilt table standing, electrical stimulation and ankle splinting) or control group (tilt table standing only). The random allocation sequence was computer-generated by a person not involved in participant recruitment. Group allocation was concealed using consecutively numbered, sealed, opaque envelopes, which were kept off-site. After baseline assessment, the investigator contacted a person who was not involved in the study to reveal the group allocation. End of intervention and follow-up assessments were conducted at Week 6 and Week 10, respectively.

Participants, therapists and centres

All patients admitted with a traumatic brain injury to one of three metropolitan brain injury rehabilitation units in Sydney (namely: Royal Rehabilitation Centre Sydney, Liverpool Hospital, and Westmead Hospital) were screened between January 2009 and December 2014. They were invited by their physiotherapists to participate in the study if they fulfilled the following criteria: first documented traumatic brain injury; a score of 4 or less on the walking item of Functional Independence Measure (ie, an inability to walk 17 m without physical assistance or 50 m with supervision); presence of an ankle contracture (defined as passive dorsiflexion ankle range of motion less than 5 deg at a torque of 12 Nm, measured using the device specified in the study); ability to participate in the assessment and intervention program; no unstable medical conditions or recent ankle fractures; no other neurological conditions such as spinal cord injury or cerebrovascular disease; anticipated length of stay in hospital of at least 6 weeks; and no botulinum toxin injection to ankle joint within 3 months.

Intervention

Participants in both groups received a 6-week program. The experimental group received 30 minutes of tilt table standing with electrical stimulation to the ankle dorsiflexor muscles, 5 days per week and ankle splinting 12 hours a day, at least 5 days a week. Participants were stood on the tilt table as vertically as they would tolerate. A wedge was placed under the foot to maximise the stretch to the plantarflexor muscles. Electrical stimulation was applied to the dorsiflexor muscles while participants stood on the tilt table. The electrical stimulation was used like this in an attempt to increase the strength of the dorsiflexor muscles in their shortest length, where they are often weakest.[15] Electrical stimulation was applied using a digital neuromuscular stimulation unit[aa]Versports stimulator, Ausmedic Mobility and Rehab, Australia. through a pair of square electrodes (5 cm x 5 cm). The stimulation parameters were: pulse width of 300 μs, frequency of 50 Hz, on time of 15 seconds, off time of 15 seconds, and a ramping-up period of 1.5 seconds. These parameters were selected to optimise any strengthening benefits.[16] The amplitude of electrical stimulation was set to produce maximum tolerable muscle contractions. For participants who were unable to indicate tolerable levels of stimulation, the amplitude of stimulation was set to generate a palpable muscle contraction. Participants were encouraged to voluntarily contract their muscles with the electrical stimulation but most were in post-traumatic amnesia and had severe cognitive and motor deficits, which limited their ability to actively participate in therapy. Physiotherapists administered both tilt table standing and electrical stimulation. The experimental group also wore an ankle splint[bb]Formit ankle resting splint, Ausmedic Mobility and Rehab, Australia. for at least 12 hours a day, 5 days per week. The splints positioned the ankles in maximum tolerable dorsiflexion. Physiotherapists, nursing staff or physiotherapy assistants, as directed by the treating physiotherapists, applied them.

Participants in the control group only received tilt table standing for 30 minutes, three times a week. They did not stand with a wedge under the foot. In short, the intervention programs of the two groups differed in three ways. Firstly, the experimental group received 30 sessions of tilt table standing, while the control group received 18 sessions. Secondly, the experimental group received maximum stretch (by using a wedge where applicable) while standing on the tilt table, while the control group did not receive stretch beyond a plantigrade position. Thirdly, the experimental group received electrical stimulation and ankle splinting, while the control group did not. During the 4-week follow-up period, participants in both groups stood on a tilt table for 30 minutes, three times a week, without a wedge. No electrical stimulation or splinting was administered to the ankle during this time. Over the course of the trial, all participants received usual multidisciplinary rehabilitation provided by the participating units, as appropriate. This consisted of physiotherapy, occupational therapy, speech therapy, recreational therapy and psychological therapy. Physiotherapy included an individualised motor training program, which, where appropriate, included practice of sitting to standing, walking and standing. The usual care for both groups involved positioning of participants' feet in dorsiflexion while seated and lying. No other passive stretch-based interventions were administered to the ankle during the trial. Physiotherapists were assigned to patients on admission (ie, prior to recruitment). Thus, the physiotherapists managed an arbitrary mix of control and experimental participants. Diaries were used to record all interventions. No other passive stretch-based interventions were administered to the ankle. In addition, no botulinum toxin injection was administered to the ankle during the study period. Use of anti-spasticity medication was not mandated by the study protocol, but was recorded. Assessors and medical staff were blinded to group allocation, but treating physiotherapists and participants were not. Success of assessor blinding was monitored.

