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A double-blind randomized controlled trial

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External focus and balance post-stroke

Are the effects of internal focus instructions different from external

focus instructions given during balance training in stroke patients? A

double-blind randomised controlled trial

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Abstract

Objective: This study aimed to assess if external focus instructions result in greater improvements in motor skill and automaticity compared to internal focus instructions in stroke patients.

Design: Double-blind randomised controlled trial.

Setting: Inpatient stroke rehabilitation unit.

Subjects: Sixty-three stroke patients ($Mean_{age} = 59.6 \pm 10.7$ years; $Mean_{days \text{ since stroke}} = 28.5 \pm 16.6$; $Median_{Functional Ambulation Categories} = 4$).

Interventions: Patients were randomly assigned to an internal (N=31) or external (N=32) focus instruction group. Both groups practiced a balance board stabilization task, three times per week, for three weeks. Balance performance was assessed at baseline, and after one and three weeks of practice.

Main measures: Primary outcome was the threshold stiffness (Nm/radian) at which patients could stay balanced. Secondary outcomes were patient's sway (root-mean-square error in degrees) at the baseline threshold stiffness under single- and dual-task conditions, and their performance on the Timed-up-and-Go and Utrecht Scale for Evaluation of Rehabilitation. *Results:* Both groups achieved similar improvements in threshold stiffness (Δ =27.1±21.1 Nm/radian), and single- (Δ =1.8±2.3° root-mean-square error) and dual-task sway (Δ =1.7±2.1° root-mean-square error) after three weeks of practice. No differences were found in improvements in clinical tests of balance and mobility. Patients with comparatively good balance and sensory function, and low attention capacity showed greatest improvements with external focus instructions.

Conclusions: External focus instructions did not result in greater improvement in balance skill in stroke patients compared to internal focus instructions. Results suggest that tailoring instructions to the individual stroke patient may result in optimal improvements in motor skill.

Key Words: Stroke; Randomised Controlled Trial; External Focus of Attention;

Rehabilitation; Motor Skill; Learning

Introduction

Reacquiring motor skills is a challenging and protracted process for patients after stroke. Many patients suffer from cognitive and language deficits.^{1–3} It is therefore pertinent that a therapist uses instructions that are concise, easy to process, but still sufficiently meaningful to help the patient improve motor performance. Recent studies in healthy adults suggest that this may be best achieved with instructions that direct attention 'externally', toward the desired movement outcome. External focus instructions are presumably less cognitively demanding than 'internal' focus instructions, which direct attention toward movement execution itself. Consequently, external focus instructions have been found to result in superior^{4–9} and more automatic^{10–12} motor skill in healthy adults and elderly.

Physical therapists increasingly use external focus strategies when treating stroke patients.¹³ However, it is unknown if external focus instructions are effective for enhancing motor skill acquisition in this patient population. To date, the few studies available have solely investigated the *immediate* effects of attentional focus on motor performance, and with mixed results.^{14–17} Only one randomised controlled trial has studied the effects of a 4-week intervention on arm function in chronic stroke patients, but it did not find any differences between groups.¹⁸

Individual patient characteristics may be important to consider when deciding on how to instruct patients. This is particularly true for therapists working in rehabilitation, given the large heterogeneity in the clinical presentation of stroke. This is supported by studies suggesting that external focus instructions could be especially effective for patients with good motor and sensory functioning, poor cognitive capacities, and weak conscious control preferences. 13,16,17

Our aim was to conduct a double-blind randomised controlled trial to assess if external focus instructions result in greater improvements in motor skill and automaticity compared to internal focus instructions in patients after stroke. We hypothesized that patients who practice with external focus instructions would achieve greater improvements in motor skill and automaticity compared to patients who practice with internal focus instructions.

In addition, we explored whether specific patient characteristics influenced the relative efficacy of internal and external instructions. We hypothesized that external instructions would be more efficacious compared to internal instructions for patients with high motor and sensory functioning, low cognitive capacity, and weak conscious control inclination.

Methods

Protocol registration

The study protocol of this double-blind randomised controlled trial was approved by the medical ethical committee of the VU Medical Center in Amsterdam (ID: 2015.354) and preregistered in the Dutch CCMO-register (NL54560.029.15).

Setting, participant recruitment and selection

Patients with stroke who were receiving inpatient care in rehabilitation centre Heliomare in Wijk aan Zee, The Netherlands were recruited between March 2016 and February 2017. At admission, the rehabilitation physician informed possibly eligible stroke patients about the study in writing and verbally, and invited them to participate. Patients were deemed possibly eligible if they had some degree of walking ability, and seemed able to follow instructions. More specifically, patients were recruited if they suffered a first-ever or recurrent stroke <6 months ago, had a Functional Ambulation Categories score >2, were able to stand independently >1 minute, were able to understand instructions and cooperate with neuropsychological assessment, had no other central nervous system or orthopedic impairments, and had no uncorrected visual or hearing impairment. Patients who were not able to follow instructions, or were not functionally ambulant (Functional Ambulation Categories score ≤ 2) at admission, were monitored throughout their stay. When they achieved Functional Ambulation Categories scores >2, their eligibility was further assessed. All patients provided written informed consent prior to inclusion.

