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Does perturbation-based balance training prevent falls among individuals with chronic stroke? A randomized controlled trial.

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1 2 3	1	Title: Does perturbation-based balance training prevent falls among individuals with chronic stroke? A
4 5	2	randomized controlled trial.
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ABSTRACT (word count: 300; max: 300) **Objectives:** No intervention has been shown to prevent falls post-stroke. We aimed to determine if perturbation-based balance training (PBT) can reduce falls in daily life among individuals with chronic stroke. Design: Assessor-blinded randomized controlled trial. Setting: Two academic hospitals in an urban area. Interventions: Participants were allocated using stratified blocked randomization to either 'traditional' balance training (control) or PBT. PBT focused on improving responses to instability, whereas traditional balance training focused on maintaining stability during functional tasks. Training sessions were 1 hour twice/week for 6 weeks. Participants were also invited to complete 2 'booster' training sessions during the follow-up. **Participants:** Eighty-eight participants with chronic stroke (>6-months post-stroke) were recruited and randomly allocated one of the two interventions. Five participants withdrew; 42 (control) and 41 (PBT group) were included in the analysis. **Primary and secondary outcome measures:** The primary outcome was rate of falls in the 12-months post-training. Negative binomial regression was used to compare fall rates between groups. Secondary outcomes were measures of balance, mobility, balance confidence, physical activity, and social integration. **Results:** PBT participants reported 53 falls (1.45 falls/person-year) and control participants reported 64 falls (1.72 falls/person-year; rate ratio: 0.85 [0.42, 1.69]; p=0.63). Per-protocol analysis included 32 PBT and 34 control participants who completed at least 10/12 initial training sessions and 1 booster session. Within this sub-set, PBT participants reported 32 falls (1.07 falls/person-year) and control participants reported 57 falls (1.75 falls/person-year; rate ratio: 0.62 [0.29, 1.30]; p=0.20). PBT participants had greater improvement in reactive balance control than the control group, and these

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- improvements were sustained 12-months post-training. There were no intervention-related serious

adverse effects.

- **Conclusions:** The results are inconclusive. PBT may help to prevent falls in daily life post-stroke, but
- ongoing training may be required to maintain the benefits.
- Trial registration: ISRCTN05434601.
 - Funding: Canadian Institutes of Health Research.

Jes OL bilitation; Exercise, **Key words:** Stroke; Rehabilitation; Exercise; Physiotherapy; Accidental Falls; Postural balance

1 2 3	57	STRE	NGHTS AND LIMITATIONS OF THE STUDY
4 5	58	٠	This study employed an assessor-blinded randomized controlled trial. As is typical of exercise
6 7	59		studies, participant blinding was not possible.
8 9 10	60	•	Attendance to the intervention was high (mean 87% of sessions attended), and rates of
11 12	61		withdrawal from the study were low (<6%).
13 14	62	•	The primary outcome (falls in daily life) was collected via self-report, which may have led to
15 16	63		under-reporting.
17 18 19	64	٠	Inclusion and exclusion criteria were minimal so that results would be generalizable to a broad
20 21	65		population of individuals with chronic stroke. However, recruited participants were, on average
22 23	66		high functioning; these results might not apply to more severely-affected individuals with
24 25 26	67		stroke.
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INTRODUCTION

People with stroke have increased fall risk compared to age-matched individuals who have not had a stroke.¹ Impaired balance control, low balance confidence, and high rate of falls post-stroke are associated with reduced quality of life and reduced physical activity as a strategy to prevent falls.^{2,3}
Physical exercise, particularly exercise that includes balance training, can reduce fall rates in older adults.⁴ However, studies including individuals with stroke have not demonstrated reduced fall rates following balance training.^{5,6}

Balance training programs typically include exercises that aim to improve the ability to maintain balance when keeping still (e.g., standing with reduced base of support) or during voluntary movement (e.g., sit-to-stand or step ups).⁷⁻¹¹ This type of balance training may prevent falls by reducing the risk of losing balance in daily life. However, occasional loss of balance may be an inevitable consequence of mobility, so the ability to react quickly after losing balance is essential to prevent falls.¹² Perturbation-based balance training (PBT) is a type of exercise where participants repeatedly experience loss of balance in order to practice and improve control of balance reactions.¹³ A review of small-sample randomized controlled trials suggests that PBT can prevent falls in older adults and individuals with Parkinson's disease.¹⁴

People with stroke have impaired reactive balance control,^{15,16} and impaired control of balance reactions is related to increased fall rates in daily life post-stroke.^{17,18} PBT can improve reactive balance control post-stroke.¹⁹ A non-randomized study found that those who completed PBT during inpatient stroke rehabilitation fell less frequently post-discharge than those who did not.²⁰

89 The main purpose of this study was to determine if PBT reduces fall rates in people with 90 chronic stroke. A secondary purpose was to determine the effect of PBT on balance control, balance 91 confidence, mobility, daily physical activity, and social integration. We hypothesized that, compared to 92 a control group who completed 'traditional' balance training, those who completed PBT would

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experience fewer falls in the year post-training and would have greater improvements in measures of functional balance and mobility. Additionally, we expected that, due to reduced fall rates and improved balance confidence, participants who completed PBT would be less likely to restrict daily physical activities; therefore, we hypothesized that participants who completed PBT would show increased daily physical activity and improved social integration compared to those in the control group.

- **METHODS**
- 18 100 **Trial design**

This assessor-blinded pragmatic randomized controlled trial took place at the Toronto Rehabilitation Institute (University Health Network) and Sunnybrook Health Sciences Centre. Individuals with chronic stroke were recruited and randomly assigned to either: 1) PBT or 2) 'traditional' balance 25 103 ²⁷ 104 training (control group). The full study protocol is available elsewhere;²¹ protocol modifications are detailed in the relevant sections below. The protocol and amendments were approved by the University 32 106 Health Network (study ID: 14-7428) and Sunnybrook Health Sciences Centre (study ID: 134-2014) 34 107 Research Ethics Boards.

39 109 **Participants**

41 1 1 0 Community-dwelling adults with chronic stroke (>6 months post-stroke) were recruited from research volunteer databases and advertisements in the community. Participants could stand independently 46 112 without upper-limb support for >30s and tolerate at least 10 postural perturbations. Exclusion criteria 48 1 1 3 were: >2.1m tall and/or weighing >150kg; other neurological conditions; lower extremity amputation; ⁵⁰ 114 unable to understand instructions in English; recent (last 6 months) significant illness, injury or surgery; severe osteoporosis (diagnosis of osteoporosis with fracture); poorly controlled diabetes or hypertension; contraindications to physical exercise;²² receiving physiotherapy or supervised exercise 55 116

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targeting balance and mobility; and/or received PBT in the year before enrolment. Due to difficulty recruiting, the protocol was amended to allow individuals <50 years old to participate. Volunteers completed telephone screening and subsequently attended an initial assessment where written informed consent was obtained and eligibility was confirmed. To help alleviate barriers to participation, participants were compensated for travel expenses (public transit fare or parking).

23 Interventions

Participants completed 2 1-hour training sessions per week for 6 weeks, and 2 1-hour 'booster' training 125 sessions 3- and 9-months after the initial training period. Interventions were administered by a physiotherapist (CJD or SK) on a 1:1 basis (i.e., one physiotherapist per participant) in research laboratories in academic hospitals. Both laboratories contained a 2.63 x 2.63m 4-post XY patient lift gantry (Prism Medical Ltd, Concord, ON, Canada), and the Sunnybrook laboratory also contained a 129 8.5m long ceiling lift track, to which the safety harness was attached during PBT. Physiotherapists were trained in delivering the control intervention by reviewing the intervention developers' documentation,²³ and in delivering the PBT intervention by study investigators (AM and VGD). 132 Interventions followed a general guide, but were tailored to participants' ability and balance impairments. Participants rated perceived level of challenge on a 5-point scale (see Supplementary Material) after completing each exercise set. The physiotherapists documented activities in each 135 session, perceived level of challenge, adverse events, and deviations from prescribed activities.

137 Control group

The control group completed the Keep Moving with Stroke program.²³ This is an exercise program for community-dwelling individuals with stroke, based on balance and mobility interventions evaluated in clinical trials.⁹⁻¹¹ This program was designed to be delivered in a group, but was delivered 1:1 in this

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study to match attention received from the physiotherapist by the PBT group. Each session included a 5-10 minute warm-up, 40 minutes of mobility and balance exercises, and a 5-10 minute cool-down with stretching. Exercises included walking, sit-to-stand, heel raises, walking while carrying an object, tap-ups or step-ups (forward and sideways), reaching and weight shifting, and standing with reduced 11 145 base of support.

16 147 PBT group

18 1 4 8 PBT sessions included a 5-10 minute warm-up, voluntary tasks intended to induce internal perturbations, voluntary tasks combined with external perturbations, and a 5-10 minute cool-down. Participants were supervised by the physiotherapist and wore a custom safety harness (ABG Concept 25 1 5 1 Médical Inc., Valcourt, QC, Canada) attached to the overhead support. Internal perturbations occurred ²⁷ 152 when participants failed to control balance during voluntary movement; 'agility' tasks, such as kicking a soccer ball, were used to induce internal perturbations. External perturbations were caused by forces 32 1 5 4 outside participants' control (e.g., push or pull from the physiotherapist). We aimed for at least 60 34 1 5 5 postural perturbations per session, and set the task difficulty such that participants required an upper extremity response, external assistance (i.e., from the overhead harness or physiotherapist), or a multi-step response ~50% of the time. The progression in voluntary tasks occurred on a continuum from 39 157 stable to mobile, and from predictable to unpredictable.²⁴ Additionally, progression occurred by 41 1 58 increasing the magnitude of external perturbation, or imposing sensory or environmental challenges. 46 160 The full PBT program is available in the Supplementary Material.

⁵⁰ 162 **Group** allocation

Participants were assigned using blocked stratified randomization with allocation concealment to either 55 164 the control or PBT group by the principal investigator (AM), who was not involved in recruiting,

1 2 3	165	assessments, or intervention administration. A variable block size of 4, 6 or 8 was used. There were	
	166	four strata from two stratification factors: site (two levels), and frequency of 'failures' during baseline	
/	167	reactive balance control assessment ¹⁷ (two levels). The random allocation sequence was computer	
8 9 10	168	generated and maintained in an electronic file by the principal investigator.	
11 12	169		
	170	Outcomes	
16 17	171	Cohort descriptors	
19	172	Demographic and stroke information were recorded at study enrolment: age, sex, time since stroke,	
	173	lesion location, falls history, National Institutes of Health Stroke Scale (NIH-SS ²⁵), and Chedoke-	
22 23 24		McMaster Stroke Assessment (CMSA) foot and leg scores. ²⁶ Demographics and medical history were	
25 26	175 176	obtained by self-report and, when possible, verified from participants' hospital charts.	
29 30		Primary outcome – falls	
31 32 33	178	A fall was defined as "an event that results in a person coming to rest unintentionally on the ground or	
	179	other lower level". ²⁷ Participants completed 12-months of falls reporting after the initial 6-week	
	180	training period. Participants were provided stamped addressed postcards containing a 2-week calendar	•
38 39 40	181	to record falls, which they completed daily, and returned to the research team fortnightly. If a postcard	l
	182	was not returned within 2 weeks the research assistant called the participant to ascertain if they fell.	
		Participants who fell completed a short telephone questionnaire regarding the cause, circumstances, and	ıd
45 46 47	184	consequences of the fall. Falls were excluded from analysis, by unanimous decision of two blinded	
	185	research assistants, if they were caused by loss of consciousness or an overwhelming external force	
	186	(i.e., if anyone would fall in that situation). If the research assistants could not agree that a fall should	
52 53 54	187	be excluded, that fall was included in the analysis.	
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1 2 189 Secondary outcomes 3 4 Balance and mobility and balance confidence were assessed immediately before, immediately after, 190 5 6 and 6- and 12-months after the end of the initial training period. Functional balance and mobility were 191 7 8 assessed using the Berg balance scale (BBS²⁸), the mini-Balance Evaluation Systems test (mini-192 9 10 BEST²⁹), and the Timed Up & Go (TUG³⁰). The Activities-specific Balance Confidence (ABC) 11 193 12 13 194 questionnaire³¹ was used to assess balance confidence in daily activities. 14 15 16 195 Physical activity and social integration were evaluated with the Physical Activity Scale for 17 Individuals with Physical Disabilities (PASIPD³²) and the Subjective Index of Physical and Social 18 196 19 ²⁰ 197 Outcome (SIPSO³³), respectively, at baseline and every 2 months during the 12-month follow-up. 21 22 23¹⁹⁸ 24 25 199 Blinding 26 ²⁷ 200 The research assistants (AA and AC) were blinded to group allocation and were responsible for 28 29 201 screening, recruiting, and collecting data. At the post-training, 6-month, and 12-month assessments, the 30 31 research assistants guessed group allocation for each participant, rated their confidence in their guess of 32 202 33 34 203 group allocation, and noted if they had received any information to violate blinding. In cases where 35 ³⁶₃₇204 blinding was violated, the balance measures were re-coded from video footage by another blinded 38 39 205 research assistant. 40 41 206 42 43 207 Sample size 44 45 46 208 The target sample size was estimated for the primary outcome (fall rate in the year post-training) using 47 a formula for negative binomial regression.³⁴ Assuming the control group would report 1.75 per 48 209 49 ⁵⁰210 person-year,¹⁷ a rate ratio of 0.54,¹⁴ mean follow-up time of 11 months per person, level of significance 51 52 53 211 of 0.05, and power of 0.8, we estimated that 37 participants per group would be required to show a 54 55 212 statistically significant between-group difference in fall rates. 56

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1 2 213 3	
$\frac{4}{5}$ 214	Statistical analysis
6 7 215	Wilcoxon-Mann-Whitney test (continuous/ordinal variables) and Fisher's exact test
8 9 216	(categorical/frequency variables) were used to compare the two groups at baseline. Negative binomial
10 11 217 12	regression was used to compare fall rates and logistic regression was used to compare the proportion of
$^{13}_{14}218$	fallers between the two groups. Intent-to-treat analysis was used; all participants with some falls-
15 16 219	monitoring data were included in the analyses. To account for variable falls-monitoring duration
17 18 220	between participants (e.g., due to premature withdrawal from the study) the natural log of the
19 20 21 221	monitoring duration was included as an offset variable in negative binomial regression, and as a
22 23 222	covariate in logistic regression. Exploratory per-protocol analysis was also conducted, comparing
24 25 223	proportion of fallers and fall rates between the two groups, including only those participants who
26 27 224	attended at least 10/12 of the initial training sessions and 1 booster session. We initially planned to
28 ²²¹ 29 30 ²²⁵	conduct repeated-measures analysis of variance, with group-by-time interaction, to evaluate the effect
31 32 226	of the interventions on secondary outcome measures. ²¹ However, because the variables were not
33 34 <u>22</u> 7	normally distributed we conducted analysis of co-variance (ANCOVA), comparing BBS, mini-BEST,
35 36 37 228	mini-BEST subscale scores, TUG, ABC, PASIPD, and SIPSO at each time point between groups,
37 38 39 229	controlling for the value at baseline. Dependent variables were rank transformed prior to entry into the
40 41 230	ANCOVA to allow for non-parametric analysis. Alpha was 0.05 for all analyses.
42 43 _{23 1}	An velo vir to unow for non parametric analysis. Anpha was 0.00 for an analyses.
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46 232 47	RESULTS
48 233 49	Recruitment
⁵⁰ 234 51	Recruiting occurred between 24 April 2014 and 29 June 2016. Initially, we planned to recruit 46
⁵² 53 235	participants per group to account for a 20% withdrawal rate. ²¹ However, recruiting was stopped when
54 55 236 56	we had at least 37 participants per group who had returned at least one fall-reporting postcard. Any
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1 participants who had started the intervention at this point continued with the study until they either 2 237 3 4 238 withdrew or completed all study elements. The trial ended when data collection for all recruited 5 6 239 participants was complete (August 2017). Forty-four participants were assigned to each group, with 42 7 8 240 (control) and 41 (PBT) returning at least 1 fall-reporting postcard (Figure 1); thus 42 control and 41 9 10 11 241 PBT participants were included in analysis of the primary outcome (falls in daily life). Baseline 12 13 242 characteristics for these participants are in Table 1; there were no significant differences between 14 15 16 2 4 3 groups on any baseline characteristics. 17 18 2 4 4 19 ²⁰ 245 **Intervention adherence** 21 22 246 During the initial 6-week training program, PBT participants attended a mean 10.5 sessions, with 34/41 23 24 participants attending at least 10 sessions (out of the prescribed 12). Participants experienced a mean of 25 2 47 26 ²⁷ 248 577 perturbations during all sessions (standard deviation: 195 perturbations; minimum: 42 28 29 249 perturbations), or a mean of 55 perturbations per session (standard deviation: 9 perturbations). For all 30 31 PBT sessions combined, mean rate of balance recovery 'failures' was 57%, and mean rate of perceived 32 250 33 34 2 5 1 challenge was 2.4 (on a five-point scale). In the initial 6-week training phase, control participants 35 36 252 attended a mean of 11 sessions, with 38/42 participants attending at least 10 sessions (out of the 37 38 39 253 prescribed 12). On average, control participants completed 87% of the prescribed exercises (standard 40 41 2 5 4 deviation: 18%). For all control training sessions combined, mean rate of perceived challenge was 2.4. 42 43 255 44 45 ₄₆ 256 **Outcomes and estimation** 47 48 2 57 Blinding 49

⁵⁰ 258 Blinding was violated for 9 participants (7 PBT and 2 control), who revealed their group allocation in 259 conversation with the research assistant. The BBS and mini-BEST scores for these participants were re-55 260 coded from video recordings by another blinded research assistant who had no interaction with

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1 participants. For the remaining participants, the research assistants correctly guessed group allocation 2 261 3 4 262 56% of the time; i.e., guesses were not correct more often than would be expected by random chance. 5 6 263

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Missing data

Data were missing at assessment time points because participants: declined to complete the assessment (15 PBT and 21 control assessments); were unavailable due to acute illness (3 control assessments); were unavailable due vacation or other personal commitments (3 control assessments); or could not be 18 268 contacted at the time of the assessment (6 control assessments). Some participants declined to come to ²⁰ 269 the laboratories for the 6- and 12-month assessments, but were willing to complete the questionnaires 270 (ABC, SIPSO, and PASIPD) over the telephone. Even when participants attended a study appointment, 25 271 some declined to complete individual tests; the number of individuals included in analysis of each ²⁷ 272 variable at each time point is detailed in the Tables.

