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The effect of exercise of the affected foot in stroke patients – a randomized controlled pilot trial

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Objective: To evaluate the effect of treatment with a portable device called Stimulo on range of motion, muscle strength and spasticity in the ankle joint and its effect on walking ability, balance, activities of daily living (ADL) and health-related quality of life in stroke patients.
Design: A randomized controlled pilot study.
Setting: A research centre.
Subjects: Ambulatory or partly ambulatory chronic stroke patients with remaining spasticity and/or decreased range of motion in the hemiparetic leg/ankle.
Interventions: Standardized and individualized programme including active and passive range of motion of the ankle with a portable device (Stimulo), performed three times a week for 30 min, over a six-week period.
Main measures: Range of motion, muscle strength, spasticity, gait variables, balance, ADL and health-related quality of life.
Results: Eighteen subjects were included in the study with a mean age of 75 years. The compliance rate was 94–99%. There were no significant differences between the groups.
Conclusion: The study showed no significant effect of an ankle-exercise intervention programme with Stimulo. Further studies with a larger sample size are of importance before any further conclusions can be drawn.

Introduction

Hemiparesis is the most common cause of disability after stroke, affecting 70–85% of all poststroke patients.[1] Most stroke survivors improve in motor function, but the degree of recovery from hemiparesis varies considerably and $>50\%$ of patients are left with residual motor deficits.[2]

From 1 to 12 months after a stroke,[3,4] health-related quality of life in stroke patients is lower than in controls, and is still low 1–3 years post stroke.[5,6] The health-related quality of life is strongly correlated with depression[4,5] and functional disability.[3–5]

Arm and leg impairments and disabilities are correlated with handicap situations and leg disability is more strongly associated with handicap than arm disability.[7] Vattanasilp *et al*.[8] reported that 37% of patients suffering from stroke have a decreased passive ankle dorsal extension and 83% of these patients exhibited spasticity in m. gastrocnemius. It has been reported that 19–38%[9,10]

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of stroke patients have spasticity. Muscle weakness is also a common consequence of stroke.[11]

Walking disability after stroke is related to many factors, such as balance,[12] spasticity in the plantar flexors,[13] active ankle dorsal extension,[14] ankle proprioception,[15] and muscle strength and sensation in the lower limb.[16]

Oulelette *et al*.[17] reported that supervised resistance training including knee extension, ankle plantar flexion and dorsal extension three times a week for 12 weeks improved strength, plantar flexion and dorsal extension in the paretic leg and reduced disability in stroke patients. One study has shown that static passive prolonged muscle stretch increased passive dorsal extension.[18] Another study showed that 30 min of both static and dynamic stretching increased passive dorsal extension but had no effect on walking speed.[19] Both studies only examined a short-term effect within an hour after a treatment session.[18,19] Zhang *et al*.[20] developed a non-portable stretching device, which stretches the ankle throughout the range of motion. Patients with neurological disorders evaluating this device have reported an increase of range of motion in the ankle and a decrease of ankle stiffness directly after intervention. No long-term effects have been reported. A recently published study showed that a 20-min single session of isotonic and isokinetic muscle stretch of the calf muscles had no effect on gait.[21]

There seems to be a lack of evidence concerning the effect of range of motion training and muscle strength training on functional ability and activities, which has also been shown in a recent published review.[22]

The aim of the present study was to evaluate the effect of treatment with a newly developed portable stretching device called Stimulo on passive and active ankle work out. Areas evaluated included range of motion, muscle strength, spasticity in the ankle joint and its effect on walking ability, balance, activities of daily living (ADL) and health-related quality of life in stroke patients.

Materials and methods

Subjects

An invitation letter ($n = 85$) was sent consecutively to subjects collected from the stroke register at Karolinska Hospital in Stockholm and subjects with stroke treated at rehabilitation clinics for the elderly in Solna and Sundbyberg, two suburbs outside Stockholm, Sweden. The 18 subjects included (see below) were asked to continue their usual habits of physical activity during the study.

Inclusion criteria were patients suffering from an ischaemic or haemorrhagic stroke in the right or left hemisphere at least one year prior to the study with a remaining spasticity and/or decreased active range of motion in the hemiparetic leg/ankle. Patients with no walking ability were excluded from the study.