Outcome measures

There were one primary and nine secondary outcomes. The primary outcome was passive ankle dorsiflexion measured with a torque of 12 Nm with the knee in extension. This was used to reflect the extensibility of the bi-articular ankle plantarflexor muscles. The secondary outcomes were: passive dorsiflexion range at 3, 5, 7 and 9 Nm; spasticity; the walking item of the Functional Independence Measure; walking speed; and physiotherapists' and participants' global perceived effect of treatment and perceived treatment credibility. All outcomes were measured at the beginning of the study (Week 0), end of the intervention (Week 6), and follow-up (Week 10). The outcomes were measured by one

of the five blinded and trained assessors who assessed participants of both groups. The end of intervention and follow-up assessments were conducted at least 24 hours and within 3 days after the last session of intervention.

Passive ankle dorsiflexion was measured using a specially made device, with a standardised procedure.[17] This torque-controlled procedure has a high test-retest reliability (ICC = 0.95). With the participant lying supine and the ankle firmly positioned on the footplate, a standardised torque was applied to the ankle by hanging weights from the rim of the wheel (Figure 1). A pre-stretch was administered by applying a constant ankle dorsiflexion torque of 12 Nm for 3 minutes. Passive ankle dorsiflexion range was then measured with progressively larger torques: 3, 5, 7, 9 and then 12 Nm. Various torques were used for two reasons. Firstly, joint angle could change in response to a treatment for a low torque but not a high torque or vice versa. Secondly, multiple torque-displacement values could provide information about the torque-angle relationship, which cannot be gauged from just one single measure. The angle of the footplate and the inclination of tibia were measured using a digital inclinometer. The procedure was modified for two participants (both in the control group) who were too restless to comply with the standard procedure. Modifications included exclusion of pre-stretch and reversing the order of measurements by starting with the largest torque (12 Nm); this was to ensure that the primary outcome measure (joint angle with 12 Nm) was obtained. The same procedure was used for all of the assessments for these two participants. This modified procedure was also used for a third participant (in the control group) who became too agitated in the follow-up assessment to adhere to the standard procedure. No other changes were made to the outcome measures or protocol since the commencement of the study.

Spasticity of ankle plantarflexor muscles was rated based on the reaction to passive stretch at high speed (not angle of catch) using the 5-point Tardieu Scale.[18] The Tardieu Scale has a high percentage agreement with laboratory measures of spasticity.[19] Participants were instructed to relax during the test in supine with the lower leg supported on a roll. The assessor moved the participant's ankle as fast as possible.

Activity limitation was assessed using the walking item of the Functional Independence Measure and the 10-m walk test (ICC 0.998).[20] The Functional Independent Measure has a high inter-rater reliability for all the motor items, including walking (ICC 0.84 to 0.97).[21] The 10-m walk test was only conducted on participants who could walk without physical assistance. Those who required walking aides on the initial assessment used the same walking aide in all assessments. Participants were asked to walk over a 14-m walkway as fast as possible. The time taken to walk the middle 10 m was used to calculate walking speed. Walking speed was recorded as 0 m/sec in those who could not walk without physical assistance.

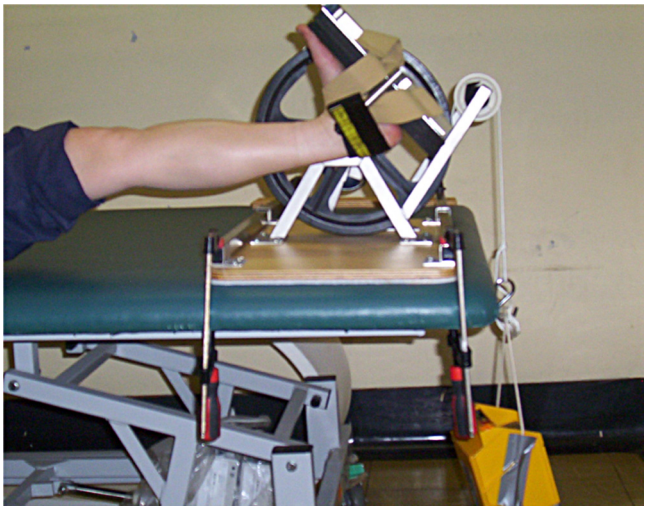

Figure 1. The device used to measure passive ankle dorsiflexion.