32 274 Falls

34 275 In the year post-training, 46% (19/41) of PBT participants and 55% (23/42) of control participants 35 36 276 reported at least one fall; the between-group difference in odds of being a 'faller' was not statistically 37 38 39 277 significant (odds ratio: 0.71 [0.30, 1.70]; p=0.44). PBT participants reported 53 falls (1.45 falls per 40 41 278 person-year) and control participants reported 64 falls (1.72 falls per person-year); the between-group 42 43 279 difference in fall rates was not statistically significant (rate ratio: 0.85 [0.42, 1.69]; p=0.63). 44

45 46²⁸⁰ Thirty-two PBT participants and 34 control participants completed at least 10/12 of the initial 47 48 281 training sessions and 1 booster session, and were included in per-protocol analysis. Within this sub-set, 49 ⁵⁰ 282 44% (14/32) of PBT participants and 59% (20/34) of control participants reported at least one fall in 51 52 283 the year after training. The between group difference in odds of being a 'faller' was not statistically 53 54 55 284 significant (odds ratio: 0.56 [0.21, 1.50]; p=0.25). PBT participants reported 32 falls (1.07 falls per

1	
2 285 3	person-year) and control participants reported 57 falls (1.75 falls per person-year). The between-group
4 286 5	difference in fall rates was not statistically significant (rate ratio: 0.62 [0.29, 1.30]; p=0.20).
$\frac{6}{7}$ 287	
8 9 288 10	Balance confidence, balance, mobility, physical activity, and social integration
11 289 12	Post-training, the PBT group had higher scores than the control group for the reactive sub-scale of the
¹³ 290	mini-BEST ($F_{1,74}$ =7.33, p=0.0084; Table 2), whereas the control group had higher scores than the PBT
15 16 291 17	group for the sensory subscale ($F_{1,74}$ =4.19, p=0.044). Scores for the reactive sub-scale of the mini-
18 292 19	BEST were higher for the PBT group than the control group at 6-months ($F_{1,57}$ =8.32, p=0.0055) and
²⁰ 293	12-months ($F_{1,53}$ =11.59, p=0.0013). Likewise, at 12-months, the PBT group had a higher score on the
22 23 294 24	total mini-BEST than the control group ($F_{1,53}$ =4.04, p=0.049). There were no other statistically
24 25 295 26	significant between-group differences for balance and mobility measures at any time point.
²⁷ 296 28	There were no significant between-group differences for the PASIPD at any time point (Table
²⁹ 30 ²⁹⁷	3). SIPSO scores were significantly higher for the control group compared to the PBT group at 6-
31 32 298 33	months ($F_{1,59}$ =6.73, p=0.012), 8-months ($F_{1,54}$ =4.25, p=0.044), 10-months ($F_{1,61}$ =4.89, p=0.031), and
34 299 35	12-months ($F_{1,59}$ =4.13, p=0.047).
³⁶ 37 300	Data showing change in secondary outcomes over time are presented in the supplementary data
38 39 301 40	(Supplementary Tables S1 and S2). No analyses were conducted on these data.
40 41 302 42	
⁴³ ₄₄ 303	Ancillary analysis
45 46 304	Additional exploratory analysis compared causes, circumstances, and consequences of falls in daily life
47 48 305 49	between groups (Table 4). There was a significant between-group difference in motor activity at the
⁴⁹ 50 306 51	time of the fall (p=0.010). Falls in control participants were more likely to occur during transfers than
⁵² 53 307	falls in PBT participants, whereas falls in PBT participants were more likely to occur during
54 55 308	reaching/bending than falls in control participants. Participants had something in their hands at the time
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1 2 309 3	of 45% of control-group falls, compared to 23% of PBT-group falls (p=0.023). PBT participants
4 310 5	attempted to stop themselves from falling by using a step response for 21%, or a grasping response for
6 7 311	18% of falls, whereas control participants tried to prevent the fall by stepping for only 9% of falls, and
8 9 312 10	grasping for 30% of falls; however, this difference was not statistically significant (p=0.18). PBT
11 313 12	participants required assistance to get up after 48% of falls, compared to just 27% of falls for control
$^{13}_{14}314$	participants (p=0.040). Injuries resulted from 18 falls (39% of falls) in the PBT group and 20 falls
15 16 315 17	(34% of falls) in the control group (p=0.68). Most injuries were minor (e.g., cuts and bruises).
18 316 19	Participants sought medical attention after 3 falls (all control): visit to emergency room (2 falls), and
²⁰ 317	treatment from an unspecified healthcare professional (1 fall).
22 23 318 24	
25 319 26	Harms
²⁷ 320 28	Forty-eight adverse events were possibly, probably, or definitely related to study procedures or
²⁹ 30321 31	interventions among the 88 randomized participants. Events were: fatigue with training (3 PBT, 1
32 322 33	control); joint pain during or soon after training (14 PBT, 11 control); delayed onset muscle soreness (5
34 323 35	PBT, 8 control); seizure during training (1 PBT participant, with history of frequent seizures);
³⁶ 37 38	abnormally elevated heart rate and low blood pressure during training (1 control; this participant was
39 325 40	withdrawn from the study). For all but this last event, medical attention was not necessary to treat
41 326 42	adverse events. In the case of fatigue or joint/muscle pain, the intensity and/or duration of training was
⁴³ ₄₄ 327	reduced until the issue resolved. Additionally, four falls that occurred during the training portion of the
45 46 328 47	study were considered related to study procedures or interventions. In one case (control) the participant
48 329 49	fell outside the hospital while on the way to a study appointment. The other three falls were reported by
50 330 51	
52 53 53 54 55	behaviour, as a result of the intervention. Eight participants experienced serious adverse events

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1 2 unrelated to study procedures, but that resulted in study withdrawal: prolonged hospitalization (1 PBT, 332 3 4 1 control); another stroke (2 PBT, 3 control); death (1 control); and cancer diagnosis (1 control). 333 5 6 334 7 8 9 335 **DISCUSSION** 10 11 336 We hypothesized that PBT would reduce fall rates among individuals with stroke; this hypothesis was 12 13 337 not supported. While the rate ratio comparing falls rates between the PBT and control groups was 0.85, 14 15 16 338 this was not statistically significant. The pooled rate ratio estimating the effect of exercise on fall rates 17 in community-dwelling older adults is 0.80,⁴ which is similar to that observed in the current study. Our 18 3 3 9 19 ²⁰ 340 sample size was based on a rate ratio of 0.54, which was estimated from a meta-analysis of PBT,¹⁴ that 21 22 ²²₂₃ 341 included studies among older adults and individuals with Parkinson's disease. Another non-randomized 24 study reported a fall rate ratio of 0.32 when comparing individuals with sub-acute stroke who 25 3 4 2 26 27 343 completed PBT during in-patient rehabilitation to those who did not.²⁰ The effect of PBT on fall rates 28 29 ²₃₀ 344 in chronic stroke may be much lower than in other patient populations or individuals with sub-acute 31 stroke and, therefore, the current study may not have had sufficient power to detect the true effect. 32 3 4 5 33 34 3 4 6 Conversely, the between-group difference in fall rates was much greater when only individuals who 35 36 37 347 completed at least 80% of initial training sessions and 1 booster session were included in the analysis. 38 The booster sessions may have helped participants to retain the training benefits.^{35,36} 39 348 40 41 349 Importantly, the control group also completed balance training; previous studies using similar 42 43 350 exercise programs found no effect of balance training on fall rates in people with chronic stroke when 44 45 46 351 compared to a sham intervention⁷ or 'usual care'.³⁷ Thus, we expect that control participants did not 47 48 3 5 2 have reduced fall risk as a result of completing this program. However, both groups improved balance 49 ⁵⁰ 353 and mobility following training, and it is possible that improved balance and mobility led to reduced 51 52 354 fall risk in the control group. 53 54 55

1 2 355 3	Consistent with specificity of training, the PBT group improved reactive balance control
$^{4}_{5}$ 356	(reactive sub-scale of the mini-BEST), but the control group did not; ³⁸ these improvements were
6 7 357	retained at 6- and 12-months. This finding agrees with those of Bhatt et al., who found that resistance
8 9 358 10	to falling following a slip was retained up to 6-months after a single PBT session. ³⁶ Despite these
11 359 12	retained improvements in reactive balance control, PBT participants did not have a significantly
¹³ 360	reduced fall risk than control participants. Falls occur when there is a loss of balance and subsequent
15 16 361 17	failure to recover. ³⁹ Improved reactive balance control following PBT should help to prevent falls by
18 362 19	improving the ability to recover from a loss of balance. Loss of balance can occur due to an external
²⁰ 363	force or failure of anticipatory balance control. Thus, it is possible that effective fall prevention post-
22 23 364 24	stroke requires sustained improvements in both anticipatory and reactive balance control; home
25 365 26	exercise may help participants to retain improvements in anticipatory balance control. ³⁷
²⁷ 366 28	Contrary to our hypothesis, control participants reported greater social integration 6-12 months
²⁹ 30 367	post-training than the PBT group. Individual-item SIPSO scores suggest that this finding was primarily
31 32 368 33	driven by control participants reporting increased independence in moving around their local
34 369 35	neighbourhoods. The control training program included walking practice during every session, whereas
³⁶ 37370	the PBT program only included short bouts of walking in later sessions. This walking practice may
38 39 371 40	have increased control participants' confidence with community mobility. While increased social
41 372 42	integration at 6-12 months was not associated with improved physical function, it is likely that the tests
43 373 44	used in the current study do not correlate highly with community mobility. ⁴⁰ Training-related
45 46 374 47	improvements in balance and mobility in both groups, and increased self-reported participation in the
48 375 49	control group, were not associated with increased physical activity post-training. While impaired
⁵⁰ 376 51	balance and mobility post-stroke may be a barrier to physical activity, ⁴¹ improved balance and mobility
52 53 54 55	alone is not sufficient to increase activity. ^{7,42} It is likely that an intervention that combines behaviour
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change techniques with physical exercise is required to increase long-term participation in physical 378 activity.43 379

Examining fall characteristics can provide further insight into intervention effects on falls.²⁰ 380 Individuals with stroke seem to be reliant upon upper-extremity reactions to prevent falls in daily life.²⁷ 381 10 11 382 In the current study, participants had something in their hands at the time of the fall for more control 12 13 383 group falls than PBT falls, which may have prevented these individuals from using an upper-extremity 14 15 reaction to prevent the fall.⁴⁴ Conversely, training, with a specific focus on reactive stepping, may have 16 384 17 18 3 8 5 made PBT participants less reliant on upper extremity reactions to prevent falls. Participants required 19 ²⁰ 386 assistance to get up from the ground after more PBT group than control group falls; this finding could 21 22 ⁻⁻₂₃ 387 suggest that those PBT participants who fell were more impaired than PBT participants who did not fall 24 or than those in the control group who fell. 25 388 26

29 ²₃₀ 390 Limitations

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The primary outcome (falls in daily life) was obtained via self-report. While the method of prospective 32 391 33 falls reporting used in the current study is the best available,⁴⁵ falls may have been under-reported. The 34 392 35 36 393 cohort was, on average, relatively high functioning (e.g., median BBS score $\sim 50/56$), but had a wide 37 38 39 394 range of physical function (minimum scores for CMSA leg: 3, CMSA foot: 2, BBS: 23, mini-BEST: 5; 40 41 3 9 5 maximum NIH-SS score: 13; highest TUG time: 119s). This study's findings apply to community-42 43 396 dwelling individuals with chronic stroke who can stand independently for at least 30s. Group allocation 44 45 blinding was violated for 9 participants. Balance measures for these participants were re-scored by a 47 48 398 truly blinded research assistant; however, knowledge of group allocation may have sub-consciously 49 50 399 influenced how other data were collected for these participants. 51

52 400 PASIPD scores were higher at the time points when the questionnaire was administered in-53 54 person compared to over the telephone. Physical activity questionnaires, including the PASIPD,³² are 55 401

2 often designed to have several methods of administration (e.g., self-administered via in-person or 402 4 telephone interview).⁴⁶ When used in practice, investigators seem to treat administration methods as 403 404 equivalent; for example, in a multi-site validation study of the International Physical Activity 8 9 405 Questionnaire, some sites administered the questionnaire via telephone interview and others via in-10 person interview.⁴⁷ We are not aware of any study that directly compared scores from the PASIPD or 11 406 12 13 407 any other physical activity questionnaire when administered using different methods. It is possible that 14 15 16 408 scores are higher when administered in-person versus over the telephone as participants' desire for 17 18 4 09 social acceptance was higher when they interacted directly with the research assistant. Alternatively, 19 ²⁰ 410 in-person administration may have led to more accurate scores than telephone administration within 21 22 $\frac{-}{23}$ 411 this population, who may have subtle cognitive-communication deficits, as the research assistant and 24 participant could avail of non-verbal communication to facilitate completing the questionnaire. 25 4 1 2 26 ²⁷ 413 However, SIPSO scores did not differ between telephone versus in-person administration. Finally, 28 29 ²⁹₃₀414 participants in the current study may have truly been more active in the week prior to the in-person 31 32 415 interview compared to the telephone interview to prepare for the tests of physical function. Future 33 34 4 1 6 studies should investigate the potential influence of administration methods on physical activity 35 36 417 questionnaire scores. 37 38 39 418 40

41 4 1 9 **Clinical implications** 42

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⁴³ 420 While this study found that PBT did not reduce fall rates among the entire cohort, PBT participants 44 45 46 421 improved reactive balance control and retained these improvements up to 12-months post-training. 47 48 4 2 2 Combined with results of previous studies reporting reduced fall rates following PBT among 49 ⁵⁰ 423 individuals with sub-acute stroke,²⁰ chronic stroke with a history of falling,⁴⁸ and without stroke,¹⁴ 51 52 424 these results suggest that PBT may be a useful addition to existing balance training post-stroke. Joint 53 54 55 425 pain was the most common adverse event related to PBT, which appeared to be most prevalent among