Materials and measures

After inclusion, the following demographic information was collected: General characteristics (age, sex, body weight and height), stroke characteristics (recurrent stroke (yes/no), days since

stroke and since admission to rehabilitation centre, stroke aetiology and subtype), ¹⁹ general functioning (Utrecht Scale for Evaluation of Rehabilitation), ²⁰ co-morbidities using the Charlson Cormorbidity Index, ²¹ motor functioning (Functional Ambulation Categories, ²²Berg Balance Scale, ²³ Ten Meter Walk-Test; ²⁴ Timed-up-and-Go), ²⁵ cognition (education, ²⁶ attention (D2-attention test), ²⁷ working memory (Digit-Symbol Substitution Test), ²⁸ executive functioning (Color-Trails), ²⁹ presence of aphasia/neglect), sensory functioning (Revised Nottingham Sensory Assessment – lower extremities), ³⁰ the degree to which patients use conscious control of movement in daily life (Movement-Specific Reinvestment Scale), ³¹ and additional hours per week of physical-, occupational-, and sports-therapy received during the intervention period.

A custom-made, validated balance board task³² was used to test patients' balance performance, and also for the interventions (Figure 1). This balance board task taxes mediolateral balance control, which is often impaired after stroke.^{33–35} Patients' goal is to stand as still as possible on the balance board, for 30 seconds and without touching the handrail surrounding the board. Task difficulty can be manipulated by adjustment of the board's rotational stiffness (0-220 Nm/rad). All patients wore a harness to ensure their safety.

Figure 1 here

We used a modified staircase procedure^{36,37} to determine the threshold stiffness (Nm/rad) at which patients were just able to maintain balance – i.e., keep board deviations below 2.5° for 70% of the trial. With this procedure, task difficulty is adjusted on a trial-to-trial basis, based on pre-specified criteria. Please see Brouwer et al. for the full test protocol.³² Patients only received unfocused instructions ("stand as still as possible"). Lower threshold stiffness values indicate better balance performance. The rotational stiffness assessment has excellent test-

retest reliability (ICC=0.87) and construct validity (r=-0.56 with Berg Balance Scale), and a minimum detectable change of 3.20 Nm/rad on group level.³²

Next, we measured patients' sway at their baseline threshold stiffness in single-task (as performance measure) and dual-task conditions (as automaticity measure). Sway was defined as the root-mean-square error deviation around the board's average position (degrees). Lower values indicate less sway and, hence, better performance. Patients performed 2 single- and 2 dual-task trials, in the following order: single-task—dual-task—dual-task—single-task. The dual-task was a tone-counting task. 11,38 Low (400 Hz) and high (1000 Hz) tones were presented randomly at 1.5-second intervals in a 1:2 ratio. Patients had to respond as quickly and accurately as possible by saying "yes" whenever a high tone was played, and reported the number of high tones after each 30-s trial. 17 Patients performed two single-task tone-counting trials to determine baseline single-task performance. After the balance board measurements, patients' movement-related knowledge was assessed. They verbally described all rules and strategies they had used to perform the balance task. This assessment serves as an extra check to determine the degree to which patients' balance performance relied on conscious motor control; a larger number of rules indicates greater reliance on conscious control. 11,39

To evaluate the clinically relevant benefits of the interventions, we additionally assessed patients' scores on the Timed-up-and-Go ²⁵in single- and dual-task (tone-counting) conditions and on the Utrecht Scale for Evaluation of Rehabilitation-mobility subscale.²⁰

Randomization and blinding

Baseline measurements were performed before randomisation took place. Hence, baseline assessors were blinded to group allocation. Patients were randomly allocated to the external or internal group by an independent researcher (MW) at a remote site who was blinded to the patient at randomisation, except for the variables for which stratification was performed. The

researcher was otherwise not involved in the trial, nor in patient care. The primary investigator (EK) notified the independent researcher when a new patient had completed the baseline assessment. The independent researcher then used random number generator software (https://www.random.org) to block-randomise patients to the internal or external group (blocks of 4, allocation ratio 1:1; both only known to the independent researcher). Patients were stratified according to lesion location (sub- vs. supratentatorial) and baseline threshold stiffness (>60 vs. <60 Nm/rad). Group allocation was shared with the investigator (EK) who provided the intervention but not with the patient or outcome assessors (MV, RP), to minimize the risk of performance, detection and attrition bias.

Interventions

Patients in both groups practiced the balance board task for three weeks, three times per week, with 15 single-task trials per session. In the first practice session, the baseline threshold stiffness was used in the first block of five trials. Depending on patients' average performance (Table 1), stiffness was either increased (+20% Nm/rad), maintained, or decreased (-20% Nm/rad) in the next block, to ensure that task difficulty remained challenging throughout practice. Before each trial, the external focus group was instructed to "focus on the board, and keep the board as still as possible", while the internal group was instructed to "focus on your feet, and keep your feet as still as possible".

*** Table 1 here ***

After each session, we checked adherence. Patients rated (1) the effort needed to focus as instructed, (2) the effort needed to maintain the instructed focus throughout the trial, and (3) the effectiveness of the instructed focus, by putting a cross on a horizontal l0cm-line (0 cm="very little/effective"; 10 cm="very much/completely ineffective"). 40 Scores below 5.0 cm indicate

that patients were able to adhere to instructions, and found these to be more helpful than harmful for their performance.

Outcome assessments

Blinded assessors (MV, RP) performed outcome assessments after one and three weeks of practice. Both followed an identical procedure as the baseline assessment, except that the Timed-up-and-Go and Utrecht Scale for Evaluation of Rehabilitation were re-assessed after 3 weeks only. Patients were explicitly instructed not to tell which instructions they had received during practice.

The primary outcome measure was patients' individual threshold rotational stiffness.