Design and settings

The study was approved by the ethics committee at the Karolinska Institute and was carried out as a single-blinded randomized controlled trial in an elderly research centre in Solna. After inclusion, subjects were paired, stratified by age and gender, and randomized into intervention group or control group. A dice was used for randomization, with even numbers assigned subjects to the intervention group and odd numbers to the control group. A physiotherapist performed all assessments, blinded to the group assignments. The success of blinding was evaluated by a questionnaire completed by the assessor after each assessment. The assessor was asked whether she had become aware of group assignment and if so, why.

Procedure

After baseline, the intervention group underwent six weeks of intervention. The first follow-up assessment was conducted directly after the intervention period and the second follow-up was carried out six weeks later. The control group was assessed at baseline and after six weeks (first follow-up) without intervention. After second follow-up, the control group received six weeks of intervention and a final follow-up (third follow-up).

Assessments

Health-related quality of life was evaluated by interviewing the subjects with the Swedish version of Short Form 36 (SF-36).[23,24]

Personal ADL was measured by interviewing the subjects with the Swedish version of the Functional Independence Measure (FIM).[25,26]

Instrumental ADL was measured by interviewing the subjects with the Swedish version of the Instrumental Activity Measure, which is a supplementary instrument to FIM. The instrument consists of eight items (e.g. cooking, cleaning and public transportation), with a seven-step scale, measuring performance and need of assistance. It is an ordinal scale from 0 to 56, where higher scores indicate less dependence.[27]

Walking ability was measured using the 10-m timed walk test (with 1 m for acceleration and deceleration).[28] The test documents habitual and maximum walking speed using normal walking aids. In the habitual walking speed, the total number of steps was documented. The six-minute walk test was also used to document total distance achieved during 6 min using normal walking aids.[29]

Mobility was measured using the Timed Up and Go. The subjects were instructed to rise from an armchair, walk 3 m using normal walking aids, turn, walk back, and sit down again while total time was documented.[30]

Balance was measured using the Romberg's test, semi-tandem stance and tandem stance (also called Sharpened Romberg) standing with feet together for a maximum of 30 s.[31,32]

Range of motion was evaluated by goniometric measurement of active and passive ankle dorsal extension and plantar flexion. The measurements were carried out with the patient lying face up with a straight knee.[33,34] Range of motion was measured in both ankle joints.

Muscle strength was measured by fulfilling the one repetition maximum strength test (i.e. the highest resistance at which one repetition can be successfully completed).[35] The dorsal extension and plantar flexion in the affected limb were examined with the patient lying face up in dorsal extension and lying face down in plantar flexion with a strap fixing the legs to the bunk. After a few warm-ups, a resistance of expected 50% of one repetition maximum was chosen. If the subject was able to perform two repetitions, the weight of resistance was increased until only one repetition could be accomplished.

As resistance, a weight shoe weighing 0.9–3.9 kg (subject's shoe weight added) was strapped to the foot. The weight was applied at the top of the foot and thus, the achieved maximum strength was transformed into newton metres. If maximum repetitions were > 1 at 3.9 kg resistance, a formula was used to calculate estimated one repetition maximum.[36]

Spasticity was measured using the Modified Ashworth Scale, which is a 6-point rating scale used to measure muscle tone, where zero indicates no spasticity.[37] Spasticity was measured in the plantar flexors, knee flexors and knee extensors in both limbs with the patient lying face up.[38,39] The numbers of taps (clonus) in the foot were also documented, after a rapid passive dorsal extension.

Self-report including medical prescriptions and habit of pedicure was obtained. The location of stroke was recorded.

Intervention

Stimulo (Farzaneh Chidopory, Sweden) is a portable device developed to maintain or increase range of motion in the ankle by passive and active dorsal extension and plantar flexion, carried out with the subject lying face up. The device changes from dorsal extension to plantar flexion automatically when maximum range of motion is reached (Figure 1).

The intervention was standardized concerning warming up (passive workout, 5 min), followed by a period of 15–20 min with active and passive workout individualized by muscle strength in the ankle and finally a cooling down period (passive work-out, 5 min).