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1 2 426	those with lower-extremity arthritis; these participants were able to complete training with
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4 427 5	modifications to avoid exacerbating pain (e.g., temporarily reducing perturbation intensity). Therefore,
6 7 428	modifications to PBT may be required for those with lower-extremity arthritis. Regular 'booster' PBT
8 9 429	training sessions may be necessary to prevent falls long-term.
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1 2 432 3	Contributorship statement: AM conceived of the study, is the grant holder, performed statistical
4 433 5	analysis and drafted the manuscript. AM, VGD, ASI, DB, ELI, and GM developed the study protocol.
6 7 434	AM and GM led implementation of the study at each site. AM, VGD, and ELI developed the
8 9 435	intervention. AA, AC and ASI collected data. CJD and SK delivered the interventions. All authors
10 11 436 12	approved the final manuscript.
$^{13}_{14}437$	Competing interests statement: The authors declare that they have no competing interests.
15 16 438 17	Data sharing statement: Due to research ethics and privacy restrictions, raw data for this study are
18 439 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48	currently not available publically.
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1 2 440 3	REF	ERENCES
3 4 441 5	1.	Batchelor FA, Mackintosh SF, Said CM, Hill KD. Falls after stroke. Int J Stroke.
6 7 442		2012;7(6):482-490.
8 9 443	2.	Andersson ÅG, Kamwendo K, Apperlros P. Fear of falling in stroke patients: relationship with
10 11 444 12		previous falls and functional characteristics. Int J Rehabil Res. 2008;31:261-264.
13 14 14	3.	Schmid AA, Van Puymbroeck M, Altenburger PA, et al. Balance and balance self-efficacy are
15 16 446		associated with activity and participation after stroke: a cross-sectional study in people with
17 18 447		chronic stroke. Arch Phys Med Rehabil. 2012;93:1101-1107.
19 20 448 21	4.	Sherrington C, Michaleff ZA, Fairhall N, et al. Exercise to prevent falls in older adults: an
21 22 23 449		updated systematic review and meta-analysis. Br J Sports Med. 2016;doi:10.1136/bjsports-
24 25 450		2016-096547.
26 27 451	5.	Verheyden GS, Weerdesteyn V, Pickering RM, et al. Interventions for preventing falls in
28 29 30 452		people after stroke. <i>Cochrane Database Syst Rev.</i> 2013;31(5):CD008728.
31	(
32 453 33	6.	Batchelor F, Hill K, Mackintosh S, Said C. What works in falls prevention after stroke? a
³⁴ 454 35		systematic review and meta-analysis. Stroke. 2010;41(8):1715-1722.
³⁶ 37 455	7.	Dean CM, Rissel C, Sherrington C, et al. Exercise to enhance mobility and prevent falls after
38 39 456		stroke: the community stroke club randomized trial. Neurorehabil Neural Repair.
40 41 457 42		2012;26(9):1046-1057.
$43 \\ 44 \\ 458$	8.	Gardner MM, Buchner DM, Robertson MC, Campbell AJ. Practical implementation of an
45 46 459		exercise-based falls prevention programme. Age Ageing. 2001;30:77-83.
47 48 460	9.	Dean CM, Richards CL, Malouin F. Task-related circuit training improves performance of
49 ⁵⁰ 461		locomotor tasks in chronic stroke: a randomized controlled pilot trial. Arch Phys Med Rehabil.
51 52 53 462		2000;81:409-417.
54		
55 56		
57 58		23

1 2 463	10.	Eng JJ, Chu KS, Kim CM, Dawson AS, Carswell A, Hepburn KE. A community-based group	
3 4 464 5		exericse program for persons with chronic stroke. Med Sci Sports Exerc. 2003;35(8):1271-1278.	
$^{6}_{7}$ 465	11.	Salbach NM, Mayo NE, Wood-Dauphinee S, Hanley JA, Richards CL, Côté R. A task-oriented	
8 9 466		intervention enhances walking distance and speed in the first year post stroke: a randomized	
10 11 467		controlled trial. Clin Rehabil. 2004;18:509-519.	
12 13 14 468	12.	Maki BE, McIlroy WE. The role of limb movements in maintaining upright stance: the	
15 16 469		"change-in-support" strategy. Phys Ther. 1997;77:488-507.	
17 18 470	13.	Gerards MHG, McCrum C, Mansfield A, Meijer K. Perturbation-based balance training for falls	
19 20 21 471		reduction among older adults: current evidence and implications for clinical practice. Geriatr	
22 23 472		Gerontol Int. 2017;doi:10.1111/ggi.13082.	
24 25 473	14.	Mansfield A, Wong JS, Bryce J, Knorr S, Patterson KK. Does perturbation-based balance	
26 27 474		training prevent falls? A review and meta-analysis of preliminary randomized controlled trials.	
28 29 30 475		<i>Phys Ther</i> . 2015;95(5):700-709.	
31 32 476	15.	Mansfield A, Inness EL, Lakhani B, McIlroy WE. Determinants of limb preference for	
33 34 477		initiating compensatory stepping post-stroke. Arch Phys Med Rehabil. 2012;93:1179-1184.	
35 36 37 478	16.	de Kam D, Roelofs JMB, Bruijnes AKBD, Geurts ACH, Weerdesteyn V. The next step in	
38 39 479		understanding impaired reactive balance control in people with stroke: the role of defective	
40 41 480		early automatic postural responses. Neurorehabil Neural Repair. 2017;31(8):708-716.	
42 43 44 481	17.	Mansfield A, Wong JS, McIlroy WE, et al. Do measures of reactive balance control predict falls	
45 46 482		in people with stroke returning to the community? <i>Physiotherapy</i> . 2015;101(4):373-380.	
47 48 483	18.	Mansfield A, Inness EL, Wong JS, Fraser JE, McIlroy WE. Is impaired control of reactive	
49 ⁵⁰ 484		stepping related to falls during inpatient stroke rehabilitation? Neurorehabil Neural Repair.	
51 52 53 485		2013;27(6):526-533.	
54 55			
56 57			
58		24	

59

1 2 486 3	19.	Mansfield A, Inness EL, Komar J, et al. Training rapid stepping responses in an individual with
4 487 5		stroke. Phys Ther. 2011;91(6):958-969.
6 7 488	20.	Mansfield A, Schinkel-Ivy A, Danells CJ, et al. Does perturbation training prevent falls after
8 9 489		discharge from stroke rehabilitation? A prospective cohort study with historical control. J
10 11 490		Stroke Cerebrovasc Dis. 2017;26(10):2174-2180.
12 13 14 491	21.	Mansfield A, Aqui A, Centen A, et al. Perturbation training to promote safe independent
15 16 492		mobility post-stroke: study protocol for a randomized controlled trial. <i>BMC Neurol</i> . 2015;15:87.
17 18 493	22.	Thomas S, Reading J, Shephard RI. Revision of the Physical Activity Readiness Questionnaire
19 20 21 494		
21		(PAR-Q). Can J Sport Sci. 1992;174:338-345.
22 23 495 24	23.	French E, Reinikka K, MacLeod A. Community-based exercise for people living with stroke.
24 25 496 26		http://www.tbrhsc.net/clinical_partners/regional_stroke_program/video_resources/community_
20 27 497 28		based_exercise.asp. Accessed 1 Aug, 2013.
29 30 498	24.	Shumway-Cook A, Woollacott MH. Motor control: translating research into clinical practice.
31 32 499		3rd ed. Philadelphia: Lippincott Williams & Wilkins; 2007.
33 34 500	25.	Goldstein LB, Bertels C, Davis JN. Interrater reliability of the NIH Stroke Scale. Arch Neurol.
35 36 37 501		1989;46(6):660-662.
38		
39 502 40	26.	Gowland C, Stratford P, Ward M, et al. Measuring physical impairment and disability with the
41 503 42		Chedoke-McMaster Stroke Assessment. Stroke. 1993;24:58-63.
$\frac{43}{44}504$	27.	Hyndman D, Ashburn A, Stack E. Fall events among people with stroke living in the
45 46 505		community: circumstances of falls and characteristics of fallers. Arch Phys Med Rehabil.
47 48 506		2002;83:165-170.
49 50 507	28.	Berg K, Wood-Dauphinée S, Williams JI, Gayton D. Measuring balance in the elderly:
51 52 53 508		preliminary development of an instrument. <i>Physiother Can.</i> 1989;41:304-311.
54		
55 56		
57		
58 59		25
60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1		
2 509 3	29.	Frachignoni F, Horak F, Godi M, Nardone A, Giordani A. Using psychometric techniques to
$\frac{4}{5}$ 510		improve the balance evaulation systems test: the mini-BES test. J Rehabil Med.
6 7 511		2010;42(4):323-331.
8 9 512 10	30.	Podsiadlo D, Richardson S. The Timed "Up & Go": A test of basic functional mobility for frail
11 513 12		elderly persons. J Am Geriatr Soc. 1991;39:142-148.
13 14 514	31.	Powell LE, Myers AM. The Activities-specific Balance Confidence (ABC) Scale. J Gerontol A
15 16 515		<i>Biol Sci Med Sci.</i> 1995;50A(1):M28-34.
17 18 516 19	32.	Washburn RA, Zhu W, McAuley E, Frogley M, Figoni SF. The Physical Activity Scale for
²⁰ 517		Individuals with Physical Disabilities: development and evaluation. Arch Phys Med Rehabil.
22 23 518		2002;83:193-200.
24 25 519	33.	Trigg R, Wood VA. The Subjective Index of Physical and Social Outcome (SIPSO): a new
26 27 520 28		measure for use with stroke patients. Clin Rehabil. 2000;14(3):288-299.
²⁹ 30 521	34.	Tang Y. Sample size estimation for negative binomial regression comparing rates of recurrent
31 32 522		events with unequal follow-up time. J Biopharm Stat. 2015;25(5):1100-1113.
33 34 523 35	35.	van Duijnhoven HJR, De Kam D, Hellebrand W, Smulders E, Geurts ACH, Weerdesteyn V.
$\frac{36}{37}524$		Development and process evaluation of a 5-week exercise program to prevent falls in people
38 39 525		after stroke: the FALLS program. Stroke Res Treat. 2012;2012:407693.
40 41 526	36.	Bhatt T, Yang F, Pai Y-C. Learning to resist gait-slip falls: long-term retention in community-
42 43 44 527		dwelling older adults. Arch Phys Med Rehabil. 2012;93:557-564.
45 46 528	37.	Batchelor FA, Hill KD, Mackintosh SF, Said CM, Whitehead CH. Effects of a multifactorial
47 48 529		falls prevention program for people with stroke returning home after rehabilitation: a
49 50 530		randomized controlled trial. Arch Phys Med Rehabil. 2012;93(9):1648-1655.
51 52		
53 54		
55		
56 57		
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59

1 2 531 3	38.	Mansfield A, Peters AL, Liu BA, Maki BE. Effect of a perturbation-based balance-training
4 532 5		program on compensatory stepping and grasping reactions in older adults: a randomized
6 7 533		controlled trial. Phys Ther. 2010;90(4):476-491.
8 9 534	39.	Maki BE, McIlroy WE. Postural control in the older adult. Clin Geriatr Med. 1996;12(4):635-
10 11 535 12		658.
12 13 14 536	40.	Robinson CA, Shumway-Cook A, Matsuda PN, Ciol MA. Understanding physical factors
15 16 537		associated with participation in community ambulation following stroke. Disabil Rehabil.
17 18 538 19		2011;33(12):1033-1042.
²⁰ 539	41.	Nicholson S, Sniehotta FF, van Wijck F, et al. A systematic review of perceived barriers and
22 23 540		motivators to physical activity after stroke. Int J Stroke. 2013;8:357-364.
24 25 541	42.	Mudge S, Barber PA, Stott S. Circuit-based rehabilitation improves gait endurance but not usual
26 27 542 28		walking activity in chronic stroke: a randomized controlled trial. Arch Phys Med Rehabil.
²⁹ 30 543		2009;90:1989-1996.
31 32 544	43.	Morris JH, MacGillivray S, Mcfarlane S. Interventions to promote long-term participation in
33 34 545 35		physical activity after stroke: a systematic review of the literature. Arch Phys Med Rehabil.
³⁶ 37 546		2014;95:956-967.
38 39 547	44.	Bateni H, Zecevic A, McIlroy WE, Maki BE. Resolving conflicts in task demands during
40 41 548 42		balance recovery: does holding an object inhibit compensatory grasping? Exp Brain Res.
43 44 549		2004;157:49-58.
45 46 550	45.	Lamb SE, Jørstad-Stein EC, Hauer K, Becker C. Development of a common outcome data set
47 48 551		for fall injury prevention trials: The Prevention of Falls Network Europe consensus. J Am
49 50 552 51		<i>Geriatr Soc.</i> 2005;53(9):1618-1622.
52 53		
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1 2 553 3	46.	Strath SJ, Kaminsky LA, Ainsworth BE, et al. Guide to the assessment of physical activity:
4 554 5		clinical and research applications. A scientific statement from the American Heart Association.
$\frac{6}{7}$ 555		Circulation. 2013;128:2259-2279.
8 9 556	47.	Craig CL, Marshall AL, Sjöström M, et al. International physical activity questionnaire: 12-
10 11 557 12		country reliability and validity. Med Sci Sports Exerc. 2003;35(8):1381-1395.
$\frac{13}{14}558$	48.	Marigold DS, Eng JJ, Dawson AS, Inglis JT, Harris JE, Gylfadóttir S. Exercise leads to faster
15 16 559		postural reflexes, improved balance and mobility, and fewer falls in older persons with chronic
17 18 560		stroke. J Am Geriatr Soc. 2005;53:416-423.
19 20 21 561	49.	Robinovitch SN, Feldman F, Yang Y, et al. Video capture of the circumstances of falls in
22 23 562		elderly people residing in long-term care: an observational study. <i>Lancet</i> . 2013;381(9860):47-
24 25 563		54.
26 27 564 28		
28 29 30 565		
30 5 6 5 31 32 566		
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TABLES

Table 1: Participant characteristics at study enrolment. Values presented are medians with interquartile range in parentheses (for continuous/ordinal variables) or number with percentage in parentheses (for count/frequency variables). The p-value is for the Wilcoxon-Mann-Whitney test 11 571 (continuous/ordinal variables) or Fisher's exact test (count/frequency variables).

	PBT (n=41)	Control (n=42)	p-value
Age (years)	66 (17)	67 (13)	0.84
Sex (number, %)			
Female	15 (36.6)	12 (28.6)	0.49
Male	26 (63.4)	30 (71.4)	
Time post-stroke (years)	2.0 (3.3)	3.2 (4.5)	0.086
More affected side (number, %)			
Left	22 (53.7)	22 (52.4)	>0.99
Right	19 (46.3)	20 (47.6)	
NIH-SS (score)	3 (4)	3 (5)	0.57
CMSA leg (score)	5 (1)	5(1)	0.54
CMSA foot (score)	5 (3)	5 (1)	0.45
ABC scale (%)	65.6 (26.3)	79.1 (33.8)	0.42
BBS (score)	50 (10)	51 (7)	0.94
Mini-BEST (score)	18 (7)	18 (5)	0.95
TUG (s)	14.4 (12.3)	13.0 (7.6)	0.62
PASIPD (score)	8.4 (9.5)	11.6 (10.9)	0.48
SIPSO (score)	30 (9)	31 (13)	0.74
Fall in the past year (number, %)			
Yes	17 (41.5)	18 (42.9)	>0.99
No	24 (58.5)	24 (57.1)	

Balance Evaluation Systems Test, CMSA=Chedoke-McMaster Stroke Assessment, NIH-SS=National

44 574 Institutes of Health Stroke Scale; PASIPD=Physical Activity Scale for Individuals with Physical

46 575 Disabilities, SIPSO=Subjective Index of Physical and Social Outcome.

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577 Table 2: Balance and mobility measures between groups. Values presented are least-square means

578 with 95% confidence intervals in brackets. The p-value is for the ANCOVA comparing groups at each

579 time point, controlling for the baseline value.