Secondary outcome measures were patients' sway at their baseline threshold stiffness in single-task and dual-task conditions, and their scores on the Timed-up-and-Go and Utrecht Scale for Evaluation of Rehabilitation.

Data processing

Potentiometer data and verbal responses on the tone-counting task were sampled at 1000 Hz using LabVIEW (National Instruments; Austin; Texas), and analysed with Matlab (Mathworks, Natick MA, USA). The balance board's potentiometer data was filtered with a bidirectional, low-pass (8Hz) Butterworth filter. We used non-linear regression to determine the patients' individual threshold stiffness (see Brouwer et al. for details).³² To determine single- and dual-task sway, we calculated the root-mean-square error of board deviations (in degrees) per trial. For the tone-counting task, we calculated reaction time (ms), and response and counting accuracy (%) per trial. These were collapsed in a composite score (Equation 1).⁴¹ Tone-counting dual-task performance was operationalized by calculating dual-task costs (DTCs; Equation 2).⁴² Positive DTC indicates performance deterioration in dual-task versus single-task conditions.

Tone Counting Performance =
$$\frac{Mean\ Accuracy}{Reaction\ Time} x\ 100\%\ [1]$$

$$DTC = \frac{Single\ Task - Dual\ Task}{Single\ Task} x\ 100\%\ [2]$$

Patient's self-reported verbal rules were transcribed verbatim and scored offline (EK) – only movement-related rules were scored. If conditions were measured twice (sway, tone-counting), values were averaged.

Sample size calculations & Statistics

Power analysis (G*power) showed a sample size of 52 to be sufficient to detect a small-to-moderate effect (f=.20), based on a repeated measures ANOVA (within-between interaction), alpha of .05, beta of .80, 2 groups, and r of 0.5. Expecting a drop-out of 10-15%, 60 patients (30/group) were needed.

All data were analysed with SPSS version 20.0. Patient characteristics were described with their appropriate central estimate and measures of dispersion, and were compared between groups to check whether randomization was successful.

Generalized Estimating Equations (GEEs) were used to compare learning effectiveness between groups. We used an autoregressive correlation matrix to define this dependency. First, we used GEE to model the association between the primary outcome, threshold stiffness, and the predictors group (external vs. internal), time (Baseline, 1 week, 3 weeks), and their interaction. Learning differences were considered present in case of significant group by time interaction. Similar GEEs were used for the analysis of the secondary outcomes, single- and dual-task sway. We a-priori decided to add the covariate "handrail support" to both sway analyses, as this factor likely influences sway. Similarly, tone-counting dual-task costs served as covariate in the dual-task sway analysis, to correct for any task-

prioritization differences. Finally, we conducted GEEs (predictors group, time(baseline – 3 weeks follow-up), interaction) on Utrecht Scale for Evaluation of Rehabilitation–mobility subscale and single- and dual-task Timed-up-and-Go. Again, tone-counting dual-task costs were added to the dual-task analysis. For all GEE-analyses, Holm-Bonferroni t-tests followed up significant effects. ⁴³ For these post-hoc t-tests, we presented the adjusted mean differences between groups or test sessions. Cohen's *d* served as measure of effect size.

We performed per-protocol analyses, and additional intention-to-treat analyses to determine whether attrition influenced results. For intention-to-treat, missing cases were imputed based on the overall median improvement in the respective outcome measures. We assumed that drop-outs would show similar improvements as the other patients. Therefore, we estimated the median percentage improvement per outcome measure, and used these to estimate patients' performance on the missing test sessions.

We a-priori decided to investigate whether cognition (Color-Trails, Digit-Symbol Substitution Test, D2-attention test), motor capacity (Berg Balance Scale), conscious control inclination (Movement-Specific Reinvestment Scale), and sensory functioning (Revised Nottingham Sensory Assessment – lower extremities) had a different effect on learning in the external group than in the internal group. Variables were submitted to the respective GEE-models of stiffness, single- and dual-task sway in turn. Variables were labeled 'effect modifiers' when the group x time x 'variable' term was significant. To assess how an effect modifier influenced learning per group, separate linear regression analyses were run with absolute learning improvements (3 weeks – Baseline) as dependent variable. Effect modification analyses were restricted to per-protocol analyses of the full three-week learning period.

Results

Sixty-three patients were included. Figure 2 shows the flow of the study. A total of 51 patients completed the whole intervention and assessment after 3 weeks.

Figure 2 here

Table 2 lists baseline characteristics of all included patients. There were no apparent baseline group differences, except that the external group seemed to be heavier than the internal group. Weight was positively associated with threshold stiffness at all three test sessions (B's \geq 0.523, p's \leq 0.011). Therefore, it was included as covariate in the analysis of threshold stiffness. Both groups indicated that they focused their attention as instructed during practice, confirming that they adhered to the assigned intervention. Please see appendix 1 for more details.

Table 2 here

Primary outcome

Table 3A summarizes threshold rotational stiffness per measurement session. Appendix 2 shows the development of rotational stiffness throughout practice.

After three weeks of practice, the external group had improved by 25.8±18.6 Nm/rad, while the internal group had improved by 28.4±23.2 Nm/rad (main effect of time, p<0.001; Table 4A). However, this improvement in rotational stiffness did not differ between groups (p=0.653). Overall, post-hoc tests showed that patients significantly improved over the whole learning period (Δ =27.1±20.9 Nm/rad, p<0.001), between baseline and 1 week of practice (Δ =19.1±17.6 Nm/rad, p<0.001), and between 1 week and 3 weeks of practice (Δ =8.0±10.5Nm/rad, p<0.001). Appendix 3 lists details of all post-hoc tests. Intention-to-treat analysis yielded similar results (Table 4A), suggesting that attrition did not influence results.