The subjects were instructed to hold for 10 s in maximum range of motion positions. The active workout was progressed during the intervention period by increased length of the active work period and decrease of the passive work period. The subjects received individual intervention with the Stimulo by a chiropodist for 30 min three times a week for six weeks (18 training sessions). Further information about the intervention programme can be obtained from the corresponding author. After completing intervention, the subjects filled in a questionnaire concerning opinions of the intervention and their self-reported evaluation of the effect(s) of the programme.

Statistical analysis

The statistical analyses were conducted in JMP 5.0.1 (SAS Institute Inc. USA). Student's t-test

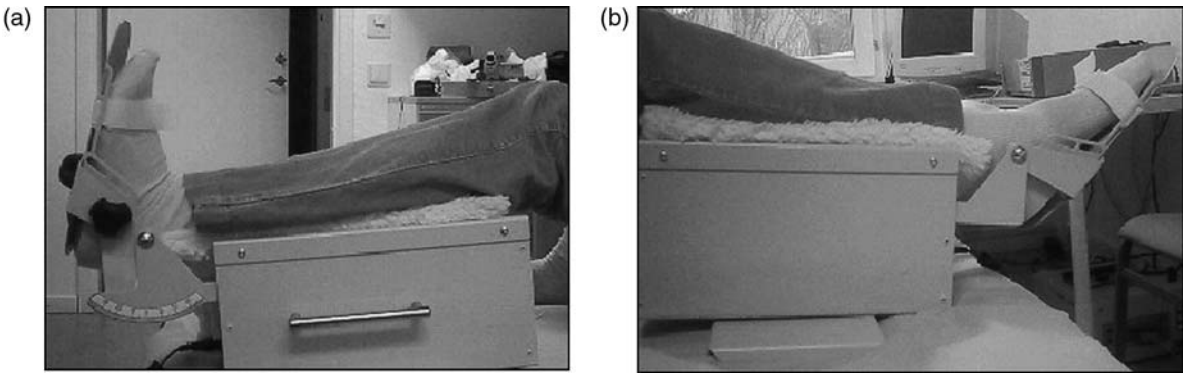

Figure 1 The Stimulo device used in dorsal extension (a) and plantar flexion (b).

was used for continuous data with normal distribution and the Wilcoxon/Kruskal–Wallis test for ordinal data and continuous data with skewed distribution. The analyses were conducted within and between the groups, comparing first follow-up with baseline in both groups. One final analysis was conducted combining the results in the intervention group and the control group before and after the first and second intervention periods, using baseline and first follow-up for the intervention group and second follow-up (as baseline) and third follow-up (as first follow-up) for the control group. A correlation analysis (Spearman's rho) was conducted to analyse whether changes between baseline and first follow-up in muscle strength and range of motion were related to changes in different walking and mobility variables.

Results

Subjects were consecutively invited until a group of at least 20 subjects accepted participation. Two subjects did not fulfil the inclusion criteria.

The remaining 18 subjects were randomized to either intervention group or control group. Table 1 shows baseline characteristics of the participants

Table 1 Baseline characteristics of the subjects

	Whole ($n = 18$)	IG ($n = 9$)	CG ($n = 9$)
Gender (women/men)	6/12	2/7	3/6
Mean age, years (mean (SD))	75.1 (6.9)	74.9 (8.7)	75.3 (4.9)
Stroke in right hemisphere (n)	9	6	3
Stroke in left hemisphere (n)	9	3	6
Type of stroke (n)			
Haemorrhage	4	1	3
Infarction	14	8	6
Time since first ever stroke, months (mean (SD))	48.7 (19.6)	42.6 (18.2)	54.9 (20)
Continuous drug prescriptions (mean (SD))	7 (3)	7 (3)	7 (3)
Walking aids (n)			
No aid	1	0	1
Stick	1	1	0
Walker	9	4	5
Walker + wheelchair	7	4	3
Regular pedicure (n)	11	5	6

SD, standard deviation; IG, intervention group; CG, control group.

and Figure 2 shows the subject participation throughout the study. Seventeen subjects completed the intervention period and the first follow-up. One subject in the intervention group refused to take part in the intervention due to transportation problems. All subjects in the control