	DDT		1
Post training	PBT	Control	p-value
Post-training N	39	38	
ABC (%)	75.6 [71.6, 79.7]	78.2 [74.1, 82.2]	0.97
BBS (score)	50.8 [50.0, 51.7]	51.2 [50.3, 52.1]	0.97
Mini-BEST (score)	20.3 [19.6, 21.0]	20.1 [19.3, 20.8]	0.99
BEST-anticipatory (score)	4.4 [4.2, 4.6]	4.4 [4.2, 4.6]	0.90
BEST-reactive (score)	4.2 [3.7, 4.7]	3.6 [3.0, 4.1]	0.044
BEST-sensory (score)	5.3 [5.2, 5.5]	5.6 [5.4, 5.7]	0.0084
BEST-gait (score)	6.4 [6.0, 6.7]	6.6 [6.2, 7.0]	0.0034
TUG (s)	17.5 [15.8, 19.2]	17.4 [15.7, 19.1]	0.44
6-month follow-up	17.5 [15.6, 17.2]	17.4 [13.7, 17.1]	0.50
N	30*	30^{*}	
ABC (%)	75.4 [70.1, 80.8]	74.1 [68.6, 79.5]	0.70
BBS (score)	50.2 [49.2, 51.2]	51.3 [50.3, 52.4]	0.11
Mini-BEST (score)	19.8 [18.9, 20.7]	19.1 [18.2, 20.0]	0.81
BEST-anticipatory (score)	4.3 [4.0, 4.6]	4.3 [4.0, 4.6]	0.99
BEST-reactive (score)	4.0 [3.4, 4.5]		0.0055
BEST-sensory (score)	5.4 [5.1, 5.7]	5.4 [5.2, 5.7]	0.44
BEST-gait (score)	6.2 [5.6, 6.7]	6.5 [6.0, 7.1]	0.25
TUG (s)	16.8 [15.3, 18.2]	15.4 [13.9, 16.9]	0.32
2-month follow-up			
N	27^{\dagger}	29 [†]	
ABC (%)	75.2 [69.3, 81.1]	78.1 [72.1, 84.0]	0.95
BBS (score)	50.6 [49.5, 51.6]	51.1 [50.0, 52.1]	0.27
Mini-BEST (score)	20.6 [19.4, 21.8]	18.7 [17.5, 19.8]	0.049
BEST-anticipatory (score)	4.3 [4.0, 4.6]	4.3 [3.9, 4.6]	0.45
BEST-reactive (score)	4.2 [3.6, 4.9]	2.6 [2.0, 3.2]	0.0013
BEST-sensory (score)	5.4 [5.1, 5.7]	5.4 [5.1. 5.6]	0.64
BEST-gait (score)	6.6 [6.0, 7.3]		0.90
TUG (s)	15.7 [14.3, 17.2]		0.79
ABC=activities-specific balance	e confidence scale; B	BS=Berg balance sca	ale; BEST=ba
watering togt			
systems test.			
*N=32 PBT and 31 control for t	he ABC at 6-month	follow-up. [†] N=31 PB	T and 31 con
at 12-month follow-up.			
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Table 3: Physical activity and social integration between groups. Values presented are least-square

585 means with 95% confidence intervals in brackets The p-value is for the ANCOVA comparing groups at

586 each time point, controlling for the baseline value.

	PBT	Control	p-value
Post-training			
N	39	38	
PASIPD (score)	12.3 [10.0, 14.6]	11.2 [8.8, 13.6]	0.92
SIPSO (score)	29.8 [28.1, 31.4]	31.2 [29.5, 32.9]	0.29
2-month follow-up			
N	38	31	
PASIPD (score)	8.6 [6.4, 10.8]	9.5 [7.1, 11.9]	0.51
SIPSO (score)	29.7 [28.2, 31.2]	31.5 [29.8, 33.21]	0.23
4-month follow-up			
N	33	34	
PASIPD (score)	9.2 [7.3, 11.2]	7.8 [5.9, 9.8]	0.34
SIPSO (score)	30.0 [28.2, 31.9]	30.2 [28.4, 32.0]	0.62
6-month follow-up			
N	32	31*	
PASIPD (score)	11.3 [7.3, 15.3]	10.9 [6.8, 15.0]	0.21
SIPSO (score)	30.3 [29.0, 31.6]	32.6 [31.3, 33.9]	0.012
8-month follow-up			
N	31	26	
PASIPD (score)	7.0 [5.6, 8.4]	6.9 [5.4, 8.5]	0.61
SIPSO (score)	30.5 [29.3, 31.7]	32.3 [31.0, 33.6]	0.037
10-month follow-up			
N	32	32	
PASIPD (score)	7.0 [5.5, 8.5]	8.2 [6.7, 9.7]	0.16
SIPSO (score)	29.9 [28.4, 31.3]	32.3 [30.9, 33.8]	0.031
12-month follow-up			
N	31	31	
PASIPD (score)	11.1 [7.4, 14.8]	10.1 [6.4, 13.9]	0.27
SIPSO (score)	30.6 [29.1, 32.0]	32.6 [31.1, 34.0]	0.047

⁴⁵ 588 physical and social outcome

 ${}^{47}_{48}$ 589 *N=30 control for the SIPSO

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Table 4: Between-group comparison of fall circumstances. Values are the number of falls in each category, with the percentage of falls in parentheses. The percentage was calculated from the total number of falls for which information was available (i.e., "do not recall" responses were excluded from the denominator). Percentages might not sum to 100 due to rounding error. The p-value is for Fisher's 11 594 exact test comparing the two groups, excluding "do not recall" responses from analysis.

	PBT (53 falls)	Control (64 falls)	p-value
Cause of fall	· · ·		
Do not recall	8	6	
Slip	16 (35.6)	22 (37.9)	0.26
Trip	11 (24.4)	6 (10.3)	
Push/external force	1 (2.2)	3 (5.2)	
Incorrect weight transfer ⁴⁹	17 (37.8)	13 (46.6)	
Posture at the time of the fall			
Do not recall	7	4	
Lying	1 (2.2)	0 (0)	0.33
Sitting	4(8.9)	7 (12.1)	0.55
	9 (20.0)		
Standing Walking		6 (10.3)	
Walking	32 (68.9)	47 (77.6)	
Motor activity at the time of the fall	7	4	
Do not recall	7	4	0.010
Not moving	4 (8.9)	2 (3.5)	0.010
Transferring	2 (4.4)	12 (20.7)	
Turning/reaching/bending	10 (22.2)	3 (5.2)	
Walking on level surface	18 (37.8)	20 (34.5)	
Walking on ramp/stairs/uneven surface	12 (26.7)	21 (36.2)	
Cognitive activity at the time of the fall			
Do not recall	10	9	
None	34 (78.6)	44 (81.1)	0.80
Distracted	9 (21.4)	11 (18.9)	
Where did the fall occur			
Outdoors	19 (35.8)	22 (34.4)	>0.99
Indoors	34 (64.2)	12 (65.6)	0.77
Using an assistive device	51 (01.2)	12 (05.0)	
Do not recall	7	5	
Never use one	11	21	
No			0.006
	16 (45.7)	24 (66.7)	0.096
Yes Uslding onto a hondrail	19 (54.3)	12 (33.3)	
Holding onto a handrail	7	6	
Do not recall	7	6	0.41
No	41 (89.1)	48 (82.8)	0.41
Yes	5 (10.9)	10 (17.2)	

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	PBT (53 falls)	Control (64 falls)	p-value
Anything in hands			
Do not recall	9	6	
No	34 (77.3)	32 (55.2)	0.02
Yes (one or both hands)	10 (22.7)	26 (44.8)	
Action to try to prevent the fall		. ,	
Do not recall	9	18	
None	27 (61.4)	28 (60.9)	0.18
Grasp	8 (18.2)	14 (30.4)	
Step or step + grasp	9 (20.5)	4 (8.7)	
Length of lie on floor or ground	(_0.0)	. (0.77)	
Do not recall	7	4	
A few minutes or less	39 (84.8)	57 (95.0)	0.09
More than a few minutes but less than an hour	7 (15.2)	3 (5.0)	0.070
	7 (13.2)	5 (5.0)	
Assistance required to get up from fall Do not recall	7	1	
	7	4	0.04
No	24 (52.2)	44 (73.3)	0.040
Yes	22 (47.8)	16 (26.7)	
Injuries	-	-	
Do not recall	7	5	
None	28 (60.9)	39 (66.1)	0.68
Cuts or bruises	17 (37.0)	19 (32.2)	
Joint sprain or dislocation	1 (2.2)	1 (1.7)	
Medical assistance required after fall			
Do not recall	-7	5	
No injuries	30	42	
Injured but did not seek treatment	16 (100)	14 (82.4)	0.23
Saw other healthcare professional	0 (0)	1 (5.9)	
Treated in hospital emergency room	0 (0)	2 (11.8)	
*Analysis compared injury vs no injury			
5 1 5 5 5 5			
[†] Analysis compared sought treatment vs did not se	eek treatment		

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11 603 16 6 05 18 606 ²⁰ 607 ₂₃ 608 25 609 ²⁷ 610 30⁶¹¹

FIGURE CAPTIONS

Figure 1: Participant flow through the study. Eight participants who consented to participate in the study were excluded on the initial assessment because they could not tolerate the lean-and-release postural perturbations. Participants were withdrawn after randomization because it became apparent that they did not meet the study criteria (1 PBT participant had osteoporosis with history of fracture, and 1 control participant had uncontrolled hypertension), or because they had a significant decline in health during the training portion of the study (1 PBT and 1 control participant). One PBT participant was withdrew from the study because she did not like the group allocation. Therefore, there were 42 control participants and 41 PBT participants available for analysis of the primary outcome (falls in daily life). Participants withdrew during the 12-month follow-up period because they: no longer wished to be in the study (2 PBT, 1 control); experienced a serious adverse event (2 PBT, 5 control); were lost to follow-up (2 PBT, 3 control); or enrolled in a conflicting study (2 PBT). C.C.Z.O.J.

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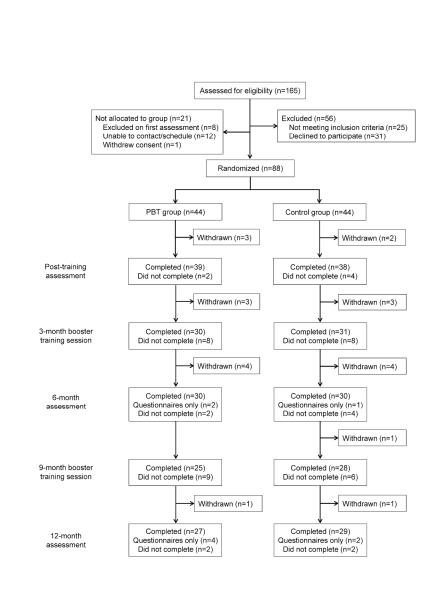


Figure 1: Participant flow through the study. Eight participants who consented to participate in the study were excluded on the initial assessment because they could not tolerate the lean-and-release postural perturbations. Participants were withdrawn after randomization because it became apparent that they did not meet the study criteria (1 PBT participant had osteoporosis with history of fracture, and 1 control participant had uncontrolled hypertension), or because they had a significant decline in health during the training portion of the study (1 PBT and 1 control participant). One PBT participant was withdrew from the study because she did not like the group allocation. Therefore, there were 42 control participants and 41 PBT participants available for analysis of the primary outcome (falls in daily life). Participants withdrew during the 12-month follow-up period because they: no longer wished to be in the study (2 PBT, 1 control); experienced a serious adverse event (2 PBT, 5 control); were lost to follow-up (2 PBT, 3 control); or enrolled in a conflicting study (2 PBT).

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SUPPLEMENTARY TABLES

Table S1: Balance and mobility measures, change over time. Values presented are the differences from pre-training with 95% confidence intervals in brackets. A positive difference value indicates an improvement for all variables except the TUG, where a negative value indicates an improvement (i.e., faster TUG time compared to baseline).

faster TUG time compared to ba	PBT	Contro
Post-training		
N	39	38
ABC (%)	5.2 [0.7, 9.8]	6.6 [1.5, 11.6
BBS (score)	1.8 [0.7, 2.9]	1.9 [1.0, 2.9
Mini-BEST (score)	2.6 [1.8, 3.4]	2.2 [1.5, 3.0
BEST-anticipatory (score)	0.5 [0.2, 0.8]	0.5 [0.2, 0.8
BEST-reactive (score)	1.5 [0.9, 2.1]	0.8 [0.3, 1.2
BEST-sensory (score)	0 [-0.2, 0.2]	0.3 [0.0, 0.5
BEST-gait (score)	0.6 [0.1, 1.0]	0.7 [0.3, 1.1
TUG (s)	-1.0 [-2.9, 0.8]	-1.1 [-2.8, 0.5
6-month follow-up		
N	30*	30
ABC (%)	3.5 [-2.3, 9.2]	0.6 [-5.2, 6.3
BBS (score)	0.3 [-0.8, 1.4]	1.3 [0.2, 2.4
Mini-BEST (score)	1.6 [0.6, 2.6]	0.8 [-0.1, 1.7
BEST-anticipatory (score)	0.3 [-0.1, 0.6]	0.3 [-0.1, 0.7
BEST-reactive (score)	1.2 [0.5, 1.8]	0.0 [-0.5, 0.5
BEST-sensory (score)	0.1 [-0.2, 0.3]	0.2 [-0.1, 0.5
BEST-gait (score)	0.1 [-0.6, 0.8]	0.3 [-0.1, 0.8
TUG (s)	1.0 [-1.0, 2.9]	-0.5 [-1.4, 0.5
12-month follow-up		
N	27^{\dagger}	29
ABC (%)	3.5 [-3.1, 10.2]	3.8 [-2.7, 10.3
BBS (score)	0.6 [-0.7, 1.8]	0.8 [-0.3, 2.0
Mini-BEST (score)	2.2 [0.9, 3.4]	0.1 [-1.1, 1.4
BEST-anticipatory (score)	0.2 [-0.1, 0.5]	0.2 [-0.2, 0.7
BEST-reactive (score)	1.4 [0.5, 2.3]	-0.4 [-1.0, 0.2
BEST-sensory (score)	0.1 [-0.2, 0.4]	0.1 [-0.1, 0.4
BEST-gait (score)	0.4 [-0.3, 1.2]	0.2 [-0.4, 0.8
TUG (s)	0.1 [-1.0, 1.2]	1.6 [-0.4, 3.6
ABC=activities-specific balance	e confidence scale:	BBS=Berg bala

ABC=activities-specific balance confidence scale; BBS=Berg balance scale; BEST=balance evaluation systems test.

^{*}N=32 PBT and 31 control for the ABC at 6-month follow-up. [†]N=31 PBT and 31 control for the ABC at 12-month follow-up.

Table S2: Physical activity and social integration, change over time. Values presented are the difference from pre-training with 95% confidence intervals in brackets. A positive difference value indicates an improvement.

indicates an improveme		Cart
	PBT	Control
Post-training		
Ν	39	38
PASIPD (score)	1.1 [-2.0, 4.2]	-1.0 [-3.1, 1.0]
SIPSO (score)	0.5 [-1.4, 2.5]	1.8 [0.0, 3.7]
2-month follow-up		
N	38	31
PASIPD (score)	-2.1 [-5.1, 0.8]	-2.8 [-5.8, 0.3]
SIPSO (score)	-0.1 [-1.7, 1.6]	1.5 [-0.4, 3.4]
4-month follow-up		
N	33	34
PASIPD (score)	-1.7 [-4.2, 0.8]	-4.1 [-6.6, -1.5]
SIPSO (score)	0.5 [-1.2, 2.2]	0.7 [-1.3, 2.7]
6-month follow-up	6	
N	32	31*
PASIPD (score)	0.4 [-5.3, 6.2]	-2.2 [-5.6, 1.1]
SIPSO (score)	0.3 [-1.0, 1.7]	2.5 [0.8, 4.2]
8-month follow-up		
N	31	26
PASIPD (score)	-4.5 [-7.3, -1.6]	-5.7 [-9.7, -1.6]
SIPSO (score)	0.2 [-1.1, 1.5]	1.8 [0.4, 3.3]
10-month follow-up		
N	32	32
PASIPD (score)	-4.1 [-6.6, -1.7]	-3.5 [-6.7, -0.4]
SIPSO (score)	-0.3 [-1.6, 1.0]	2.2 [0.4, 3.9]
12-month follow-up		
N	31	31
PASIPD (score)	0.4 [-4.6, 5.4]	-2.9 [-6.0, 0.2]
SIPSO (score)	0.8 [-0.7, 2.3]	2.7 [0.9, 4.4]
PASIPD=physical activ		

PASIPD=physical activity scale for individuals with physical disabilities; SIPSO=subjective index of physical and social outcome

^{*}N=30 control for the SIPSO

Program Manual

Program developed and manual written by: Avril Mansfield, Vincent DePaul, Cynthia Danells, Elizabeth Inness, Louis Biasin, Vivien Poon, and Svetlana Knorr

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Toronto Perturbation-Based Balance Training: Program Manual

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Toronto Perturbation-Based Balance Training: Program Manual

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INTRODUCTION

The goal of PBT is to improve reactive balance control in order to optimize safe independent mobility. The program requires that individuals repeatedly experience loss of balance (i.e., internal or manual postural perturbations) and are provided the opportunity to practice stepping reactions to regain balance following this instability. As participants adapt to the challenge and improve their balance control, the challenge should be increased. Challenge can be increased by increasing the ribar nsory fer clarity of expressic. pist, and masculine pro. magnitude of the manual perturbation, adding more challenging secondary movement and cognitive tasks, removing or altering sensory feedback, and changing the environment.

Note, for convenience and clarity of expression in this document, we use feminine pronouns to refer to the treating physiotherapist, and masculine pronouns to refer to the participant.

I. SCREENING AND ASSESSMENT

I.I An initial assessment is required to inform and guide treatment, and ensure patient safety.