Secondary outcomes

Table 3A summarizes the sway (root-mean-square error degrees) in single- and dual-task conditions per group, while Table 3B presents the results of the Timed-up-and-Go test and the mobility subscale of the Utrecht Scale for Evaluation of Rehabilitation.

Regarding single-task sway, both the external (Δ =0.93±1.97°) and internal group (Δ =1.37±2.37°) showed substantial improvements after three weeks of practice (main effect of time, p<0.001; Table 4A). However, results also showed that the external group showed larger initial improvements than the internal group (significant group by time interaction, p=0.031). Specifically, post-hoc tests showed that the external group significantly improved between baseline and 1 week of practice (Δ =0.97±1.72°, p=0.016), but did not further improve afterwards (Δ =-0.05±0.84°, p=0.779). The internal group showed the opposite pattern. It did not significantly improve in the first week (Δ =0.60±2.14°, p=0.320), but only achieved significant improvements between 1 and 3 weeks of practice (Δ =0.77±1.29°, p=0.018; Appendix 3). Results were similar with intention-to-treat analyses (Table 4A).

With regard to dual-task sway, both the external (Δ =1.28±1.77°) and internal group (Δ =0.69±1.66°) showed improvements after three weeks of practice (main effect of time, p<0.001; Table 4A). However, this improvement in dual-task sway did not differ between groups (p=0.330; Table 4A). Overall, post-hoc tests showed that patients significantly improved over the whole learning period (Δ =0.98±1.88°, p<0.001), and showed near-significant improvements between baseline and 1 week of practice (Δ =0.62±2.03°, p=0.060), and between 1 week and 3 weeks of practice (Δ =0.36±1.43°; p=0.076). Intention-to-treat analysis yielded similar results (Table 4A).

With regard to the clinical tests of general balance and mobility, after three weeks of practice the external and internal group both showed significant improvements in single-task ($\Delta_{\text{external}}=5.55\pm6.07$ seconds; $\Delta_{\text{internal}}=5.95\pm6.60$ seconds) and in dual-task ($\Delta_{\text{external}}=5.78\pm7.99$ seconds; $\Delta_{\text{internal}}=6.27\pm7.43$ seconds) Timed-up-and-Go performance. They also both showed significant improvements ($\Delta_{\text{external}}=10.2\pm6.0$ points; $\Delta_{\text{internal}}=7.2\pm6.2$ points) in the mobility subscale of the Utrecht Scale for Evaluation of Rehabilitation (main effects of time, p's<0.001; Table 4B). For all three outcomes, these improvements did not differ between groups ($p \ge 0.094$). Intention-to-treat analyses yielded similar results for all three outcomes (Table 4B).

Tables 3 & 4 here

Influence of patient characteristics on effectiveness of focus instructions

We found that patients with comparatively good balance and sensory functioning, and with low attentional capacity generally showed stronger improvements in balance board performance with external than with internal instructions.

First, baseline Berg Balance Scale score predicted whether patients improved their threshold rotational stiffness more with external or with internal focus instructions (Wald χ^2 =29.64, p<0.001). In the internal group, worse Berg Balance Scale scores were predictive of greater improvements in threshold stiffness (B=-1.665). This pattern was less pronounced for the external group (B=-0.392).

Second, sensory functioning of the lower extremities (Revised Nottingham Sensory Assessment) modified learning on all three balance board outcomes (threshold rotational stiffness: Wald χ^2 =17.69, p=0.001; single-task sway: Wald χ^2 =21.59, p<0.001; dual-task sway: Wald χ^2 =6.709, p=0.082). In the external group, better sensory functioning predicted greater improvement in threshold stiffness (B=0.485) and single-task sway (B=0.152). In contrast, in

the internal group lower sensory functioning predicted greater improvement in threshold stiffness (B=-1.410) and single-task sway (B=-0.061). Effects on dual-task sway were similar but less distinct.

Finally, attention (D2-attention test) scores predicted whether dual-task sway improved most with external or internal focus instructions (Wald χ^2 =7.843, p=0.049). In the external group, lower attention scores predicted greater improvement in dual-task sway (B=-0.013). In the internal group, by contrast, better attention scores predicted greater improvement in dual-task sway (B=0.008).

Discussion

This RCT found that the external group did not show greater improvements in the primary outcome, threshold rotational stiffness, compared to the internal focus group. Analysis of the secondary outcome measure of single-task sway revealed that the external group showed greater improvements early in learning after 1 week, but not after 3 weeks of practice. Yet, the external group did not show enhanced automaticity: Both groups showed comparable improvements in dual-task sway. In line with this, both groups reported a similar amount of declarative movement-related knowledge (appendix 1), which also indicates that balance performance was similarly automated. 11,39 Finally, the lack of group differences in the Timedup-and-Go and Utrecht Scale for Evaluation of Rehabilitation suggests that both attentional focus interventions had similar clinical benefits. Overall, external focus instructions did not result in greater improvements in motor skill and automaticity compared to internal focus instructions in rehabilitating stroke patients.