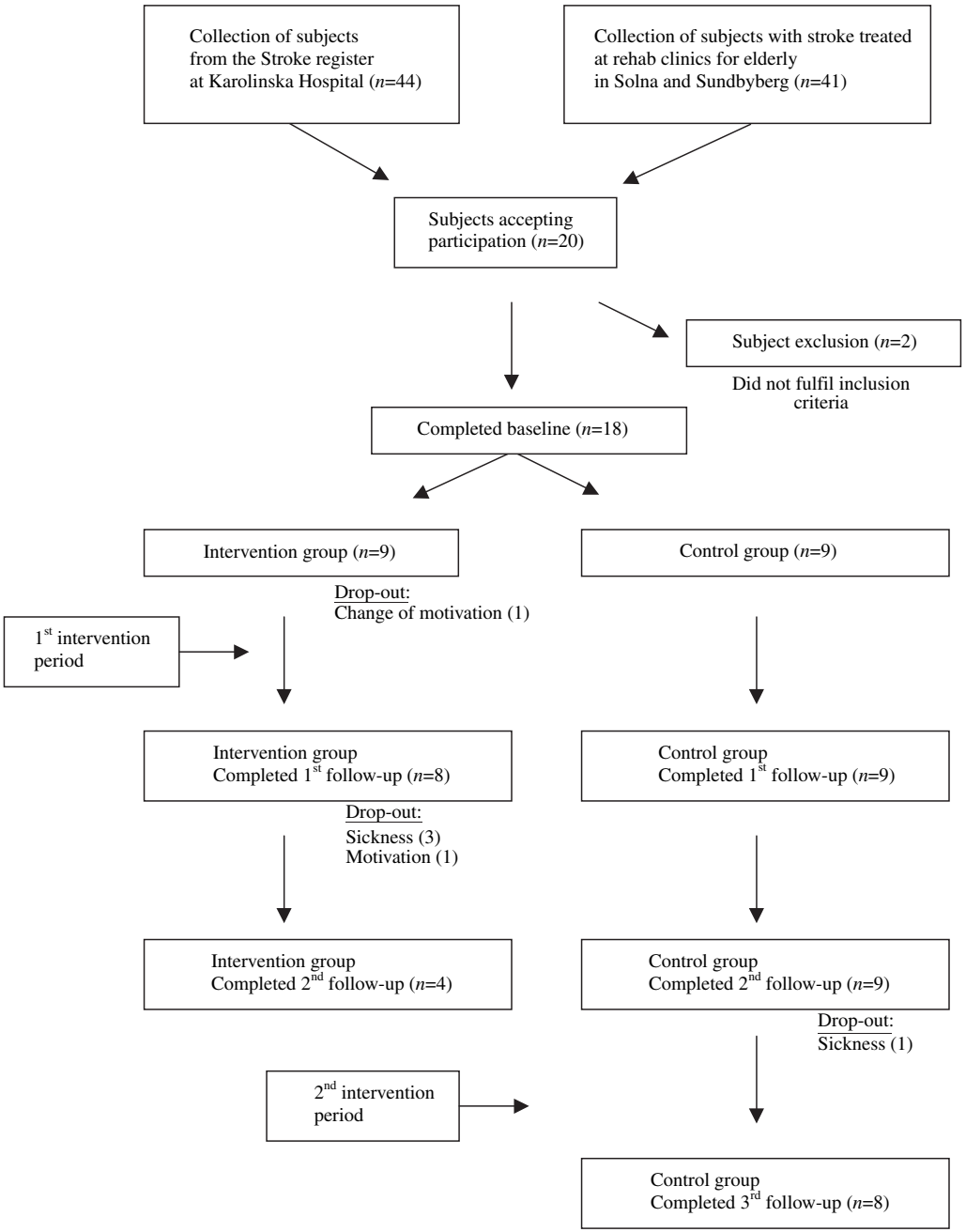

Figure 2 Flowchart showing exclusion and drop-out from the study.

group completed the second follow-up, but only four in the intervention group, therefore the results of the second follow-up will not be presented.

The compliance rate (completed sessions) of the participants was 99% (94–100) ($n = 8$) for the intervention group and 94% (67–100) ($n = 8$) for the control group during the first and second intervention periods, respectively.