The global perceived effect of treatment was rated by the treating physiotherapists and by the participants (or their carers if the participants did not have the capacity to answer the questions). Using separate questionnaires, the treating physiotherapists and participants (or their carers) were initially asked if they thought the ankle was better, the same or worse. They were then asked to rate the improvement or deterioration between 1 (a little better/a little worse) and 6 (a very great deal better/a very great deal worse). These responses were then combined into a single 13-point scale with –6 reflecting a very great deal worse, 0 reflecting no change and +6 reflecting a very great deal better.

At Week 6, the participants (or their carers) and treating physiotherapists evaluated perceived treatment credibility using separate questionnaires. Participants were asked to provide ratings for tolerance to treatment, perceived treatment worth and perceived treatment benefit using 5-point scales. They were also asked if they were willing to continue with the same treatment if it was to be provided (scored as 'yes' or 'no'). Treating physiotherapists were asked to rate their perceived treatment worth and treatment effectiveness using 5-point scales, and indicate if they would recommend the same protocol to the participants if further treatment was needed for the ankle (scored as 'yes' or 'no'). Using open-ended questions, the physiotherapists and participants were also asked to report any issues or concerns about the intervention(s) and how they were managed.

Data analysis

The sample size was calculated a priori based on best estimates. A sample of 36 participants was recruited to provide an 80% probability of detecting a between-group difference of 5 deg for the primary outcome, assuming a standard deviation of 5 deg[22] and a 10% drop-out rate. The minimum worthwhile treatment effect for the primary outcome was set at 5 deg, in line with a number of previous studies on contractures.[23–28]

Linear regression analyses were performed to assess passive dorsiflexion, walking speed and global perceived effect of treatment. One-factor ANOVA was used to analyse categorical data namely the walking item of the Functional Independence Measure and spasticity. Chi-square tests were used to analyse perceived treatment credibility. The significance level was set at < 0.05. Analyses were conducted separately for the end of intervention and follow-up assessments. Missing data were not imputed. All analyses were performed according to 'intention to treat'.

Results

Flow of participants and therapists through the study

A total of 681 patients with traumatic brain injury were screened between January 2009 and December 2013. Ultimately, 36 patients were randomised. The flow of the participants through the study is illustrated in Figure 2. Table 1 outlines the demographics and injury characteristics of the experimental and control groups; the characteristics of the two groups were similar. The median (IQR) length of post-traumatic amnesia was 180 (143 to 217) and 125 (79 to 171) for the experimental group and control group, respectively. This reflects the severe nature of participants' brain injury. Most participants were in post-traumatic amnesia at the time of recruitment, as indicated by the median (IQR) time between injury and baseline assessment. In addition, the majority of the participants could not walk or needed a lot of assistance with walking. Only six participants (those who scored 4 for the walking item of the Functional Independence Measure) could participate in the 10-m walk test at baseline. The number of participants who could participate in the walk test increased to 17 and 18 at end of intervention and follow-up