Information regarding significant medical history is obtained; specifically, does the participant:

- Have arthritis in the lower extremities or any other joint pain;
- Normally wear glasses or contact lenses;
- Normally use a cane, a rollator, or any other mobility aid;
- Normally wear an orthotic (brace) around the ankle and/or knee;
- Normally wear a sling around the arm/shoulder;
- Have diabetes;
- Take any medication on an "as needed" basis (i.e., PRN medication);
- Report any recent falls; and
- Have fear of falling?

Modifications to the manner in which the program is provided may be made based on responses to the questions above. For example, some activities might be avoided to prevent exacerbation of a previous injury.

The initial assessment includes:

- Assessment of reactive stepping using
 - Forward-fall lean-and-release perturbations under two conditions: usual response and encouraged use (5 trials per condition); and
 - Observation of reactions in the 'Reactive' component of the mini-Balance Evaluation Systems (mini-BES) test.
- Consideration of some of the contributors to impaired reactive stepping:
 - Stroke severity/stroke symptoms e.g., using the National Institutes of Health Stroke Scale;
 - Stage of motor recovery e.g., using the Chedoke McMaster Stroke Assessment (CMSA);
 - Balance confidence e.g., using the Activity-specific Balance Confidence scale; and
 - Sensation (see Sections 1.4 and 1.5).

I.2 Lean and release assessment instructions.

Control of reactive stepping following a postural perturbation is assessed using a lean-and-release system. Participants wear a safety harness attached to an overhead support system. The harness is also connected at the back to a beam via a quick-release mechanism (i.e., a modified crossbow trigger). The participant must lean forward from the ankles far such that approximately 10% of his body weight supported by the cable. Once achieved, the cable is released creating a forward fall from which the participant needs to recover. He is instructed step as quickly as possible to regain balance and come to stable stance. If he cannot regain stability independently, then the assessor can aid in the recovery and prevent a 'fall' (i.e., being caught by the safety harness).

Two conditions are assessed and recorded on the score sheet (see Section 1.3) – the 'usual response' and the 'encouraged use'. The first five trials are completed as described above and the limb that

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responds first to the release is recorded. This is the **'usual response'**. If the same limb responds $\geq 4/5$ times, this is considered to be the 'preferred limb'. In the **'encouraged use'** condition, five trials are completed with the preferred limb blocked and the participant is instructed to attempt to react with the non-preferred limb. The blocking is accomplished with the hand or foot of the physiotherapist/assessor. If it appears that the participant is going to step with the blocked limb, the hand/foot can be removed quickly, but the participant is not told that the block will be removed. If there is no obvious preferred limb (i.e., participant stepped 3 times with one leg and 2 with the other), then the limb that is blocked should alternate 2 times for one limb and 3 for the other.

The lean-and-release assessment is video-recorded and the video is reviewed later to observe any participant-specific impairments in reactive stepping (see also Section 4). While it might be possible to observe some obvious impairments in 'real time', often the reaction happens so quickly that this is not possible.





Figure 1.1: The lean-andrelease system. Panel A (left) shows the usual response condition. Panel B (right) shows the encouraged-use condition. Figure taken from Mansfield et al., BMC Neurol. 2015;15:87



1.3 Lean and release collection sheet.

Usual response

- Participant wearing harness
- □ Aim for 10% body weight on the cable
- □ Random delay between 'ready' signal and perturbation
- Review video to determine preferred limb & assists (if not clear during testing)
- □ Record limb for first step

Test	Trial #	Comments	Limb	Assist
Ι			🛛 Right	🛛 No
			Left	Yes
2			🛛 Right	🛛 No
			Left	Yes
3			🛛 Right	🛛 No
			Left	Yes
4		<u> </u>	🛛 Right	🛛 No
			Left	Yes
5			🛛 Right	🛛 No
			Left	Yes

Preferred limb (initiated stepping in $\geq 4/5$ trials with this limb):

- 🛛 Right
- Left
- □ No clear preference

Encouraged use

- Block preferred limb with researchers hand/foot; if no limb preference do two trials blocking one limb and three blocking the other
- □ Aim for 10% body weight on the cable
- □ Random delay between 'ready' signal and perturbation
- □ Review video to determine preferred limb & assists (if not clear during testing)
- Record limb for first step

Test	Trial #	Comments	Limb	Assist
6			🛛 Right	🛛 No
			🖵 Left	🛛 Yes
7			🛛 Right	🛛 No
			🖵 Left	Yes
8			🛛 Right	🛛 No
			🖵 Left	Yes
9			🛛 Right	🛛 No
			🖵 Left	Yes
10			🛛 Right	🛛 No
			Left	Yes

I.4 Sensation assessment instructions.

Exteroceptive and proprioceptive sensation are assessed in the affected foot and ankle. It is necessary to know if the participant appreciates light touch and movement of the ankle and foot. If these are absent or decreased, steps should be taken to accommodate the deficits in order to minimize potential injury due to PBT.

Sensation is assessed with the participant sitting on a raised plinth, feet dangling, with shoes and socks removed. Demonstration of the test should be done with the participant's eyes open and administered to the less-affected foot/ankle. The actual test should be administered to the more-affected foot/ankle following the demonstration with the participant's eyes closed.

Light touch is assessed using a cotton ball; the cotton ball should lightly touch but not brush the sole of the participant's foot. The foot is touched 5 times and the participant is instructed to respond when the touch is felt. Responses are recorded on the score sheet (see Section 1.5). If there is no response (and you are certain that the participant understood the instructions) this is recorded as a negative response.

The **perception of joint movement** is assessed in the ankle (dorsiflexion and plantar flexion) and in the foot (inversion and eversion). The participant's foot is held in two places: the bony prominences of the first and fifth meta-tarsal phalangeal joints and at the medial and lateral malleoli. Movements of the ankle should be demonstrated on the less-affected side as "up" for dorsiflexion and "down" for plantar flexion and, of the foot, as "in" for inversion and "out" for eversion. Care should be taken not to change the pressure of the hold during the movement. When being tested, movements should be through small ranges and time should be allowed for the participant to respond. If the participant is unsure of the direction of the movement, the range should be increased. If the participant is still unsure, then this is a negative response for the test. Five movements should be tested at the ankle and five at the foot.

Each correct, incorrect, or absent response is recorded on the score sheet (Section 1.5). If the participant scores <4/5 for light touch appreciation, and/or <8/10 for joint movement perception, then consideration is made for use of an Aircast Airsport Ankle Brace during training.

1.5 Sensation assessment collection sheet.

Position recognition

Position	Correct response?
Dorsiflexion	Yes
	🛛 No
Plantarflexion	Yes
	🛛 No
Dorsiflexion	Yes
	🛛 No
Dorsiflexion	□ Yes
	No
Plantarflexion	Yes
	🛛 No
Number	
correct	

Position	Correct response?
Inversion	Yes
	🛛 No
Eversion	Yes
	🛛 No
Inversion	Yes
	🛛 No
Eversion	Yes
	🛛 No
Eversion	Yes
	🛛 No
Number correct	

If number correct is <8/10, an AirSport ankle brace should be used to prevent injury during PBT.

Light touch sensation

Light touch sen	sation	
Trial	Correct response?	
Trial I	□ Yes	
	🛛 No	· ·
Trial 2	□ Yes	
	🛛 No	
Trial 3	☐ Yes	4
	🛛 No	
Trial 4	☐ Yes	
	🛛 No	
Trial 5	□ Yes	
	🛛 No	
Number correct		

If number correct is <4/5, an AirSport ankle brace should be used to prevent injury during PBT.

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2.1 The program is individualized to the participant's specific impairments in reactive balance control

In order to create an effective training program, consideration is made of the participant's unique areas of dyscontrol (identified on initial assessment; see Section 1). Section 4 (Perturbation Training Log) outlines areas of dyscontrol and suggested treatment approaches for each problem. The principle of individual differences considers an individual's response to exercise. Therefore, progression should be gradual and systematic and occur at the individual participant's rate of improvement. Task difficulty is not absolute and could vary from participant-to-participant depending on specific control problems and other deficits.

2.2 List of equipment

The following equipment is required for this specific program:

- Overhead harness support track;
- Fall-arrest approved safety harness;
- Equipment for task-specific activities:
 - Thin foam mat (e.g., thickness of yoga mat or 2.5 cm gym mat);
 - Thick foam pad (dense blue foam);
 - Hand ball (2 sizes; e.g., 10 cm diameter and tennis ball);
 - Soccer ball;
 - Steps (10 cm and 20 cm high);
 - Stop watch;
 - Unstable 'step' (if an unstable step is not available, place a regular step on a thin foam mat);
 - Cross marked out in tape on the floor (2 pieces of tape each at least 60 cm long placed to intersect at right angles (see Figure 6.24);
 - Set of 6 23 cm diameter multi-colored Agility Dots;
 - Foam obstacles (e.g., pool noodles or half-round foam rollers); and
- Participant-specific equipment (e.g., walking aid, ankle brace/orthosis, helmet, arm sling).

2.3 Ensuring safety during training

2.3.1 Safety harness

Participants wear a safety harness attached to an overhead track at all times to prevent a fall to the ground. However, the harness system should be used as a back-up; the supervising physiotherapist still intervenes and provides physical assistance to 'brake the fall' when she feels the individual will not be able to recover balance. (Note, to allow participants the opportunity to practice stepping reactions, the physiotherapist **only** provides hands-on assistance if the participant is unable to regain stability alone.) The harness can prevent a fall to the floor but cannot prevent all possible injuries. Appropriate selection of participants, consideration of their underlying impairments, and appropriate supervision is still required. For example, it is possible that an individual could experience an ankle sprain while stepping in response to a perturbation (see Section 2.3.2). It is also possible that a frail individual who falls completely into the harness will experience an injury (e.g., bruise) because he is caught by the safety harness; a fracture could also be possible with a participant who has very low Version date: 20 October 2017 Page 10 of 59

bone mineral density. Participants should not be left 'dangling' in the safety harness as the straps can restrict circulation.

2.3.2 Protective equipment for ankle

An ankle-foot orthosis (AFO; if prescribed) or an Aircast AirSport Ankle Brace is used during PBT if the participant meets one or more of the following criteria:

- Participant typically uses an AFO during home and/or community walking;
- CMSA foot score is stage 3 or lower;
- Ankle joint position sense score is <8/10 (see Section 1.4 and 1.5);
- Light touch sensation of the plantar surface of the foot score is <4/5 (see Section 1.4 and 1.5); and/or
- The treating physiotherapist feels this is necessary to preserve stability of the ankle joint and prevent injury.

Use of the AirSport Ankle Brace, AFO, or any other assistive devices should be documented in the Perturbation Training Log (Section 4).

2.3.3 Monitoring heart rate and blood pressure

Heart rate (HR) and blood pressure (BP) are taken from the less affected arm using an automatic BP cuff. The less-affected arm is repositioned in an extended position resting on a table slightly below the level of the heart. If BP and/or HR fall outside of an 'acceptable' range (systolic BP is outside 90-140 mmHg; diastolic BP is outside 60-90 mmHg; or, HR is outside 60-100 bpm), a second measure is obtained. If the values continue to be outside of the range, the participant is asked to sit quietly for 5 minutes and perhaps, take a few deep breaths or drink a glass of water, before taking a third measurement. Participants with HR/BP measurements outside of the acceptable range are also questioned regarding recent medications (what they have taken and when, or if they have not taken their usual medications), when they last had something to eat/drink, and if the recently took caffeine, exercised, or smoked. The decision to continue or terminate the session is made by the physiotherapist considering factors such as the participants' usual resting HR/BP, how far the measured values are outside of the acceptable range, the participants' usual medication (e.g., betablockers), and the participants' perception of how they are feeling. If the visit is terminated, the physiotherapist may advise that the participant follow-up with his primary care physician. If the visit continues, the physiotherapist may choose to monitor HR and BP regularly throughout the visit and observe cardiovascular responses to exercise.

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3. THE PROGRAM

3.1 Overview

The PBT program involves 12 1-hour training sessions provided 2 times per week for 6 weeks. Each session is 60 minutes in length and is provided in a one-to-one format. This core program is modified to fit with delivery of in-patient rehabilitation to allow for evaluation among individuals with sub-acute stroke.

Sessions begin with a 10-minute warm-up and end with a 10-minute cool-down following the warmup and cool-down from the Keep Moving with Stroke program. Each session involves a minimum of ten 'voluntary' tasks that are each practiced for about 2 minutes. Once the participant is comfortable doing the task, the physiotherapist provides a manual perturbation to cause the participant to lose balance with the intent of evoking a reactive step (see Section 3.3). Six external perturbations are provided per task such that there are 60 external perturbations per session; however, fewer perturbations may be performed if participant tolerance is low. Participants might also experience a loss of balance (i.e., internal perturbation) due to failure to properly control balance during the voluntary task. Intensity of the session is determined by participant response; the participant should successfully regain stability with 1 or 2 steps and no assistance from the physiotherapist or safety harness 50% of the time. If the participant is too 'successful', the level of challenge is increased, or vice versa.

3.2 Voluntary Tasks

Each session involves 'voluntary' tasks that progress along a mobility continuum to evoke internal perturbations (i.e., loss of balance or self-destabilization):

- a) 'Stable' the voluntary task is to maintain a static base of support;
- b) 'Quasi-mobile' the voluntary task is to move the feet (e.g., stepping forward with alternate feet); however, the participant remains in place;
- c) 'Mobile' the voluntary task is to move from one location to another (e.g., walking, sidestepping); and
- d) 'Unpredictably mobile' the voluntary task is to move from one location to another in an unpredictable manner (e.g., kicking a soccer ball).

The challenge of each voluntary task can be influenced by manipulating other factors, such as:

- a) The sensory condition (e.g., firm to compliant surfaces, eyes open to eyes closed).
- b) The cognitive requirements (e.g. single task to multi-task, counting backwards, moving on cue).
- c) The environment (e.g., walking on even surface to walking over obstacles).

See "Description of Voluntary Tasks" in Section 5 for further information.

3.3 Methods of Perturbation

Internal perturbations are evoked when the participant attempts to perform a task that causes instability. Various voluntary tasks, including rapid 'agility' tasks (e.g., rapid step-ups) are used to evoke internal perturbations. A task that appears as easy as standing with eyes closed may cause an internal perturbation for a participant with poor balance control. However, some participants do not put themselves in situations causing a loss of balance or necessitating a stepping reaction (i.e., they will

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perform agility tasks slowly); therefore, external perturbations are also included in every session to ensure a sufficient training dose.

External perturbations are caused by a force outside of the participant's control. Small-magnitude external perturbations may be used with participants who have lower functional abilities. It is usually easiest to start with perturbations that cause a fall towards the physiotherapist (i.e., pull or lean-and-release) so that the physiotherapist can control the outcome and alleviate participants' anxiety and facilitate participants' perceptions of safety. There are three methods for evoking external perturbations: 1) lean-and-release (predictable direction/magnitude; 2) push/pull (can be unpredictable in terms of direction and magnitude; or 3) trip during walking (see Section 5 for details).

3.4 Measurement

Measures are taken throughout the training to ensure: 1) focus on participant-specific problems; 2) ongoing progression; and 3) participant safety. The Perturbation Training Log (Section 4) is used to document the following:

- Performance on reactive stepping linked to key areas of focus (e.g., if a goal is to reduce frequency of multiple stepping then frequency of multiple stepping should be documented);
- Number of repetitions (i.e., number of times the participant experiences a loss of balance): '0'
 = balance recovered using 2 steps or fewer; '1' = balance recovered using more than 2 steps; and, 'X' = assistance provided by the safety harness or physiotherapist to recover balance;

iez

- Additional tasks/conditions;
- Number of rest breaks;
- 'Rating of perceived challenge' (RPC) (Section 6);
- HR and/or BP (if indicated);

3.5 Format of training session

- I) Participant arrives.
- 2) HR and BP are taken.
- 3) Warm-up is completed.
- 4) Harness is donned.
- 5) Tasks, as outlined in the Perturbation Training Log (Section 4), are performed for that particular session. Detailed descriptions of each task can be found in Section 5.
- 6) Documentation about and scoring of each task are completed before moving on to the next task.
- 7) Rest is taken as required, or after each task.
- 8) Cool-down and stretching are completed.

e: Participant Equipment: AFO AirsSport Arm Sling Other Goal(s):	Affected side of body:	Does HR &/or BP need monitoring through session? Y N		
Goal(s): f Assessment Findings: ge (/7): Leg Foot ecognition (#correct/5): DF/PF INV/EV n (#correct/5): ce scale (/56): Reactive Postural Control (/12):	Affected side of body:			
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lease – Encouraged use trials (#): Right Left	Comments:			
lease – Encouraged use trials (#): Right Left				

BMJ Open

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Participant ID: _____

Date: _____

Treatment planning:

Area of dyscontrol	Treatment suggestions	Additional treatment strategies/comments
Requires external assist to regain stability	 Start with low-magnitude perturbation, increase magnitude as tolerated Consider other problems that contribute, like delayed stepping or no stepping 	
Does not step when magnitude of perturbation requires a step	 Instruct participant to step when s/he feels unstable Start with low-magnitude perturbations Start with predictable time/direction of perturbation Practice the step prior to perturbation Consider other problems that contribute, like unwillingness to step with paretic limb 	
Has low foot clearance during step: foot 'slides', or shuffles	Use obstacles to 'force' a step-over	O_{n}
Demonstrates delayed stepping reaction	 Instruct participant to step as quickly as possible Start with predictable time/direction of perturbation If delay is with non-paretic limb, have participant weight-shift to paretic limb prior to perturbation 	J.