The assessor became aware of group assignment for 25% of the subjects during first follow-up. She worked in the same building where the research centre was located, and saw some of the subjects coming and going during the intervention programme. A few subjects in the intervention group told her that they had participated in the intervention programme during first follow-up.

Table 2 shows the results of health-related quality of life at baseline and first follow-up. The groups were not comparable at baseline in four of the eight subscales (role physical, general health, vitality, social functioning). At first follow-up the intervention group scored significantly better in the subscale social functioning than the control group.

Table 3 shows the results of the functional performance tests at baseline and first follow-up as well as the mean of the subjects' differences between baseline and first follow-up for the intervention group and the control group respectively and the mean difference between the two groups including confidence intervals. The groups were comparable at baseline. The subjects in the control group took significantly fewer steps during the 10-m habitual walk compared with the intervention group at first follow-up in comparison with baseline. There were no other significant differences within or between the groups.

Concerning the analysis of spasticity measured by the Modified Ashworth Scale, the intervention group had a median score of 1.5 (0–3), 1 (0–1.5) and 0 (0–2) in plantar flexion, knee flexion and knee extension respectively at baseline and 1st follow-up. The control group had a median score of 1 (0–3), 1 (0–2) and 1 (0–1.5) in plantar flexion, knee flexion and knee extension respectively at baseline and 1 (0–3), 1 (0–1.5) and 1 (0–2) at first follow-up. Concerning foot clonus, the intervention group had a median score of 0 (0–5) at baseline and first follow-up and the control group 0 (0–4) at baseline and 0 (0–6) at first follow-up. There were no significant differences between or within the groups.

When combining the results of the intervention group and control group before and after the first and second intervention periods, there were no significant changes.

When correlating the mean difference at baseline and first follow-up in range of motion and one repetition maximum with the mean difference between baseline and first follow-up in habitual and maximal walking speed, Timed Up and Go and six-minute walk test, we found significant correlations in the following three variable pairs: one repetition maximum plantar flexion/maximal gait speed ($r = 0.85$), range of motion plantar flexion/maximal walking speed ($r = 0.89$) and one repetition maximum dorsal extension/Timed Up and Go ($r = 0.55$).

Table 2 Health-related quality of life (SF-36) at baseline and follow-up for the intervention group (IG) and the control group (CG)

	Baseline		First follow-up	
	IG ($n = 9$)	CG ($n = 9$)	IG ($n = 8$)	CG ($n = 9$)
SF-36 (median (q1–q3))				
Physical functioning	10 (5–30)	20 (15–35)	18 (4–28)	20 (15–25)
Role-physical	25 (0–50)	100 (50–100)*	50 (19–81)	75 (75–100)
Bodily pain	61 (41–100)	62 (61–84)	84 (59–100)	72 (62–72)
General health	45 (37–50)	67 (52–82)*	38 (28–46)	47 (45–77)
Vitality	45 (35–60)	70 (60–80)*	43 (38–50)	55 (35–75)
Social functioning	63 (50–75)	100 (100–100)*	94 (34–100)*	88 (63–100)
Role-emotional	67 (33–100)	100 (67–100)	67 (58–75)	100 (33–100)
Mental health	60 (48–68)	84 (76–96)	64 (48–87)	76 (64–92)

* $P < 0.05$.

Table 3 Results of the functional performance tests at baseline and follow-up in the intervention group (IG) and the control group (CG) as well as the difference between baseline (B) and first follow-up (F1) showed as mean for each group. Dif-mean shows the difference between the IG and CG with 95% confidence interval (CI)