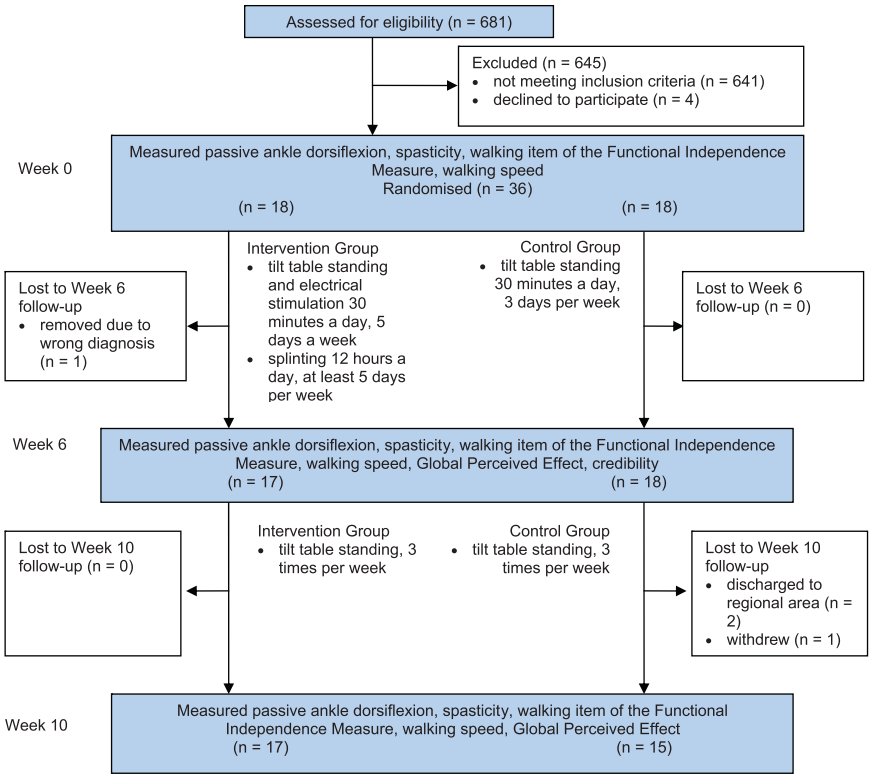

Figure 2. Recruitment and flow of participants through the study.

Table 1
Baseline characteristics of participants.

Participant characteristics	Exp (n = 17)[a]	Con (n = 18)
Age at injury *(yr)*, mean (SD)	38 (14)	38 (15)
Gender, n male (%)	14 (82)	15 (83)
Cause of injury *(motor vehicle accident/fall/assault/other)*, n	10/4/2/1	14/1/2/1
Time from injury to baseline assessment *(d)*, median (IQR)	140 (96 to 226)	83 (66 to 161)
Glasgow Coma Scale score, mean (SD)	5 (3)	5 (3)
Post-traumatic amnesia duration, median (IQR)[b]	180 (115 to 180)	125 (90 to 180)
Anti-spasticity medication, n (%)	8 (47)	7 (39)
FIM scale score for walking, median (IQR)	1 (1 to 1)	1 (1 to 1)
Ankle dorsiflexor strength *(grade 0/1/2/3/4/5)*, n	7/0/6/0/4/0	6/3/1/0/8/0

Exp = experimental group, Con = control group, FIM = Functional Independence Measure.
[a] One participant was withdrawn from the experimental group immediately following recruitment.
[b] Post-traumatic amnesia duration was transcribed as 180 days for the participants with protracted (> 6 months) but undetermined length of post-traumatic amnesia.

assessments, respectively. Those who could not participate in the walk test (that is, unable to walk 14 m without physical assistance) had their walking speed recorded as 0 m/sec in accordance with the study protocol. The data of all participants were entered into the analysis for walking speed, irrespective of whether they participated in the walk test or not. Approximately 14 physiotherapists working in the participating units administered the interventions as per group allocation and provided usual care over the course of the study. All participants (except one) were assessed in hospital. Data collection was completed in April 2014.

Adherence to the study protocol

Adherence to the various aspects of the intervention is summarised in Table 2. The overall adherence was fairly good but there was considerable variability due to a number of factors; for instance, adherence with tilt table standing was reduced in the intervention period due to fainting, storming, fatigue or behavioural issues (10 participants) and tilt table standing was discontinued in the follow-up period due to medical or psychological reasons, or early discharge (three participants). The adherence to electrical stimulation was reduced primarily due to the reduced standing time and not related to any intolerance of electrical stimulation. The adherence to splinting was reduced because of behavioural issues (three participants), poor tolerance (one participant) and skin problems (one participant).

One participant violated the protocol and received botulinum toxin injection for his ankle 4 days into the follow-up period. The use of anti-spasticity medication during the course of the study is summarised in Table 3. Importantly, the doctors prescribing the medications were blinded to participants' group allocation. There

Table 2
Adherence to elements of the study protocol.

Protocol element	Exp (n = 17)		Con (n = 18)	
	Protocol	Actual median (IQR)	Protocol	Actual median (IQR)
Intervention period				
Tilt table standing *(min)*	900	890 (780 to 900)	540	540 (517 to 568)
Electrical stimulation *(min)*	900	870 (800 to 900)	n/a	n/a
Splinting *(hr)*	≥ 360	359 (197 to 436) (n = 16)	n/a	n/a
Follow-up period				
Tilt table standing *(min)*	360	330 (270 to 380)	360	360 (328 to 360) (n = 15)
Timing of assessments				
6-week assessment *(wk)*	6	7 (6 to 8)	6	6 (6 to 7)
10-week assessment *(wk)*	10	10 (10 to 10)	10	10 (10 to 10)

Exp = experimental group, Con = control group, n/a = not applicable.

Table 3
The use of anti-spasticity medication during the course of the study.