Area of dyscontrol	Treatment suggestions	Additional treatment strategies/comments
Is unwilling to step with paretic limb	Block the non-paretic limb with obstacles, or hand/ foot of physiotherapist Instruct participant to step with paretic limb Start with predictable time/direction of perturbation Time perturbation to coincide with paretic leg/foot being un-weighted	
Demonstrates multi-step reactions	Instruct participant to take as few steps as possible Instruct participant to take long(er) steps	
Stands asymmetrically prior to perturbation	Instruct participant to increase loading on the less-loaded limb Consider using video or feedback of stance symmetry	
Takes short steps	Instruct participant to take longer steps Step to targets Step over obstacles	
Attempts to use upper extremity to regain stability	Physiotherapist should stand as far away as safely possible Instruct to not use reach-to-grasp reactions Have participant hold object to prevent grasping	3

Area of dyscontrol	Treatment suggestions	Additional treatment strategies/comments
□ Falls laterally on step termination	 Instruct participant to take as few steps as possible Start with low-magnitude perturbation Try forward/backward perturbations initially with a narrow base of support 	
Uses 'crossover' steps to respond to lateral perturbations	 Instruct participant to use side- stepping strategy Place large obstacles in front and behind participant to deter cross- overs 	
Is unable to step equally well in all directions	 Use multi-directional perturbations Do more perturbations in the most challenging direction 	
		9 J

'Stable' tasks: session 1

Initial - HR: B	BP:	Repeat I	HR: BP:	Repeat	2 - HR:		BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, 1=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Standing still with feet hip- width apart	U Wide BOS	□ Feet together	6 multi-directional lean-and-release				
Standing still with feet hip- width apart, eyes closed	U Wide BOS	□ Feet together	6 multi-directional lean-and-release				
Standing still with feet hip- width apart, on a thin foam mat	Wide BOS	□ Feet together	6 multi-directional lean-and-release	•			
Standing still with feet hip- width apart, on a thick foam pad	Wide BOS	□ Feet together	6 multi-directional lean-and-release	ey.			
Standing still with feet hip- width apart, turning head left and right	Wide BOS	☐ Feet together	6 multi-directional lean-and-release	00			
Standing still with feet hip- width apart, looking up and down	Wide BOS	□ Feet together	6 multi-directional lean-and-release				
Standing with feet hip- width apart, counting backwards by 3's	Wide BOS	□ Feet together	6 multi-directional lean-and-release				

to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	Rests during task	after task (Y/N)
U Wide BOS	□ Feet together	6 multi-directional lean-and-release				
Wide BOS	□ Feet together	6 multi-directional push/pull				
Wide BOS	Given Feet together	6 multi-directional push/pull				
U Wide BOS	□ Feet together	internal				
U Wide BOS	Given Feet together	internal	24			
BP:			Overall rating of	perceiv	ed challei	nge:
S			=			
the session:						
	 Wide BOS Wide BOS Wide BOS Wide BOS Wide BOS BP: 	Wide BOS Feet together BP:	Wide BOS Feet together 6 multi-directional lean-and-release Wide BOS Feet together 6 multi-directional push/pull Wide BOS Feet together 6 multi-directional push/pull Wide BOS Feet together 6 multi-directional push/pull Wide BOS Feet together internal BP:	Image: Second	Image: Control of y Image: Control of y Image: Control of y Image: Control of y Image: Wide BOS Image: Feet together 6 multi-directional push/pull Image: Control of y Image: Control of y Image: Wide BOS Image: Feet together 6 multi-directional push/pull Image: Control of y Image: Control of y Image: Wide BOS Image: Feet together 6 multi-directional push/pull Image: Control of y Image: Control of y Image: Wide BOS Image: Feet together Image: Image: Control of y Image: Control of y Image: Control of y Image: Wide BOS Image: Feet together Image: Image: Control of y Image: Control of y Image: Control of y Image: Wide BOS Image: Feet together Image: Image: Control of y Image: Control of y Image: Control of y Image: BP: Image: Control of y Image: Solution of the point of y Image: Control of y Image: Solution of y Image: Control of y Image: Control of y Image: Control of y Image: Control of y Image: Contr	Image: Sector of the sector

'Stable' tasks: Session 2

Initial - HR:	3P:	Repeat I	- HR: BP:		Repeat	2 - HR	•	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	ncrease Perturbation		ne nulti step, lance)	RPC	# Rests during task	Rest after task (Y/N)
Standing still with feet hip- width apart	Wide BOS	Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, eyes closed	Wide BOS	Given Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, on a thin foam mat	Wide BOS	Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, on a thick foam pad	Wide BOS	Given Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, turning head left and right	U Wide BOS	Given Feet together	6 multi-directional lean-and-release	Ch-				
Standing still with feet hip- width apart, looking up and down	Wide BOS	Given Feet together	6 multi-directional lean-and-release	C	5			
Standing with feet hip- width apart, counting backwards by 3's	U Wide BOS	Given Feet together	6 multi-directional lean-and-release					
Standing with feet hip- width apart, eyes closed & counting backwards by 3's	U Wide BOS	Given Feet together	6 multi-directional lean-and-release					
Standing with feet hip- width apart, rapid weight- shifting left and right	U Wide BOS	Given Feet together	6 multi-directional push/pull					

BOS Feet together	6 multi-directional push/pull				(Y/N)
BOS Get together					
	internal				
3OS 🛛 Feet together	internal				
steps 🗖 Long steps	internal				
steps 🔲 Long steps	internal				
steps 🔲 Long steps	internal				
steps 📮 Long steps	internal	rh.			
	Ove	erall rating of perce	ived cha	ıllenge:	
		0= = X=			
	steps Long steps steps Long steps steps Long steps Long steps Long steps	steps Long steps internal steps Ove	steps Long steps internal Steps Overall rating of perceiver Image: Steps Image: Steps Image: Steps <td< td=""><td>steps Long steps internal steps Long steps internal steps Long steps internal steps Long steps internal Overall rating of perceived choon Image: Steps <t< td=""><td>steps Long steps steps Long steps internal steps Long steps internal steps Long steps internal steps Long steps internal Steps Long steps internal Steps Long steps internal Steps Long steps internal Overall rating of perceived challenge: Image: Steps Image: Steps Steps Image: Steps <t< td=""></t<></td></t<></td></td<>	steps Long steps internal steps Long steps internal steps Long steps internal steps Long steps internal Overall rating of perceived choon Image: Steps Image: Steps <t< td=""><td>steps Long steps steps Long steps internal steps Long steps internal steps Long steps internal steps Long steps internal Steps Long steps internal Steps Long steps internal Steps Long steps internal Overall rating of perceived challenge: Image: Steps Image: Steps Steps Image: Steps <t< td=""></t<></td></t<>	steps Long steps steps Long steps internal steps Long steps internal steps Long steps internal steps Long steps internal Steps Long steps internal Steps Long steps internal Steps Long steps internal Overall rating of perceived challenge: Image: Steps Image: Steps Steps Image: Steps <t< td=""></t<>

'Quasi-mobile' tasks: Session 3

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	2 - HR	:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, I=r X=loss of ba	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Rapid stepping forward with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull					
Rapid stepping backward with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull					
Rapid stepping to alternate sides	□ Short steps	Long steps	6 multi-directional push/pull	•				
Rapid tap-ups forward with alternate feet	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull	ch,				
Walking in place	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull	C	5			
Rapid stepping forward with alternate feet, on a thin foam mat	G Short steps	Long steps	6 multi-directional push/pull					
Rapid stepping backward with alternate feet, on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull					

sides, on a thin foam mat I bit steps I bit steps push/pull Rapid tap-ups forward with alternate feet, on a thin foam mat I bow step Step Height: Unstable surface (e.g. soccer ball) 6 multi-directional push/pull I bit steps Walking in place, on a thin foam mat Feet barely off floor Knees to hip-height 6 multi-directional push/pull I bit steps HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1= X= I = X= I	sides, on a thin foam mat I Short steps I Long steps push/pull Rapid tap-ups forward with alternate feet, on a thin foam mat I Low step Step Height: I Unstable surface (e.g. soccer ball) 6 multi-directional push/pull I I I I I I I I I I I I I I I I I I I	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, 1=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
with alternate feet, on a thin foam mat Step Height:	with alternate feet, on a thin foam mat Step Height:		□ Short steps	Long steps					
foam mat floor hip-height push/pull Overall rating of perceived challenge:	foam mat floor hip-height push/pull Overall rating of perceived challenge:	with alternate feet, on a		surface (e.g.					
TOTALS/AVERAGES 0= 1= X= 0	TOTALS/AVERAGES 0= 1= X= 0								
1= X=	1= X=				Ov		ved cha	llenge:	
Overall comments for the session:	Overall comments for the session:	TOTALS/AVERAGE			CL.	1=			
	<u> </u>	Overall comments for	r the session:			Ch On			

'Quasi-mobile' tasks: Session 4

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	2 - HR	:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, I=r X=loss of ba	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Rapid stepping forward and backward with right foot	□ Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid stepping forward and backward with left foot	Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid tap-ups forward with alternate feet	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull	•				
Rapid step-ups with alternate feet	Low step Step Height:	Unstable surface (e.g. dense foam)	6 multi-directional push/pull	ch,				
Rapid tap-ups to alternate sides	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull	C	5			
Rapid stepping forward and backward with right foot, on a thin foam mat	Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid stepping forward and backward with left foot, on a thin foam mat	Short steps; rest in stance	Long steps	6 multi-directional push/pull					

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with alternate feet, on a thin foam mat Low step surface (e.g. soccer ball) 6 multi-directional push/pull Rapid step-ups with alternate feet, on a thin foam mat Low step Unstable surface (e.g. dense foam) 6 multi-directional push/pull Rapid tap-ups to alternate sides, on a thin foam mat Low step Unstable surface (e.g. dense foam) 6 multi-directional push/pull Rapid tap-ups to alternate sides, on a thin foam mat Low step Unstable surface (e.g. soccer ball) 6 multi-directional push/pull	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
alternate feet, on a thin foam mat I Low step Step Height: surface (e.g. dense foam) 6 multi-directional push/pull Rapid tap-ups to alternate sides, on a thin foam mat I Low step Step Height: 0 Unstable surface (e.g. soccer ball) 6 multi-directional push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1= X=	Rapid tap-ups forward with alternate feet, on a thin foam mat		surface (e.g.					
Rapid tap-ups to alternate sides, on a thin foam mat I Low step Step Height:	Rapid step-ups with alternate feet, on a thin foam mat		surface (e.g.					
TOTALS/AVERAGES 0= 1= X= I I	Rapid tap-ups to alternate sides, on a thin foam mat		surface (e.g.					
1= X=	HR:	BP:		Ov	verall rating of perceiv	ved cha	llenge:	
Overall comments for the session:	TOTALS/AVERAGE	ES		er,	1=			
	Overall comments for	r the session:			h			I

'Quasi-mobile' tasks: Session 5

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	2 - HR	•	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, I=n X=loss of bal	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Rapid stepping forward and backward with right foot	Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid stepping forward and backward with left foot	Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid stepping to alternate sides	□ Short steps	Long steps	6 multi-directional push/pull	•				
Rapid diagonal forward stepping with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull	Ch.				
Walking in place	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull	C	5			
Walking in place, eyes closed	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull					
Rapid stepping with alternate feet in random cued direction	□ Short steps	Long steps	6 multi-directional push/pull					

Rapid step-ups with alternate feet Low step Unstable surface (e.g. dense foam) 6 multi-directional push/pull Rapid tap-ups forward with alternate feet Low step Unstable surface (e.g. soccer ball) 6 multi-directional push/pull Rapid tap-ups forward with alternate feet Low step Unstable surface (e.g. soccer ball) 6 multi-directional push/pull Rapid tap-ups to alternate sides Low step Unstable surface (e.g. soccer ball) 6 multi-directional push/pull Rapid tap-ups to alternate Low step Step Height: 6 multi-directional push/pull Rapid tap-ups to alternate Low step Step Height: 6 multi-directional push/pull Rapid tap-ups to alternate Low step Step Height: 6 multi-directional push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1= Overall comments for the session:	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Rapid tap-ups forward with alternate feet I Low step Step Height:			surface (e.g.					
Rapid tap-ups to alternate sides I Low step Step Height: surface (e.g. soccer ball) 6 multi-directional push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1= X= X= I = X=			surface (e.g.					
TOTALS/AVERAGES 0= 1= X= I I			surface (e.g.					
1= X=	HR:	BP:		Ov	rerall rating of perceiv	ved cha	llenge:	
Overall comments for the session:	TOTALS/AVERAGE	S		(9L)	1=			
	Overall comments for	the session:			h		· ·	
	Version date: 20 October 20	017						

'Quasi-mobile' tasks: Session 6

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	2 - HR	:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, 1=n X=loss of bal	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Rapid stepping forward with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull					
Rapid stepping backward with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull					
Rapid stepping to alternate sides	□ Short steps	Long steps	6 multi-directional push/pull					
Walking in place, eyes closed	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull	Ch.				
'Jogging' (or fast walking) in place	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull	C	5			
Rapid diagonal forward stepping with alternate feet	Short steps	Long steps	6 multi-directional push/pull					
Rapid stepping with alternate feet in random cued direction	Short steps	Long steps	6 multi-directional push/pull					

Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, 1=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
'Jogging' (or fast walking) in place, on a thin foam mat	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull				
Rapid diagonal forward stepping with alternate feet, on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull				
Rapid stepping with alternate feet in random cued direction, on a thin foam mat	Short steps	Long steps	6 multi-directional push/pull				
HR:	BP:		Ov	erall rating of perceiv	ved cha	llenge:	
TOTALS/AVERAGE	S		(er	0= = X=			
Overall comments for	the session.			The second	•		
				0			
Version date: 20 October 20	DI7 Eor p	eer review only - ht	tp://bmiopen.bmi.com	n/site/about/guidelines.xht	ml		

'Mobile' tasks: Session 7

Initial - HR:	BP:	Repeat I ·	HR: BP:		Repea	t 2 - HF	R:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcon (0=≤2 steps, 1=m X=loss of bala	ulti step,	RPC	# Rests during task	Rest after task (Y/N)
Walking forward	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull					
Walking forward, turning head left and right	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull					
Walking forward, looking up and down	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull	•				
Walking and stepping over obstacles	 Low/short obstacles Define: 	 High/long obstacles Define: 	6 multi-directional push/pull	er,				
Forward braiding	Walk on the line	Step further across; long steps; traffic light	6 multi-directional push/pull	C	5			
Side stepping	Short steps	Long steps	6 multi-directional push/pull					
Turning on the spot (alternate between turning to the left and to the right)	Turn slowly	Turn quickly	6 multi-directional push/pull					

urning on the spot with yes closed (alternate etween turning to the ift and to the right) I Turn slowly I Turn quickly 6 multi-directional push/pull urning on the spot, in ued direction I Turn slowly I Turn quickly 6 multi-directional push/pull IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII	Furning on the spot with eyes closed (alternate between turning to the eff and to the right) Image: Turn slowly image: Turn quickly image: T	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
ued direction Intrinsiowity Intrinsiowity our square stepping Short steps Long steps Image: A stepping Short steps Image: A stepping Short steps Image: A stepping Image: A stepping I	cour square stepping Short steps Long steps 6 multi-directional push/pull HR: BP: Overall rating of perceived challenge: 0= 1= X= Overall comments for the session:	Turning on the spot with eyes closed (alternate between turning to the left and to the right)	Turn slowly	Turn quickly					
our square stepping I Short steps I Long steps push/pull IR: BP: Overall rating of perceived challenge: Image: Otal Steps 0= Image: Imag	-our square stepping I Short steps I Long steps push/pull HR:<	Turning on the spot, in cued direction	Turn slowly	Turn quickly					
TOTALS/AVERAGES 0= 1= X= 0= 1= X= 0= 1= X= 0= 1= X= 0= 0= 1= X= 0= 0= 0= 0= 0= 0= 0= 0= 0= 0= 0= 0= 0=	OTALS/AVERAGES 0= 1= X= Overall comments for the session:	Four square stepping	□ Short steps	Long steps					
x=	Overall comments for the session:				01		ved cha	Illenge:	
Overall comments for the session:					V	-			
						- V			
		Overall comments fo	or the session:						
		Overall comments fo	or the session:			<u></u>			
		Overall comments fo	or the session:						