	Baseline		1st Follow-up		Dif B-F1	Dif B-F1	Dif-mean
	IG ($n=9$)	CG ($n=9$)	IG ($n=8$)	CG ($n=9$)	Mean IG	Mean CG	(95% CI)
ADL, points (median (q1–q3))							
Personal	109 (100–115)	107 (103–116)	107 (99–113)	112 (105–114)	−0.6	1.9	−2.5 (−8.5 , 8.5)
Instrumental	20 (14–36)	26 (20–35)	21 (18–39)	28 (15–40)	3	−0.4	3.4 (−7.6 , 8.4)
Balance, (mean (SD))							
Romberg	17 (6)	17 (15)	16 (14)	16 (15)	1.3	−1.6	2.9 (−4.1 , −3)
Semi-tandem	21 (13)	23 (13)	10 (13)	11 (14)	−10	−11.9	1.9 (−17.7 , 13.9)
Tandem	2 (6)	1 (1)	1 (5)	0 (1)	−1	−0.2	−0.8 (−0.9 , −0.7)
Timed Up and Go, s (mean (SD))	25 (12) $n=8$	47 (45) $n=8$	23 (9) $n=7$	44 (40)	−3	−10	7 (−10 , 10)
6-minute walk, m (mean (SD))	180 (71) $n=6$	234 (103) $n=6$	215 (72) $n=6$	256 (111) $n=6$	46.4	21.8	24.6 (−47.7 , 96.8)
Walking speed, m/s (mean (SD))							
Habitual	0.4 (0.2)	0.4 (0,3)	0.5 (0.2) $n=7$	0.5 (0.3) $n=8$	0	0.08	−0.08 (−0.2 , 0.04)
Maximal	0.7 (0.3) $n=8$	1.0 (0.4) $n=6$	0.7 (0.3) $n=7$	0.9 (0.4) $n=7$	−0.029	0.014	−0.04 (−0.22 , 0.14)
Number of steps (mean (SD))	28 (9) $n=8$	44 (28)	30 (10) $n=7$	33* (16) $n=8$	2.1	−3.6	5.7* (0.7 , 10.7)
One repetition maximum, N m (mean (SD))							
Dorsal extension	15 (10)	14 (12)	16 (9)	13 (10)	1	−0.89	1.89 (−3.4 , 7.1)
Plantar flexion	24 (5) $n=5$	13 (10) $n=6$	27 (8) $n=4$	12 (11) $n=5$	2.3	1	1.3 (−7.2 , 9.7)
Range of motion, degrees (mean (SD))							
Passive dorsal extension	−1 (9)	−8 (14)	−1 (9)	−7 (13)	1.25	1.1	0.14 (−2.9 , 3.1)
Active dorsal extension	−4 (9) $n=8$	−3 (6) $n=7$	−1 (9) $n=7$	−2 (5) $n=7$	3.6	0.7	2.9 (−2 , 7.7)
Passive plantar flexion	37 (12)	34 (8)	32 (12)	33 (8)	−1.3	−0.6	−0.7 (−6.7 , 5.3)
Active plantar flexion	32 (13) $n=8$	33 (9) $n=6$	31 (12) $n=7$	33 (9) $n=6$	−14	0	−1.4 (−9 , 6.1)

*$P<0.05$,
SD, standard deviation.

Subjective improvements were reported by 15 of 16 subjects (94%) after the intervention programme in one or several variables, such as increased range of motion, muscle strength, walking (speed and steadiness) and/or balance. One subject reported no effect.

Discussion

The study aimed at analysing the effect(s) of a six-week individually targeted, intense training programme of active and passive range of motion in the ankle joint in poststroke patients using a newly developed training device. We used a battery of outcome variables including subjective assessment, health-related quality of life, 16 physical performance tests and spasticity.

Two significant changes were obtained during the statistical analysis concerning the social functioning subscale of SF-36 in favour of the intervention group and number of steps in favour of the control group. The improvement of these outcome measures in the two groups may be explained by a familiarization with the different tests and/or might have been affected by fluctuating daily physical shape. Also, using many different outcome variables may lead to a random statistical significance for one of the variables.[40]

Compared with the intervention group, the control group had significantly higher median score in four of the eight subscales of SF-36 at baseline and thus the groups were not comparable at baseline for these variables. The significant difference in one of the subscales in favour of the intervention group is difficult to interpret; it could have been a specific treatment effect or an effect of the friendly treatment atmosphere around the chiropodist and/or a possible change in daily routines.

The subjective improvements stated by the subjects are difficult to interpret since this could not be verified by the objective measurements. It could have been an effect of the friendly treatment situation or perhaps a lack of sensitivity in the chosen assessments variables. However, in a clinical setting it is of importance to consider both subjective and objective effects in the evaluation of different treatment situations.