	Baseline n (%)		Intervention period n (%)		Follow-up period n (%)	
	Exp (n = 18)	Con (n = 18)	Exp (n = 17)	Con (n = 18)	Exp (n = 17)	Con (n = 15)
On anti-spasticity medication	8 (44)	7 (39)	8 (47)	8 (44)	8 (47)	8 (53)
Increased dose	n/a	n/a	3 (18)	2 (11)	0 (0)	0 (0)
Stopped medication	n/a	n/a	1 (6)	0 (0)	0 (0)	0 (0)
Started medication	n/a	n/a	1 (6)	1 (6)	0 (0)	0 (0)
Decreased dose	n/a	n/a	0 (0)	0 (0)	0 (0)	1 (7)
Changed medication	n/a	n/a	0 (0)	1 (6)	0 (0)	1 (7)

Exp = experimental group, Con = control group, n/a = not applicable.

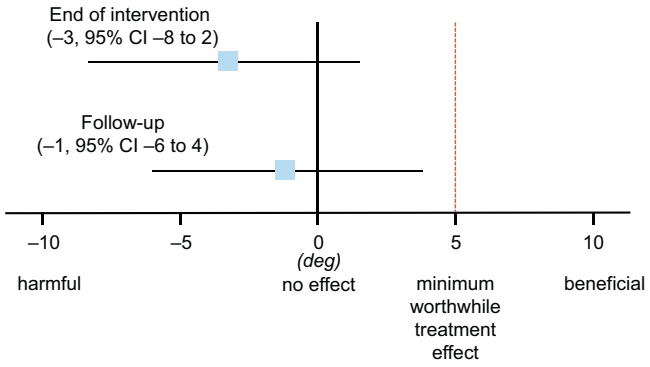

Figure 3. The mean between-group difference (and 95% CI) for passive ankle dorsiflexion at 12 Nm at end of intervention and follow-up. The blue squares represent the mean between-group differences and the horizontal lines represent the 95% CI.

were also minor deviations from the protocol related to the timing of assessments (Table 2). The deviations were due to early discharges, public holidays, medical problems and acute illnesses. The blinding of the assessors was reasonably successful. Assessors were unblinded in two of the end-of-intervention assessments and one of the follow-up assessments. In two of these assessments, a third person, who was otherwise not involved in the study, was asked to take the readings from the dynamometer for the passive ankle range.

Effect of multimodal treatment

The mean between-group differences (95% CI) for passive ankle dorsiflexion with 12 Nm torque at Week 6 and Week 10 were –3 deg (–8 to 2) and –1 deg (–6 to 4), respectively (Figure 3). Both were in favour of the control group (ie, the control group had 3 deg and 1 deg more passive dorsiflexion, on average, compared to the experimental group at Week 6 and Week 10, respectively). However, both effects were less than the pre-specified minimum worthwhile treatment effect of 5 deg. There was a mean reduction in spasticity of 1 point (95% CI 0.1 to 1.8) at Week 6, favouring the experimental group, but this effect disappeared at Week 10. No between-group differences were found for walking speed, the walking item of the Functional Independence Measure, and participants' and physiotherapists' global perceived effect of treatment. All the primary and secondary outcome measures are shown in Tables 4 and 5 (individual participant data are presented in Table 6 in the eAddenda).

Overall, there were no differences between groups for participants' tolerance to treatment, perceived treatment benefit, perceived treatment worth, and willingness to continue with treatment. In contrast, the physiotherapists administering the intervention for the experimental group rated perceived treatment effectiveness and perceived treatment worth higher than the physiotherapists administering the control intervention. They were also twice as likely as the physiotherapists administering the control intervention to recommend the intervention protocol to the participants if further treatment for ankle contracture was indicated (81 versus 39%). Tables 7 and 8 show participants' and physiotherapists' perceived treatment credibility, respectively.

Discussion

This study compared a multimodal treatment program with a single modality treatment program for contracture management. It was conducted because a systematic review has indicated that passive stretch alone is ineffective.[3] It was hypothesised that a program of tilt table standing combined with electrical stimulation and splinting may be more effective than tilt table standing alone for the treatment of contracture. In the present study, electrical stimulation was added because it may improve strength and reduce spasticity, and thus address important contributors to contracture. Splinting and additional sessions of tilt table standing sessions were provided to the experimental group in order to increase the dose of passive stretch. Contrary to expectations, the present study showed that 6 weeks of regular standing on a tilt table combined with electrical stimulation and ankle splinting did not provide added benefits when compared to a less-intensive program of tilt table standing alone, for people with severe traumatic brain injury and ankle contractures. The upper end of the 95% CI, associated with the mean between-group difference of ankle range, was below the pre-specified minimally worthwhile treatment effect of 5 deg. This indicates that the failure to detect a treatment effect was not due to an inadequate sample size. Despite the findings, the physiotherapists who implemented the multimodal program scored treatment effectiveness and worth higher than physiotherapists who implemented the tilt table standing alone. They were also twice as willing to recommend the treatment they provided compared to those who implemented tilt table standing alone. This is possibly a reflection of the physiotherapists' preconceived beliefs and expectations about the multimodal program.