Our results are different from those of the majority of studies in healthy adults, which reported that external focus interventions result in superior motor skill and dual-task performance. One explanation for this stems from the single-task sway analysis. This suggested that external instructions may accelerate learning in the very short term – within the first week of practice – but not in the longer term – after three weeks of practice. Notably, in healthy adults, balance board studies that reported greater improvements in performance with an external focus typically concerned practice periods of a few days. 6,9,12 Possibly, benefits in healthy adults will also decrease or even disappear with prolonged practice.

From a clinical viewpoint, one could speculate that accelerated learning with external focus instructions may increase patients' feelings of competence, 45 motivation, and self-efficacy, and could eventually shorten inpatient rehabilitation duration. Note, though, that accelerated

learning was not observed in stiffness and automaticity, and clinical benefits were similar for both groups. Also, patients found it more difficult to use external focus instructions, which possibly decreases motivation. This difficulty with focusing externally may be related to patients' overall strong inclination to consciously control their movements, which is evidenced by patients' high scores on the Movement-Specific Reinvestment Scale (Table 2). 31,46,47

The effect modification analyses partly confirmed our hypothesis that the effects of focus instructions would be dependent on patients' motor functioning, sensory functioning, cognition, and conscious control inclination. Specifically, external instructions resulted in greater improvements in balance board performance for patients with comparatively good balance and sensory functioning, while internal instructions were more effective for patients with larger impairments. This skill-dependent effect of attentional focus was also found in a previous study that compared the immediate effects in stroke patients.¹⁷ Wulf et al.¹² argued that an internal focus hinders learning because it disrupts automaticity. Our findings suggest that this is only the case if some degree of sensory function and motor skill has been established in the first place (cf. Masters and Maxwell⁴⁸). In addition, when it comes to improving dual-tasking, we found that patients with more severe attentional deficits benefitted more from external focus instructions than from internal focus instructions. This is in line with the idea that an internal focus is more attention-demanding than an external focus. 10,12 Focusing internally would therefore be more easy for patients with intact attentional capacity, especially in dual-task situations when resources need to be shared with an additional cognitive task.

For rehabilitation practice, these results imply that a tailored use of attentional focus instructions may be more effective than an exclusive reliance on external focus instructions. This study suggests that a patients' motor, sensory, and attentional functioning may be

important. However, we do not know how therapists should weigh these different characteristics; e.g. what to do if a patient has both good balance *and* large attentional capacity? A challenge for future research is to replicate our analyses, investigate other possibly relevant factors such as imagery capacity,⁴⁹ and explore how different factors interact.

To the best of our knowledge, this is the first RCT that compared attentional focus instructions on motor skill and automaticity in rehabilitating stroke patients. Our results seem generalizable to the larger stroke population, given the large heterogeneity in terms of patient characteristics. Recent reviews have emphasized the need for motor learning research to improve on reporting, methodology, sample size, and statistics. ^{50–52} Accordingly, we preregistered the study design, a-priori defined the primary and secondary outcomes, and blinded outcome assessment and group allocation. Further, this study involved a comparatively large number of patients and an adequately long practice period. Finally, intention-to-treat analyses confirmed the robustness of our results to drop-outs and missing cases.

A limitation is the absence of a control group that received no specific instructions, making it impossible to assess whether the focus instructions hindered or promoted learning. Also, we only used one specific standardised focus instruction per group. These exact same instructions have been used extensively in prior research in healthy adults and elderly, ^{9,12} larger contrast between the interventions might have been achieved by using a larger set of attentional focus instructions. Another limitation was that it is impossible to blind the person providing the intervention to group allocation. A third point concerns the clinical relevance of the chosen tasks. While often used for research purposes, ^{6,9,12} the balance task primarily taxes mediolateral balance control in a laboratory setting. Future studies may compare the effects of focus instructions on walking, or more complex (e.g., perturbation) and functional balance tasks. ⁵³ Fourth, we did not include a retention test after a couple of weeks or months, and thus

could not compare the longer-term retention of skill improvements. A final issue concerns our effect modification analyses. In contrast to the factors planned for this analysis, the sensory functioning test (Revised Nottingham Sensory Assessment) was added to our analysis plan when the study was already underway. During a meeting on a related topic, a physical therapist argued that patients may compensate for impaired sensory functioning with conscious, internally focused control. Although our data seem to confirm this hypothesis, further research is needed to replicate these findings. This is especially true given that our sample size was powered for the analysis of our primary outcome variable only

Conclusions

No overall benefit was found of external focus instructions over internal focus instructions for improving balance skill and automaticity after stroke. For clinical practice, our results suggest that it may be more effective to tailor instructions to the individual patient, rather than uniformly use external instructions for all patients.

Clinical Messages

- External focus instructions did not enhance learning on a balance task in rehabilitating stroke patients compared to internal focus instructions
- External focus instructions seem more effective than internal focus instructions for patients with higher balance (Berg Balance Scale) and sensory (Nottingham Sensory Assessment) capacity, and with lower attention capacity (D2-attention test)

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Conflict of interest statement

The authors declare no conflicts of interest.

Data availability

All underlying research materials (including anonymized data, customized software, SPSS-

files and syntaxes) can be accessed by contacting the primary investigator (e.kal@heliomare.nl).

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TABLES

Table 1. Criteria for evaluating success during practice sessions.

Performance criteria for practice sessions			
Average % of trial duration that board deviates < 2.5 degrees	Number of trials participant grabbed handrail for support	Stiffness for next block of 5 trials	
>70%	1 or 2 trials	Stiffness-20%	
>70%	>2 trials	No change	
60%-70%	1 or 2 trials	No change	
60%-70%	>2 trials	Stiffness+20%	
<60%	Any number	Stiffness+20%	

NB: Handrail support was scored by observation by the experimenter.