'Mobile' tasks: Session 8

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	2 - HR	•	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, I=r X=loss of ba	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Walking forward	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull					
Walking backward	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull					
Walking forward with eyes closed	Short steps; walk slowly	Long steps; walk quickly	6 multi-directional push/pull	• (
Tandem walking forward	Not heel-toe; steps close to line	Traffic light	6 multi-directional push/pull	24				
Side stepping	□ Short steps	Long steps	6 multi-directional push/pull	C	5/			
Sideways braiding	Steps not fully crossed	□ Traffic light	6 multi-directional push/pull					
Side stepping over obstacles	 Low/short obstacles Define: 	 High/long obstacles Define: 	6 multi-directional push/pull					

Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, 1=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Turning on the spot (alternate between turning to the left and to the right)	Turn slowly	Turn quickly	6 multi-directional push/pull				
Turning on the spot in cued direction	Turn slowly	Turn quickly	6 multi-directional push/pull				
Four square stepping	□ Short steps	Long steps	6 multi-directional push/pull				
HR:	BP:		Ov	verall rating of perceiv	ved cha	llenge:	
TOTALS/AVERAG	GES		(er	0= = X=			
Overall comments f	or the session:			"h			
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'Mobile' Tasks: Session 9

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	2 - HR	:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, I=r X=loss of ba	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Walking forward on a thin foam mat	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull					
Walking backward on a thin foam mat	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull					
Side stepping on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull					
Four square stepping on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull	Ch,				
Tandem walking forward	Not heel- toe; steps close to line	Traffic light	6 multi-directional push/pull	C	5			
Tandem walking backward	Not heel- toe; steps close to line	Traffic light	6 multi-directional push/pull					
Sideways braiding	Steps not fully crossed	Traffic light	6 multi-directional push/pull					

Turning on the spot with eyes closed (alternate between turning to the left Turn slowly Turn quickly 6 multi-directional push/pull Forward braiding Walk on the line Step further across; long steps; traffic light 6 multi-directional push/pull Image: Closed Walking forward with eyes closed Short steps; walk slowly 6 multi-directional push/pull Image: Closed HR: BP: TOTALS/AVERAGES 0= 1= X= 0= 1= X=	Turning on the spot with eyes closed (alternate between turning to the left and to the right) Turn slowly Turn quickly 6 multi-directional push/pull Forward braiding Walk on the line Step further across; long steps; traffic light 6 multi-directional push/pull 6 Walking forward with eyes closed Short steps; walk slowly 6 multi-directional push/pull 6 HR: BP: BP: Overall rating of perceived challenge: 1 0= 1= 0= 1=	Turning on the spot with eyes closed (alternate between turning to the left and to the right) Turn slowly Turn quickly 6 multi-directional push/pull Forward braiding Walk on the line Step further across; long steps; traffic light 6 multi-directional push/pull 0 Walking forward with eyes Short steps; walk slowly Long steps; walk quickly 6 multi-directional push/pull 0 HR: BP:	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Forward braiding Image: Walk on the line across; long steps; traffic light 6 multi-directional push/pull Walking forward with eyes Image: Short steps; walk slowly Image: Long steps; walk quickly 6 multi-directional push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES Image:	Forward braiding Walk on the line across; long steps; traffic light 6 multi-directional push/pull Walking forward with eyes Short steps; walk slowly Long steps; walk quickly 6 multi-directional push/pull Image: Constraint of the second steps is walk quickly HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= Image: Constraint of the second steps is walk quickly 0= Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Consteps is walk q	Forward braiding Walk on the line across; long steps; traffic light 6 multi-directional push/pull Walking forward with eyes Short steps; walk slowly Long steps; walk quickly 6 multi-directional push/pull Image: Constraint of the second steps is walk quickly HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= Image: Constraint of the second steps is walk quickly 0= Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Constraint of the second steps is walk quickly Image: Consteps is walk q	eyes closed (alternate between turning to the left	Turn slowly	Turn quickly					
closed walk slowly walk quickly push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1= X=	closed walk slowly walk quickly push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1= X= Overall comments for the session:	closed walk slowly walk quickly push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1= X= Overall comments for the session:	Forward braiding		across; long steps; traffic					
TOTALS/AVERAGES	TOTALS/AVERAGES 0= 1= ×= Overall comments for the session:	TOTALS/AVERAGES 0= 1= ×= Overall comments for the session:								
X=	Overall comments for the session:	Overall comments for the session:				Ov	0=	ved cha	llenge:	
			Overall comments for	the session:			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			
			Version date: 20 October 20							

'Mobile' tasks: Session 10

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	2 - HR	:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, I=r X=loss of ba	multi step,	RPC	# Rests during task	Rest after task (Y/N)
Tandem walking forward	Not heel- toe; steps close to line	Traffic light	6 multi-directional push/pull					
Tandem walking backward	Not heel- toe; steps close to line	□ Traffic light	6 multi-directional push/pull					
Forward braiding	Walk on the line	Step further across; long steps; traffic light	6 multi-directional push/pull	•				
Backward braiding	Walk on the line	Step further across; long steps; traffic light	6 multi-directional push/pull	ch.				
Tandem walking forward on a thin foam mat	Not heel- toe; steps close to line	Traffic light	6 multi-directional push/pull		2			
Tandem walking backward on a thin foam mat	Not heel- toe; steps close to line	Traffic light	6 multi-directional push/pull					
Forward braiding on a thin foam mat	Walk on the line	Step further across; long steps; traffic light	6 multi-directional push/pull					

Backward braiding on a thin foam mat Walk on the line Step further across; long steps; traffic light 6 multi-directional push/pull Sideways braiding on a thin foam mat Steps not fully crossed Traffic light 6 multi-directional push/pull Sideways braiding on a thin foam mat Steps not fully crossed Traffic light 6 multi-directional push/pull Turning on the spot with eyes closed in cued direction Turn slowly Turn quickly 6 multi-directional push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= I= I= X=	Backward braiding on a thin foam mat Walk on the line Step further across; long steps; traffic light 6 multi-directional push/pull Sideways braiding on a thin foam mat Steps not fully crossed Traffic light 6 multi-directional push/pull Sideways braiding on a thin foam mat Steps not fully crossed Traffic light 6 multi-directional push/pull Turning on the spot with eyes closed in cued direction Turn slowly Turn quickly 6 multi-directional push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1=	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
foam mat fully crossed I Traffic light push/pull Turning on the spot with eyes closed in cued direction I Turn slowly Turn quickly 6 multi-directional push/pull HR: BP: TOTALS/AVERAGES 0= 1= X=	foam mat fully crossed I Traffic light push/pull Turning on the spot with eyes closed in cued direction I Turn slowly I Turn quickly 6 multi-directional push/pull HR: BP: TOTALS/AVERAGES 0= I= X= I			across; long steps; traffic					
eyes closed in cued Turn slowly Turn quickly direction BP: HR: BP: Overall rating of perceived challenge: Image: state of the state of	eyes closed in cued direction Imath-directional push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1= X=			□ Traffic light					
TOTALS/AVERAGES	TOTALS/AVERAGES 0= 1= X=	eyes closed in cued	Turn slowly	Turn quickly					
= X=		HR:	BP:		Ov	rerall rating of perceiv	ved cha	llenge:	
Overall comments for the session:	Overall comments for the session:	TOTALS/AVERAGE	S		er.	45.			
		Overall comments for	the session:			00			

'Mobile & Unpredictable' Tasks: Session 11

Initial - HR:	BP:	Repeat I -	HR: BP:	1	Repeat	2 - HR		BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcom (0=≤2 steps, I=mu X=loss of balan	ulti step,	RPC	# Rests during task	Rest after task (Y/N)
Kicking soccer ball against wall	[none]	Stand further from wall; kick outside BOS; kick with each leg	6 perturbations: PT attempts to take ball, nudges participant					
Throwing hand ball against a wall	Large ball	Small ball; stand further from wall; throw with each arm	6 perturbations: PT attempts to take ball, nudges participant					
Kicking soccer ball against wall, standing on a thin foam mat	[none]	Stand further from wall; kick outside BOS; kick with each leg	6 perturbations: PT attempts to take ball, nudges participant	en.				
Throwing hand ball against a wall, standing on a thin foam mat	Large ball	Small ball; stand further from wall; throw with each arm	6 perturbations: PT attempts to take ball, nudges participant	0	7/			
Walking with sudden stops and changes in direction	Walk slowly	Walk quickly	6 multi-directional push/pull/trip					
Move to different corners of the room	Walk slowly	Walk quickly	6 multi-directional push/pull/trip					

and changes in direction, bstacles around the room Walk slowly Walk quickly Inditi-directional push/pull/trip love to different corners Walk slowly Walk quickly 6 multi-directional push/pull/trip round the room Walk slowly Walk quickly 6 multi-directional push/pull/trip our square stepping to predictable cued Short steps Long steps 12 multi-directional push/pull/trip pod geball' Ball thrown at upper body Ball thrown rapidly at feet internal IR: BP: Overall rating of perceived challenge: rottals/AVERAGES 0=	and changes in direction, bstacles around the room Walk slowly Walk quickly Binduc-directional push/pull/trip love to different corners fi the room, obstacles round the room Walk slowly Walk quickly 6 multi-directional push/pull/trip oour square stepping to npredictable cued irrection Short steps Long steps 12 multi-directional push/pull/trip Dodgeball' Ball thrown at upper body Ball thrown rapidly at feet internal dR: BP: Overall rating of perceived challenge:	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
if the room, obstacles ound the room Walk slowly Walk quickly G multi-directional push/pull/trip our square stepping to predictable cued rection Short steps Long steps 12 multi-directional push/pull/trip Dodgeball' Ball thrown at upper body Ball thrown rapidly at feet internal Image: Comparison of the perceived challenge:	f the room, obstacles round the room round the room our square stepping to npredictable cued increasion Image: Short steps Image: Short step	Walking with sudden stops and changes in direction, obstacles around the room	Walk slowly	Walk quickly					
hpredictable cued rection Ball thrown at upper bodgeball' Ball thrown at upper body Ball thrown rapidly at feet IR: BP: Overall rating of perceived challenge: I= I= X=	Impredictable cued irection Impredictable cued irection Impredictable cued irection Impredictable cued Impredictable cued <t< td=""><td>Yove to different corners of the room, obstacles rround the room</td><td>Walk slowly</td><td>Walk quickly</td><td></td><td></td><td></td><td></td><td></td></t<>	Yove to different corners of the room, obstacles rround the room	Walk slowly	Walk quickly					
Dodgeball' at upper body Ball thrown rapidly at feet internal IR: BP: Overall rating of perceived challenge: OTALS/AVERAGES 0= 1= X=	Dodgeball' at upper body Ball thrown rapidly at feet internal IR: BP: Overall rating of perceived challenge: OTALS/AVERAGES 0= 1= X=	our square stepping to inpredictable cued lirection	□ Short steps	Long steps					
TOTALS/AVERAGES	TOTALS/AVERAGES	Dodgeball'	at upper		internal				
I= X=	= X=	HR:	BP:		Ov	verall rating of perceiv	ved cha	llenge:	
overall comments for the session:	Overall comments for the session:	TOTALS/AVERAGE	S			I=			
		Overall comments for	the session:			2			

'Mobile & unpredictable' tasks: Session 12

Initial - HR: B	SP:	Repeat I	- HR: BP:		Repeat	2 - HR	k:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcon (0=≤2 steps, I=m X=loss of bala	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Kicking soccer ball back and forth with physiotherapist	Within reach; kicked slowly	Step to reach; kicked quickly	internal					
Throwing ball back and forth with physiotherapist	Large ball; within reach	Small ball; step to reach	internal					
Kicking soccer ball with physiotherapist, standing on a thin foam mat	Within reach; kicked slowly	Step to reach; kicked quickly	internal					
Throwing ball with physiotherapist, standing on a thin foam mat	Large ball; within reach	Small ball; step to reach	internal	EN C				
Walking with sudden stops and changes in direction	Walk slowly	Walk quickly	l 2 multi-directional push/pull/trip		7/			
Move to different corners of the room	Walk slowly	Walk quickly	l 2 multi-directional push/pull/trip					
Walking with sudden stops and changes in direction, obstacles around the room	Walk slowly	Walk quickly	l 2 multi-directional push/pull/trip					

Move to different corners of the room, obstacles around the room Walk slowly Walk quickly 12 multi-directional push/pull/trip Image: Conserve of the room Four square stepping to unpredictable cued direction Short steps Long steps 12 multi-directional push/pull/trip Image: Conserve of the room 'Dodgeball' Ball thrown at upper body Ball thrown rapidly at feet Image: Conserve of the room Image: Conserve of the room HR: BP: Coverall rating of perceived challenge: Image: Conserve of the room Overall comments for the session: Image: Conserve of the room Image: Conserve of the room	of the room, obstacles around the room Four square stepping to unpredictable cued direction 'Dodgeball' HR:	 Short steps Ball thrown at upper body 	 Long steps Ball thrown rapidly at 	push/pull/trip I 2 multi-directional push/pull/trip				
unpredictable cued direction Short steps Long steps If 2 multi-directional push/pull/trip 'Dodgeball' Ball thrown at upper body Ball thrown rapidly at feet internal HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= I= X=	unpredictable cued direction 'Dodgeball' HR:	Ball thrown at upper body	Ball thrown rapidly at	push/pull/trip				
'Dodgeball' at upper body rapidly at feet internal HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= I= X=	HR:	at upper body	rapidly at	internal				
TOTALS/AVERAGES 0= I= I <thi< th=""></thi<>		BD.						
I= X=				o o	verall rating of perceiv	ved cha	llenge:	
Overall comments for the session:	TOTALS/AVERAGE	S		61	i=			
	Overall comments for	the session:			Ch .			·
								_
	Version date: 20 October 20							

Booster sessions

Initial - HR:	BP:	Repeat I	- HR: BP:		Repeat	: 2 - HR	:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, 1=r X=loss of ba	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Standing still with feet hip- width apart, eyes closed	Wide base of support	Feet together	6 multi-directional lean-and-release					
Rapid tap-ups forward with alternate feet	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull					
Rapid tap-ups to alternate sides	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull					
Rapid stepping with alternate feet in random cued direction	□ Short steps	Long steps	6 multi-directional push/pull	ch.				
Turning on the spot, in cued direction	Turn slowly	Turn quickly; eyes closed	6 multi-directional push/pull	C	5			
Side stepping/braiding	Short steps	Long steps; thin foam mat	6 multi-directional push/pull/trip					
Forward tandem/braiding	Steps close to line	Long steps; thin foam mat	6 multi-directional push/pull/trip					

Walking with sudden stops and changes in direction, obstacles Walk slowly Walk quickly 6 multi-directional push/pull/trip	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, 1=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
stops and changes in direction, obstacles around the room Image: Walk slowly Image: Walk glowly Image: Walk glowly	Backward tandem/braiding	-	thin foam					
Kicking soccer ball against wall [none] BOS; on thin foam mat HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= 1= X=	Walking with sudden stops and changes in direction, obstacles around the room	Walk slowly	quickly	push/pull/trip				
TOTALS/AVERAGES 0= 0= I= X= I I		[none]	BOS; on thin foam	attempts to take ball, nudges				
= x=	HR:	BP:			verall rating of perceiv	ed cha	llenge:	
Overall comments for the session:	TOTALS/AVERAGE	ES						
	Overall comments for	r the session:						
	Overall comments for	r the session:						
	Overall comments for	r the session:						
	Overall comments for	r the session:						
	Overall comments for	r the session:						

5. TASK DESCRIPTIONS

Types of external perturbations

I) Lean and release

a. Forward-directed lean-and-release perturbation. The participant stands facing the physiotherapist, leaning forward with some of his body weight supported by the physiotherapist. He should be leaning far enough forward that his shoulders and hips are ahead of his toes; however, smaller lean angles can be used with more impaired individuals. The physiotherapist's hands are on the participants' shoulders. At an unexpected time, the physiotherapist releases her hands and the participant starts to fall forward, requiring a step to regain stability. The goal is for the participant to take as few steps as possible to recover.