A number of reasons may explain why our study did not demonstrate a treatment effect. Firstly, the control group received some passive stretch (tilt table standing), although in a considerably lower dose than the experimental group. This was done because tilt table standing is often used in people with brain injury for purposes other than stretching. For example, it is used to get them upright and to provide initial training for standing so we could not justify depriving participants in the control group of this intervention. However, the inclusion of tilt table standing for the control group inevitably reduced the treatment contrast between the experimental and control groups, which may have diluted any possible treatment effects of the multimodal program. Secondly, the study recruited participants with severe traumatic brain injury and ankle contractures. These participants often had severe cognitive and behavioural impairments and complex medical issues. These characteristics imposed considerable challenges for the implementation of the treatment program. This reduced adherence might have influenced the outcome.

Electrical stimulation was used in this study to address the contributors to contracture; namely, muscle weakness and spasticity. The feedback from participants and physiotherapists indicated that the use of electrical stimulation was feasible. However, the present study did not find an improvement in joint range. Electrical stimulation was applied for 30 minutes a day, 5 days a week over 6 weeks; this dose may have been insufficient. A trial that used a supramaximal dose of electrical stimulation

Table 4
Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups for passive ankle dorsiflexion at Weeks 0, 6 and 10.

Outcome	Groups						Difference within groups				Difference between groups	
	Week 0		Week 6		Week 10		Week 6 minus Week 0		Week 10 minus Week 0		Week 6 minus Week 0	Week 10 minus Week 0
	Exp (n = 17)	Con (n = 18)	Exp (n = 16)	Con (n = 17)	Exp (n = 16)	Con (n = 15)	Exp	Con	Exp	Con	Exp minus Con	Exp minus Con
Passive ankle dorsiflexion at 12 Nm (*deg*)	−5 (6)	−6 (6)	−5 (6)	−3 (9)	−2 (5)	−3 (7)	−1 (6)	2 (8)	2 (7)	4 (7)	−3 (−8 to 2)	−1 (−6 to 4)
Passive ankle dorsiflexion at 9 Nm (*deg*)	−8 (6)	−8 (6) (n = 16)	−9 (6)	−8 (7) (n = 15)	−7 (5)	−6 (8) (n = 13)	−1 (5)	0 (5)	2 (6)	2 (7)	−1 (−5 to 3)	−1 (−6 to 4)
Passive ankle dorsiflexion at 7 Nm (*deg*)	−11 (6)	−11 (6) (n = 16)	−11 (6)	−10 (8) (n = 15)	−10 (5)	−10 (7) (n = 12)	1 (5)	0 (5)	2 (5)	2 (7)	1 (−3 to 5)	0 (−5 to 5)
Passive ankle dorsiflexion at 5 Nm (*deg*)	−15 (6)	−13 (5) (n = 16)	−15 (6)	−15 (6) (n = 14)	−13 (5)	−14 (8) (n = 12)	1 (6)	−1 (5)	2 (5)	1 (7)	2 (−2 to 6)	1 (−3 to 6)
Passive ankle dorsiflexion at 3 Nm (*deg*)	−17 (7)	−16 (6) (n = 16)	−17 (6)	−17 (7) (n = 14)	−16 (6)	−15 (9) (n = 12)	1 (7)	−1 (6)	1 (6)	1 (9)	2 (−3 to 7)	0 (−6 to 5)

Exp = experimental group, Con = control group, Shaded row = primary outcome.
Note: Passive ankle dorsiflexion data for two participants at the end of intervention (one in exp and one in con) were not included in the analyses because of a technical problem with data collection. The decision to exclude these data was made before analysing the results.
Note: Angle data in the first 6 columns is expressed relative to a neutral position where a negative angle denotes degrees of plantarflexion from neutral.

Table 5
Mean (SD) of groups and mean (95% CI) between-group difference in change for spasticity, walking speed, walking item of the Functional Independence Measure and Global Perceived Effect of treatment at Weeks 0, 6 and 10.