Table 2. Baseline characteristics per group.

<u>Variable</u>	Internal Focus Group (N=31)	External Focus Group (N=32)
General characteristics		
Age in years (mean±SD)	58.5±10.3	60.7±11.1
Sex (male/female)	23/8	20/12
Weight in kg (mean±SD)	77.6±12.1	83.7±16.1
Height in cm (mean±SD)	176.8±8.7	176.0±9.0
Leg length in cm (mean±SD) ^c	102.9±6.5	103.5±5.8
Stroke characteristics		
Days since stroke at baseline ^a (mean±SD)	30.5±21.3	26.6±10.3
Days since admission at baseline (mean±SD)	14.3±10.9	11.7±8.4
Stroke aetiology (haemorrhagic/infarction)	7/24	8/24
Stroke subtype		
Total Anterior Circulation Stroke	2	1
Partial Anterior Circulation Stroke	15	15
Lacunar Stroke	8	9
Posterior Circulation Stroke	6	7
Recurrent Stroke (yes/no)	3/28	4/28
Revised Nottingham Sensory Assessment – lower	71.7±10.5	74.8±5.2
extremities (0-80; mean±SD) ^a		
Charlson Comorbidity Index (mean±SD) ^a	0.52±0.6	0.78±1.2
Additional hours of therapy/week (mean±SD) ^a	8.1±2.3	8.3±1.7
Motor characteristics		
Berg Balance Scale (0-56; mean±SD) ^{a,b}	46.3±10.1	49.0±7.3
Functional Ambulation Categories (0-5; median±IQR)	4±2	4±1
Ten Meter Walk Test (s; mean±SD) ^a	17.1±9.9	14.1±8.6
Timed-up-and-Go -ST (s; mean±SD) ^a	19.5±11.1	16.6±11.3
Timed-up-and-Go -DT (s; mean±SD) ^a	21.1±11.7	18.0±11.8
USER-MOB (0-35; mean+SD) ^b	23.3±6.7	24.4±7.0
Cognitive characteristics		
Education level (1-7; median±IQR)	5±2	5±2
USER-COG (0-50; mean+SD) ^{a,b}	43.5±4.5	44.5±5.7
Aphasia (yes/no)	7/24	3/29
Neglect (yes/no)	9/22	6/26
Attention (D2-attention test; mean±SD) ^d	118.6±48.4	120.6±41.4
Working Memory (DSST; mean±SD) ^c	43.5±16.9	47.1±18.3
Executive Function (Color Trails Test; mean±SD) ^e	0.91±0.56	0.97±0.47
Conscious motor control preference		
MSRS-Total (mean±SD)	37.7±10.5	34.0±11.0
MSRS-CMP (mean±SD)	22.6±6.2	20.3±6.1
MSRS-MS-C (mean±SD)	15.2±5.4	13.7±5.9

NB: The group comparisons were performed to check whether randomization was successful. Near-significant differences are emphasized. ^a Variable was not normally distributed, therefore a Mann-Whitney U test was performed; ^b Data unavailable for 1 patient; ^c Data unavailable for 4 patients; ^d Data unavailable for 5 patients; ^c Data unavailable for 7 patients. Abbreviations: CMP=Conscious Motor Processing subscale; COG=Cognitive subscale; CTT=Color Trails Test; DSST=Digit Symbol Substitution Test; IQR=Interquartile range; MOB=Mobility subscale; MS-C=Movement Self-Consciousness subscale; MSRS=Movement-Specific Reinvestment Scale; s=seconds; SD=Standard deviation; SE=Standard error; USER=Utrecht Scale for Evaluation of Rehabilitation;

Table 3. Summary of balance board (A) and clinical test (B) results (mean±standard error). Data presented here concern the raw unadjusted data for patients for whom complete data was available (i.e., per protocol; N=51).

A. Balance Board Measures				
Threshold Stiffness	Test Session	Internal Focus	External Focus	
Threshold Rotational Stiffness	Baseline	44.08±7.13	40.00±5.05	
(Newton meter/radian)	1 week	25.03±5.01	20.89±3.89	
	3 weeks	15.64±4.46	14.21±3.45	
Single-Task Sway				
Single-Task sway (degrees RMSE)	Baseline	2.48±0.51	2.34±0.36	
	1 week	1.46±0.41	0.78 ± 0.16	
	3 weeks	0.57±0.17	0.66 ± 0.20	
Single-Task Handrail Support	Baseline	1.56±0.33	1.77±0.30	
(number of times)	1 week	0.70±0.25	0.58±0.21	
	3 weeks	0.46±0.17	0.23±0.09	
Dual-Task Sway ^a				
Dual-Task sway (degrees RMSE)	Baseline	2.13±0.48	2.58±0.42	
	1 week	1.30±0.39	1.15±0.33	
	3 weeks	0.69±0.19	0.72±0.19	
Dual-Task Handrail Support	Baseline	1.35±0.26	2.08±0.44	
(number of times)	1 week	0.98±0.37	0.67 ± 0.20	
	3 weeks	0.50±0.24	0.60±0.21	
Tone-counting dual-task costs (%)	Baseline ^b	9.15±3.78	4.63±3.45	
	1 week	5.23±3.56	3.34±2.17	
	3 weeks	1.14±3.42	0.48±2.13	
B. Clinical Balance & Mobility Tests				
Single-Task Timed-up-and-Go	Test Session	Internal Focus	External Focus	
Single-Task Timed-up-and-Go(s)	Baseline	20.45±2.48	17.89±2.37	
	3 weeks	14.64±2.55	12.34±1.66	
Dual-Task Timed-up-and-Go ^a				
Dual-Task Timed-up-and-Go (s)	Baseline	22.04±2.60	19.11±2.48	
	3 weeks	16.18±2.50	12.81±1.54	
Timed-up-and-Go -tone-counting	Baseline	5.18.±3.41	1.77±3.56	
dual-task costs (%)	3 weeks	7.67±3.49	-1.08±4.94	
USER-Mobility				
USER-Mobility	Baseline ^c	23.54±1.41	23.27±1.26	
	3 weeks ^d	30.71±1.05	33.44±0.35	