The combined intervention group did not show any significant improvements in functional performance. However, improvements in range of motion and one repetition maximum correlated significantly with improvements in maximal walking speed and Timed Up and Go. The reason for assessing ADL, walking ability and balance was to see if an intervention on the body function level had any effect on the activity level.[41] The significant correlations may be an effect of this. However, this must be interpreted with caution, since walking performance alone is affected by range of motion and muscle strength. The result may therefore not be an effect of treatment alone.

An important limitation of this pilot study is that we were not able to calculate the statistical power beforehand. The reason for this is that we did not know the potential effect of the intervention device regarding the various outcome variables. Table 3 shows the difference between the intervention group and the control group and the confidence intervals for the mean values (difmean). After completion of the study, we can conclude that the sample size was not sufficient to detect significant changes between the groups. Only four subjects remained in the intervention group at second follow-up, therefore a statistical analysis was not appropriate.

The heterogeneity of the participants can be seen as another limitation from a statistical point of view, but on the other hand this reflects the heterogeneous population in a clinical setting. One way of dealing with this in the future would be to use baseline values as a covariate in the analyses. Another way of dealing with this problem would be to alter the inclusion criteria: maybe this type of training is only effective for stroke patients with a certain degree of reduction in range of motion and muscle strength. Further studies should target this specific population.

Range of motion in the ankle joint was measured with an extended knee. It should have been measured with a flexed knee since the intervention programme was conducted with a flexed knee. However, the ability to perform dorsal extension of the ankle with an extended knee is of importance for preparing the stance phase during the gait cycle and with a flexed knee during the swing phase. Perhaps the exercises would have been more effective if they had been conducted with both an

Clinical messages

- The evaluated device is portable and feasible to provide assistance to stroke patients with disabilities.
- The intervention programme was well received by the subjects (compliance rate 94–99%).
- Further studies with a larger sample size are of importance to find subjects that will benefit the most from this type of intervention.

extended and a flexed knee. Muscle strength was measured with a weight shoe, with a maximum weight of 3.9 kg. Several of the patients exceeded this weight with more than one repetition and therefore we were forced to use a formula to estimate one repetition maximum. This method is not as accurate as the 'real' one repetition, which may have made the results uncertain. To measure one repetition maximum plantar flexion, the subjects had to lie face down. Several of the subjects therefore could not perform this assessment.

The intensity of the training (30 min, three times a week for six weeks) may have inhibited several subjects from participating. The programme was free of charge, but the subjects had to pay for transportation to and from the research centre, which may also have been a reason for not participating.

Since the training device is newly developed and not previously tested, the optimal type and intensity of training must be addressed in future studies. Maybe the active workout period should be prolonged and, as has been discussed above, perhaps a combination of workout with flexed and extended knee is more optimal for stroke patients. Kautz and Patten[42] have shown that symmetric exercises with both the paretic and the non-paretic leg improved results during a pedalling manoeuvre. This information may also be of importance in designing further studies.

The training device we used has not been tested previously. One advantage of the device used in the present study is that it is portable and feasible to use in a rehabilitation setting for stroke patients. It would also be interesting to test the device in a variety of clinical settings, such as in an orthopaedic unit after a severe foot fracture or for healing of skin ulcers on the legs or feet.

Before any further conclusions can be drawn, the study should be repeated using a more targeted group of stroke patients with substantial reduction of muscle strength and range of motion in the affected leg. The results in the present study can provide some information regarding potential treatment effect over time and thus be instrumental in power calculations to determine an adequate sample size.

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Competing interest

There is no conflict of interest for any of the authors. Frida Söderblom lent us the device for free and followed our instructions during the intervention programme but has not been involved in the design of the study or in writing this report. She developed the device in co-operation with an engineer and owns the company Farzaneh Chidopory.

Authors' contributions

The first and last writers (ER, GA) were involved in the design of the study. ER was involved in monitoring the process of the study. SE was involved in all the assessments and in writing the Background and Methods. Both ER and SE were in charge of the design of the intervention but the actual intervention was conducted by the chiropodist Frida Söderblom. ER processed and analysed the data and was involved in writing the Results and Discussion. GA supervised and commented on the writing and analyses of the article.

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