Outcome	Groups						Difference between groups	
	Week 0		Week 6		Week 10		Week 6 minus Week 0	Week 10 minus Week 0
	Exp (n = 17)	Con (n = 18)	Exp (n = 17)	Con (n = 18)	Exp (n = 17)	Con (n = 15)	Exp minus Con	Exp minus Con
Tardieu Scale (*0 to 5*)	2 (1)	1 (1)	2 (1)	3 (1)	3 (1)	2 (1)	−1 (−1.8 to −0.1)	0 (−1.2 to 0.6)
Walking speed *(m/s)*	0.1 (0.2)	0.1 (0.4)	0.3 (0.5)	0.4 (0.5)	0.4 (0.6)	0.4 (0.5)	−0.1 (−0.4 to 0.2)	0 (−0.4 to 0.4)
Functional Independence Measure, walking item *(1 to 7)*	2 (1)	2 (1)	3 (2)	3 (2)	3 (3)	3 (3)	0 (−1.4 to 0.9)	0 (−1.9 to 0.9)
Participants' global perceived effect of treatment *(−6 to 6)* [a]	n/a	n/a	1 (2) (n = 15)	2 (2) (n = 16)	2 (2) (n = 15)	3 (3) (n = 13)	−1 (−3 to 0)	−1 (−3 to 0)
Physiotherapists' global perceived effect of treatment *(−6 to 6)*	n/a	n/a	1 (1)	1 (2)	1 (1) (n = 14)	1 (1)	0 (−1 to 2)	0 (−1 to 1)

Exp = experimental group, Con = control group, n/a = not applicable.
Note: A negative between-group difference reflects a treatment effect in favour of the intervention group for the Tardieu Scale.
[a] 55% (11/31) and 54% (15/28) of the responses were provided by carers on behalf of the participants at the end of intervention assessment and at the follow-up assessment, respectively.

Table 7
Feedback from participants on perceived treatment effectiveness and treatment credibility at Week 6. A total of 55% (11/31) of the questionnaires were answered by carers on behalf of the participants.

Outcome	Groups		Between-group comparison *p*-value
	Int (n = 15)	Con (n = 16)	
Considered the treatment beneficial, n (%)			0.886
yes	9 (60)	10 (63)	
no	6 (40)	6 (37)	
did not answer	0 (0)	0 (0)	
unsure	0 (0)	0 (0)	
Rating for treatment worth, n (%)			0.563
1 highly worthwhile	4 (27)	8 (50)	
2 reasonably worthwhile	6 (40)	6 (37)	
3 not sure	2 (13)	2 (13)	
4 not too worthwhile	1 (7)	0 (0)	
5 definitely not worthwhile at all	0 (0)	0 (0)	
did not answer	2 (13)	0 (0)	
Rating for tolerance, n (%)			0.157
1 comfortable	1 (7)	6 (37)	
2 slightly uncomfortable	6 (40)	7 (44)	
3 moderately uncomfortable	3 (20)	1 (6)	
4 very uncomfortable but still tolerable	4 (26)	2 (13)	
5 intolerable	0 (0)	0 (0)	
did not answer	1 (7)	0 (0)	
Willing to continue the intervention, n (%)			0.583
yes	14 (93)	14 (87)	
no	1 (7)	2 (13)	
did not answer	0 (0)	0 (0)	

Exp = experimental group, Con = control group.

(9 minutes a day over 4 weeks) found a small effect on joint range (5 deg, 95% CI 3 to 8) and spasticity, when compared with a group without electrical stimulation.[22] The participants in the present study with severe traumatic brain injury, however, may have not been able to tolerate supramaximal doses or longer durations of electrical stimulation. In addition, electrical stimulation was applied to the ankle dorsiflexor muscles with the ankle in maximal dorsiflexion. This was done to maximise stretch and to strengthen the dorsiflexor muscles in their inner range, where they are often weakest.[15] The induced muscle contractions were isometric. It is not clear whether different results would have been obtained if electrical stimulation had been applied in a different way or applied to the gastrocnemius muscles instead.