NB: ^a One internal group member excluded as outlier; ^b No data for 1 internal group member due to malfunctioning microphone; ^c No data for 1 internal group member; ^d No data for 1 external and 3 internal group members; Abbreviations: RMSE=Root-mean-square error; USER=Utrecht Scale for Evaluation of Rehabilitation;

Table 4. Results of per protocol (N=51) and intention-to-treat (N=63) GEE-analyses of balance board (A) and clinical test results (B).

A. Balance Board Measures	Per prote	ocol (N=51)	Intention-to	-treat (N=63)
Threshold Stiffness	Wald χ2	p	Wald χ2	p
Group (Internal, External)	1.47	0.226	2.594	0.107
Time (Baseline, 1 week, 3 weeks)	85.82	<0.001	116.73	<0.001
Group x Time	0.85	0.653	1.04	0.595
Weight ^a	9.64	0.002	20.52	<0.001
Single-Task Sway				
Group (Internal, External)	0.40	0.526	0.00	0.952
Time (Baseline, 1 week, 3 weeks)	15.46	<0.001	23.29	<0.001
Group x Time	6.92	0.031	6.40	0.041
Handrail Support	11.57	<0.001	14.01	<0.001
Dual-Task Sway ^b				
Group (Internal, External)	0.27	0.603	0.71	0.400
Time (Baseline, 1 week, 3 weeks)	14.33	0.001	25.06	<0.001
Group x Time	2.22	0.330	2.76	0.252
Handrail Support	4.97	0.026	6.89	0.009
Tone-counting dual-task costs	6.47	0.011	3.92	0.048
B. Clinical Balance & Mobility Tests	Per prote	ocol (N=51)	Intention-to	-treat (N=63)
Single-Task Timed-up-and-Go	Wald χ2	p	Wald χ2	p
Group (Internal, External)	0.65	0.421	1.16	0.282
Time (Baseline, 3 weeks)	40.96	<0.001	51.96	<0.001
Group x Time	0.05	0.823	0.14	0.710
Dual-Task Timed-up-and-Gob				
Group (Internal, External)	0.84	0.359	1.38	0.240
Time (Baseline, 3 weeks)	35.42	<0.001	45.05	<0.001
Group x Time	0.00	0.970	0.01	0.907
Tone-counting dual-task costs	5.11	0.024	5.44	0.020
USER-Mobility ^c				
Group (Internal, External)	1.07	0.302	3.33	0.068
Time (Baseline, 3 weeks)	89.27	<0.001	99.44	<0.001
Group x Time	2.81	0.094	2.59	0.108

NB: aSensitivity analysis revealed the effect of group (p=0.611) and group by time interaction (p=0.653) to be similar when weight was excluded from the stiffness analysis; bOne internal group member was excluded as outlier, but sensitivity analyses showed that the group by time interaction remained nonsignificant when this patient was included (p=0.574); Baseline USER mobility scores unavailable for 6 patients. Abbreviations: RMSE=Root-mean-square error; USER=Utrecht Scale for Evaluation of Rehabilitation;

FIGURES

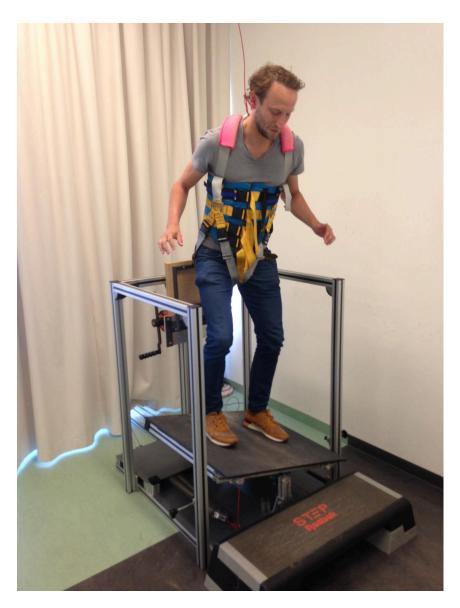


Figure 1. Balance board set-up. Springs were attached to each side of the front of the balance board. Rotational stiffness could be adjusted (0-220 Nm/rad) by using either one or two parallel springs on each side, by altering the springs' moment arm, or by changing the springs themselves (800 N/m vs. 390 N/m). Patients wore a safety harness.