Another possible reason for not finding an effect is that many of the participants (64%) had severe weakness or no muscle activity (Grade 2 or less) in their ankle dorsiflexor muscles at baseline, and many also did not have the cognitive ability to contract their ankle muscles in synchronisation with the electrical stimulation. There is increasing evidence supporting the combination of electrical stimulation with volitional muscle contractions for motor training.[29–37] The potential value of electrical stimulation may be undermined if participants are unable to work voluntarily with the electrical stimulation. Three other trials have investigated electrical stimulation in people with acquired brain injury and severe motor impairments, and the findings of all three were inconclusive.[23,38,39] It is possible that electrical stimulation is not effective for contracture management in people with severe traumatic brain injury. However, these findings may not be generalisable to other clinical conditions or people with less-severe brain injury.

Our study's results indicate that there was no difference between a single modality treatment program of tilt table standing and a multimodal treatment program combining tilt table standing, electrical stimulation and ankle splinting. While it is always tempting to look at within-group changes in trials like this and use the data to conclude that both programs were equally effective (or ineffective), this is not a valid interpretation without a control group that had no intervention. No attempt was made to assess the effectiveness of individual modalities in the present study. The findings, however, did suggest that the addition of splinting was not therapeutic; this is consistent with previous clinical trials on splinting that also failed to demonstrate treatment effects.[27,28,40]

In summary, this study, along with the many others that have preceded it, does not provide a solution to contractures. Tilt table standing, electrical stimulation and ankle splinting were selected because they are commonly used in people with severe brain injury, and their effectiveness when used in combination has never been investigated. In addition, they are amongst the few modalities that can be used in people with severe brain injury who have a limited ability to actively participate in treatment. Despite the failure to demonstrate a treatment effect, the findings of the present study should not deter further research on this topic. Impaired motor control is a main contributor to contractures; thus, treatments that promote activity, such as active movement through range, electromyographically activated electrical stimulation or task-specific motor training, may be worth further investigation. However, most of these interventions rely on some motor and cognitive abilities, which most people with severe brain injury do not have. Therefore, future research for this population may be better directed at combining high dosages of passive stretching with medical interventions such as anti-spasticity medications or botulinum toxin injections.

Table 8
Feedback from physiotherapists on perceived treatment effectiveness and treatment credibility at Week 6.

Outcome	Groups		Between-group comparison *p*-value
	Exp (n = 17)	Con (n = 18)	
Rating for treatment effectiveness, n (%)			0.046
1 very effective	0 (0)	0 (0)	
2 effective	9 (53)	3 (17)	
3 unsure	8 (47)	13 (72)	
4 ineffective	0 (0)	2 (11)	
5 very ineffective	0 (0)	0 (0)	
Rating for treatment worth, n (%)			0.025
1 highly worthwhile	0 (0)	1 (6)	
2 reasonably worthwhile	12 (70)	4 (22)	
3 not sure	4 (24)	7 (39)	
4 not too worthwhile	1 (6)	6 (33)	
5 definitely not worthwhile at all	0 (0)	0 (0)	
Recommended the treatment, n (%)			0.009
yes	14 (82)	7 (39)	
no	3 (28)	11 (61)	

Exp = experimental group, Con = control group.
Note: n = number of responses from physiotherapists, not the number of physiotherapists.

What is already known on this topic: Contracture is common after acquired brain injury. Commonly used passive-stretch interventions do not have clinically worthwhile effects on contracture, perhaps partly because they do not address muscle weakness and spasticity.
What this study adds: This trial assessed whether the effect of regular standing on a tilt table on ankle plantarflexion by contracture in people with brain injury could be improved by adding electrical stimulation to the dorsiflexors and adding splinting at other times. Passive dorsiflexion range was not increased by the additional interventions. An improvement in spasticity occurred but it was small and unsustained.

Footnote:
***eAddenda*:** Table 6 can be found online at doi:10.1016/j.jphys.2014.09.007.
***Ethics approval*:** The study was approved by the ethics committees of the Northern Sydney Central Coast Area Health Service, Royal Rehab, South Western Sydney Area Health Service and Sydney West Area Health Service. Written consent was obtained from all the participants or their legal guardians before data collection began.

Competing interests: Nil.

Source(s) of support: The Rehabilitation and Disability Research Grants of the Royal Rehabilitation Centre Sydney, and the Research Infrastructure Block Grants of the University of Sydney.

Acknowledgements: We thank the staff and participants of the Royal Rehabilitation Centre Sydney, Liverpool Hospital and Westmead Hospital, in particular: Charis Tse, Siobhan Barry, Peter Zhu, Lakshmi Arunachalam, Rajeevan Yoganathan and Shivani Bansal. A special thanks to the Department of the Assistive Technology and Seating of the Royal Rehabilitation Centre Sydney, especially James Puttock, the Senior Technical Officer, for manufacturing the measuring devices.

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