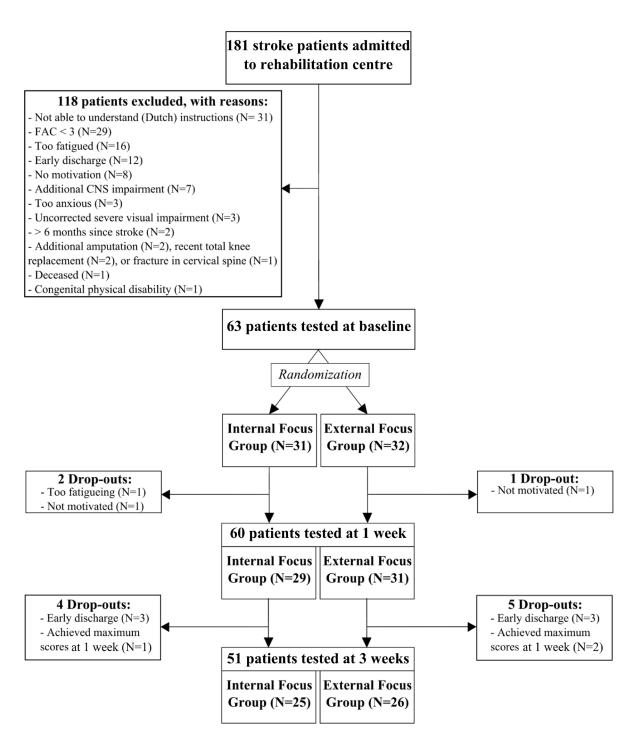


Figure 2. Study flow. Abbreviations: CNS=Central nervous system; FAC=Functional Ambulation Categories;

Appendix 1. Results of manipulations checks

Adherence to instructions

Patients were able to maintain their focus throughout the trial, and found the provided instructions effective for improving their performance (average scores on all three checks < 5.0 cm). The external group did tend to rate it more effortful to focus as instructed (mean=3.23, SE=0.32; t(49)=1.860, p=0.070, d=0.260) and to maintain this focus throughout each trial (mean=4.08, SE=0.31; t(49)=1.737, p=0.089, d=0.243) compared to the internal group (mean=2.30, SE=0.38; and mean=3.18, SE=0.42; respectively). Both groups judged the effectiveness of instructions similar (mean_{External}=3.37, SE=0.33 vs. mean_{Internal}=2.88, SE=0.36, respectively; t(49)=1.01, p=0.318, t=0.141).

Amount of movement-related declarative knowledge of balance board performance The external and internal group reported a similar number of movement-related rules at baseline (mean=2.42, SE=0.24, vs. mean=2.04, SE=0.28, respectively), after 1 week (mean=2.19, SE=0.22, vs. mean=1.96, SE=0.23, respectively) and after 3 weeks (mean=2.23, SE=0.31, vs. mean=1.84, SE=0.28, respectively; t's(49) \leq 1.049, $p\geq$ 0.299, $d\leq$ 0.150). The number of movement-related rules did also not change over time in either group (t's(24-25) \leq 0.894, p's \geq 0.380, d's \leq 0.179).

Appendix 2. Threshold rotational stiffness over time

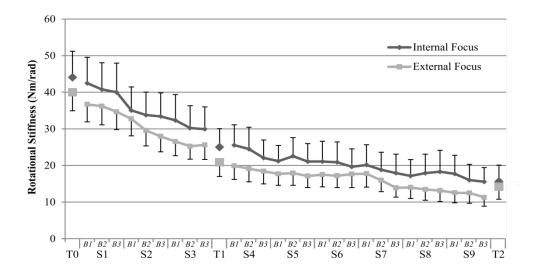


Figure A2. Development of threshold rotational stiffness (Mean Newton meter/radian ± standard error) over time for all patients who completed the whole 3-week training period (per protocol; N=51). Results are presented for both groups for the test sessions at baseline (T0), after 1 week of practice (T1), and after 3 weeks of practice (T2). Results are also presented per block (B1-B3) of each practice session (S1-S9) for both groups. Lower values indicate better performance.

Appendix 3. Details of post-hoc tests per analysis

Analysis			
Threshold rotational stiffness	Both groups combined	External group	Internal group
Baseline vs. 1 week	t(50)=7.735	N/A	N/A
	<i>p</i> <0.001		
	d=1.083		
1 week vs. 3 weeks	t(50)=5.463	N/A	N/A
	<i>p</i> <0.001		
	d=0.765		
Baseline vs. 3 weeks	t(50)=9.248	N/A	N/A
	<i>p</i> <0.001		
	d=1.295		
Single-task sway	Both groups	External group	Internal group
Baseline vs. 1 week	combined N/A	±(25)=2 007	+(24)-1.405
Buseline vs. 1 week	1 N/A	t(25)=2.887	t(24)=1.405 p=0.320
		p=0.016 d=0.566	p=0.320 d=0.281
1 week vs. 3 weeks	N/A		
1 week vs. 5 weeks	N/A	t(25)=-0.280	t(24)=2.976
		p=0.779	p=0.018
Baseline vs. 3 weeks	N/A	d=0.055	d=0.595
Baseline vs. 3 weeks	N/A	t(25)=2.403	t(24)=2.898
		p=0.016	p=0.020
D. I.I. I.	D 41	d=0.471	d=0.580
Dual-task sway	Both groups combined	External group	Internal group
Baseline vs. 1 week	$t_{T0-T1}(49)=1.769$	N/A	N/A
	p=0.060		
	d=0.310		
1 week vs. 3 weeks	$t_{T0-T2}(49)=1.035$	N/A	N/A
	p=0.076		
	d=0.254		
Baseline vs. 3 weeks	t(49)=3.698	N/A	N/A
	p<0.001		
	d=0.528		

 $\overline{\text{NB: N/A}} = \text{not applicable};$