Figure 6.1. Forward-directed lean-and-release perturbation. The participant leans forward and the physiotherapist supports his weight (left). The physiotherapist releases her support and the participant steps to recover his balance (right).

b. Backward-directed lean-and-release perturbation. The participant stands in front of and facing away from the physiotherapist, leaning backward with some of his body weight supported by the physiotherapist. He should be leaning far enough backward that his shoulders and hips are behind his heels; however, smaller lean angles can be used with more impaired individuals. The physiotherapist's hands are on the participants' shoulders. At an unexpected time, the physiotherapist releases her hands and the participant starts to fall backward, requiring a step to regain stability. The goal is for the participant to take as few steps as possible to recover upright standing balance.



Figure 6.2. Backward-directed lean-and-release perturbation. The participant leans backward and the physiotherapist supports his weight (left). The physiotherapist releases her support and the participant steps to recover his balance (right).

c. Lateral-directed lean-and-release perturbation. The participant stands with his feet close together, leaning to the right (or left) with some of his body weight supported by the physiotherapist's hands. He should be leaning far enough to the right (or left) that the midline of the pelvis is aligned over the right (or left) foot; however, smaller lean angles can be used with more impaired individuals. The physiotherapist's hands are on the participant's right (or left) shoulder and

right (or left) hip. At an unexpected time, the physiotherapist releases her hands and the participant starts to fall to the right (or left), requiring a step to regain stability. The goal is for the participant to take as few steps as possible to recover balance.



Figure 6.3. Backward-directed lean-and-release perturbation. The participant leans to the left and the physiotherapist supports his weight (left). The physiotherapist releases her support and the participant steps to recover his balance (right).

2) Multi-directional push/pull/trip

a. Multidirectional push. The physiotherapist places her hands on the participant's hips or shoulders and pushes him forward, requiring a reactive step to regain stability. Alternatively, one of the physiotherapist's hands could be on the hip and the other on the shoulder; a push forward at the level of one scapula would facilitate a diagonal reactive step. In all scenarios, the physiotherapist should be ready to assist with the recovery, if necessary, by having a light hold of the safety harness. The physiotherapist should only provide assistance if the participant is unable to regain stability independently; this is true with every reaction. Note that backward-directed pushes are not performed.



Figure 6.4. Forward-directed push perturbation. The physiotherapists' hands may be placed at the hips (top images) or with one hand on the hips and one on the shoulders.

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Figure 6.5. Lateral-directed push perturbation. The physiotherapist places her hands on the participant's right (or left) hip or shoulder and pushes him to the left (or right), requiring a reactive step to regain stability.

b. Multi-directional pull perturbation. The physiotherapist may pull the participant's shoulders or pull on the harness to cause the participant to start to fall forward, requiring a reactive step to regain stability.



Figure 6.6. Forward-directed pull perturbation. The physiotherapist places her hands on the participant's shoulders (top) or pulls on the harness (bottom).



Figure 6.7. Backward-directed pull perturbation. The physiotherapist uses the shoulders, hips, or harness to pull the participant backward, requiring a reactive step to regain stability.



Figure 6.8. Lateral-directed pull perturbation. The physiotherapist uses the shoulders, hips or harness, to pull the participant to the right (or left), requiring a reactive step to regain stability.

c. Trip perturbation while walking. As the participant walks (forward, backward, sideways), the physiotherapist places her foot in the path of the swing limb causing a trip. A reactive step is required to regain stability. A second person is recommended in this scenario as it is difficult for the physiotherapist doing the tripping to be in a place to provide support should it be needed.



Figure 6.9. Trip perturbation. The physiotherapist catches the participants' limb with her foot while walking.

Descriptions of voluntary tasks

Standing still with feet hip-width apart – participant stands unassisted with the eyes open and the feet positioned as wide as the hips. The lean-and-release perturbations are performed in random directions (forward, backward and lateral).

Adaptation to reduce difficulty – have participant adopt a wider base of support (BOS) Adaptation to increase difficulty – have participant stand with the feet together Progressions of this task:

Eyes closed – if participant is unable, the lights in the room should be dimmed (alternatively, dark sunglasses may be worn)

Standing on a thin foam mat

- Standing on a thick foam mat
- Turning head to the right and left to spot a target
- Looking up and down to spot a target
 - Counting backwards by 3's from a random number given by physiotherapist Eyes closed and counting backwards – as written above, but combined

Rapid weight-shifting left and right – participant shifts his body weight from one foot to the other as quickly as possible, and the feet remain in contact with the floor. The task is repeated until all perturbations are accomplished.

Adaptation to reduce difficulty – have participant adopt a wider BOS

Adaptation to increase difficulty – have participant stand with the feet together

Rapid weight-shifting forward and backward –participant stands with feet either 'side-by-side' or in a 'stride position' and shifts his body weight forward and backward; if feet are 'side-by-side' then body weight rocks from toes to heels and back; if feet are in stride then body weight transfers from one foot to the other as quickly as possible; part of each foot always remains in contact with the floor. The task is repeated until all perturbations are accomplished.

Adaptation to reduce difficulty -have participant adopt a wider BOS, with the feet either sideby-side or in stride

Adaptation to increase difficulty – have participant stand with the feet together (if side-by-side) or with the feet in tandem (if in stride position)

Throwing and catching a ball – if the participant has use of both arms he should catch and throw a ball back and forth with the physiotherapist; if the participant has functional use of only one arm he should hit a ball back that has been thrown by the physiotherapist.

Adaptation to reduce difficulty – have participant adopt a wider BOS

Adaptation to increase difficulty – have participant stand with the feet together

Rapid arm raises forward and to the sides – participant raises one arm, then both arms, to 90 degrees of shoulder flexion as quickly as possible and stops as quickly as possible; participant raises two arms, then one arm at a time, to 90 degrees of shoulder abduction as quickly as possible and stops as quickly as possible.

Adaptation to reduce difficulty – have participant adopt a wider BOS

Adaptation to increase difficulty - have participant stand with the feet together

Rapid stepping forward with alternate feet – participant steps forward as quickly as possible with the right foot then returns it to the starting position, then steps forward as quickly as possible with the left foot, and then returns it to the starting position; there should be a transfer of body weight to the stepping foot once it touches down in the forward position. The task is repeated until all perturbations are accomplished.



Figure 6.10. Rapid stepping forward with alternate feet

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps Progressions of this task: Standing on a thin foam mat

Rapid stepping backward with alternate feet – participant steps backward as quickly as possible with the right foot, then returns it to the starting position, then steps backward as quickly as possible with the left foot, and then returns it to the starting position; there should be a transfer of body weight to the stepping foot once it touches down in the backward position. The task is repeated until all perturbations are accomplished.



Figure 6.11. Rapid stepping backward with alternate feet

Adaptation to reduce difficulty – have participant take short steps

Adaptation to increase difficulty – have participant take long steps

Progressions of this task:

Standing on a thin foam mat

Rapid stepping to the right (right foot) – participant steps with the right foot to the right as quickly as possible, then back to the starting position; there should be transfer of body weight to the right foot once it touches down in the lateral position. The task is repeated until all perturbations are accomplished.



Figure 6.12. Rapid stepping to the right (right foot)

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps

Rapid stepping to the left (left foot) – participant steps with the left foot to the left as quickly as possible, then back to the starting position; there should be transfer of body weight to the left foot once it touches down in the lateral position. The task is repeated until all perturbations are accomplished.

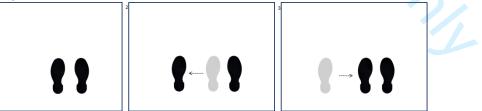


Figure 6.13. Rapid stepping to the left (left foot)

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps

Rapid stepping to alternate sides– participant steps with the right foot to the right as quickly as possible (including body weight transfer), then back to the starting position; then he steps with the left foot to the left as quickly as possible (including body weight transfer), then back to the starting position. The task is repeated until all perturbations are accomplished.

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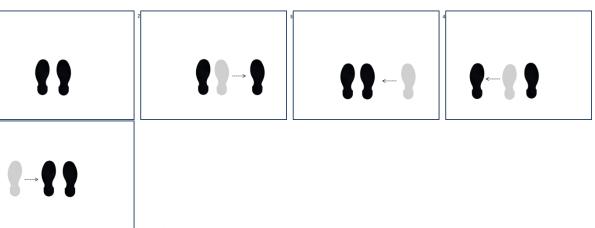


Figure 6.14. Rapid stepping to alternate sides

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps Progressions of this task:

Standing on a thin foam mat

Rapid tap-ups forward with alternate feet – participant stands with a step in front of his feet; he lifts up the right foot and lightly touches the step, then places it back on the floor; then he lifts up the left foot and lightly touches the step, then places it back on the floor. The goal is to maintain the body weight over the stance limb, i.e. no transfer of body weight forward. The task is repeated until all perturbations are accomplished.

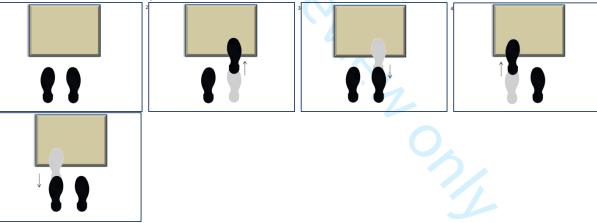


Figure 6.15. Rapid tap-ups forward with alternate feet

Adaptation to reduce difficulty – have participant tap-up to a low step Adaptation to increase difficulty – have participant tap-up to an unstable surface, e.g. a soccer ball

Progressions of this task:

Standing on a thin foam mat

Walking in place – participant alternates stepping with the right and the left foot. The participant should not move from the spot, though a small amount of 'drift' is typical. The task is repeated until all perturbations are accomplished.

Adaptation to reduce difficulty - have participant step with minimal height from floor

Adaptation to increase difficulty – have participant step with maximum height from floor, i.e. knees raised to hip-height

Progressions of this task:

Walking on the spot on a thin foam mat

Eyes closed - if participant is unable, the lights in the room should be dimmed

Increased speed to 'jogging', or fast walking, on the spot

Jogging, or fast walking, on the spot on a thin foam mat

Rapid stepping forward and backward with the right foot – participant shifts his body weight to the left foot and then steps forward with the right foot, shifting some body weight forward but not enough to completely unweight the left; then the participant shifts his body weight back to the left foot in order to take a full step as far backward as possible with the right foot, and accepts some body weight on the right. The task is repeated until all perturbations are accomplished.



Figure 6.16. Rapid stepping forward and backward with the right foot

Adaptations to reduce difficulty – have participant take short steps; have participant rest momentarily between transitioning from front to back or from back to front Adaptation to increase difficulty – have participant take long steps Progressions of this task:

Standing on a thin foam mat

Rapid stepping forward and backward with the left foot – participant shifts his body weight to the right foot and then steps forward with the left foot, shifting some body weight forward but not enough to completely unweight the right; then the participant shifts his body weight back to the right foot in order to take a full step as far backward as possible with the left foot, and accepts some body weight on the left. The task is repeated until all perturbations are accomplished.



Figure 6.17. Rapid stepping forward and backward with the left foot

Adaptations to reduce difficulty – have participant take short steps; have participant rest momentarily between transitioning from front to back or from back to front Adaptation to increase difficulty – have participant take long steps Progressions of this task:

Standing on a thin foam mat

Rapid step-ups with alternate feet - participant stands with a step in front of his feet; he steps up onto the step with the right foot, shifts his body weight forward and steps up with the left foot, placing it on the step in a comfortably-wide position; then he steps down with the right foot, shifts his

body weight back onto the right foot and steps down with the left. The process is repeated with the right foot leading until 3 perturbations are completed; then the left leads until the final 3 perturbations are completed.

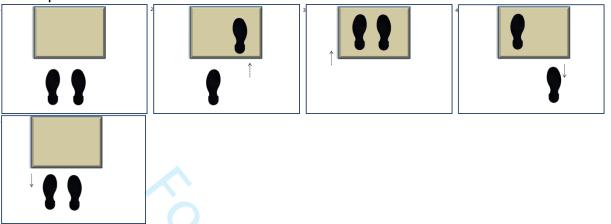


Figure 6.18. Rapid step-ups with alternate feet

Adaptation to reduce difficulty – have participant step-up to a low step

Adaptation to increase difficulty – have participant step-up to an unstable surface, for e.g., a step placed on a thin foam mat, or thick foam pad

Progressions of this task:

Standing on a thin foam mat -i.e. the person is standing on the mat, but the step may be on a hard surface, depending on the adaptation for difficulty

Rapid tap-ups to alternate sides – participant stands with a step lateral to each foot; he lifts up the right foot and lightly touches the step on the right, then places it back on the floor; then lifts up the left foot and lightly touches the step on the left, then places it back on the floor. The goal is to maintain the body weight over the stance limb, i.e., no transfer of body weight to the side tapping-up. The task is repeated until all perturbations are accomplished.

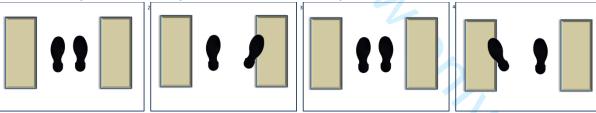


Figure 6.19. Rapid tap-ups to alternate sides

Adaptation to reduce difficulty – have participant tap-up to a low step Adaptation to increase difficulty – have participant tap-up to an unstable surface, e.g. a soccer ball

Progressions of this task:

Standing on a thin foam mat – i.e. the person is standing on the mat, but the step/obstacle may be on a hard surface, depending on the adaptation for difficulty

Rapid diagonal forward stepping with alternate feet – participant steps diagonally forward (a 45° angle) as quickly as possible with the right foot, then returns it to the starting position, then steps diagonally forward as quickly as possible with the left foot, then returns it to the starting position; there should be a transfer of body weight to the stepping foot once it touches down in the diagonal position. The task is repeated until all perturbations are accomplished.

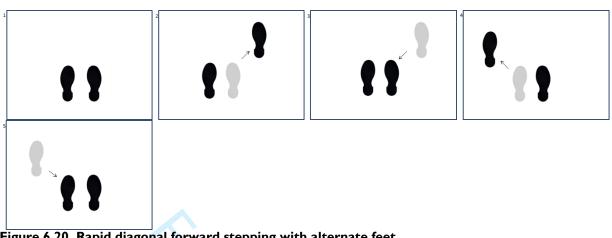


Figure 6.20. Rapid diagonal forward stepping with alternate feet

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps Progressions of this task:

Standing on a thin foam mat

Rapid stepping with alternate feet in random physiotherapist-cued directions – participant

stands in the centre of 6 targets placed on the floor (e.g., different colored Agility Dots); physiotherapist calls out a color and the participant steps to the colored dot with one foot (transferring some body weight) and then returns that foot to the centre; the process repeats with the next randomly called color. The task is repeated until all perturbations are accomplished.

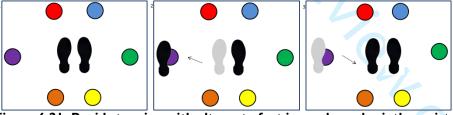


Figure 6.21. Rapid stepping with alternate feet in random physiotherapist-cued directions

Adaptation to reduce difficulty – targets require short steps Adaptation to increase difficulty – targets require long steps Progressions of this task: Standing on a thin foam mat

Walking forward – participant takes steps to travel in a forward direction. Walking continues until all perturbations are accomplished.

Adaptations to reduce difficulty – have participant take short steps, or walk slowly Adaptation to increase difficulty – have participant take long steps; traffic light^{*} Progressions of this task:

Turning head to the right and left - to spot a target Looking up and down – to spot a target Stepping over obstacles –e.g. pool noodles

^{*} Traffic Light = participant walks at a fast pace like he would if crossing a street; physiotherapist counts down like the traffic light would in the crosswalk

Eyes closed – if participant is unable, the lights in the room should be dimmed Walking on a thin foam mat

Forward braiding – participant takes a step forward with the right foot that crosses the midline path and lands lateral to, and slightly ahead of, the left foot; then he brings the left foot out and around the right foot, taking a step across the midline path that lands lateral to, and slightly ahead of, the right foot; then the process repeats until all perturbations are accomplished.

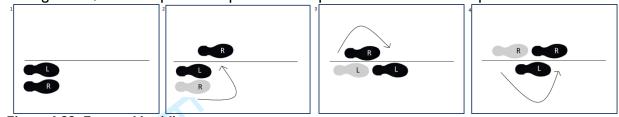


Figure 6.22. Forward braiding

Adaptation to reduce difficulty – walk on the line Adaptations to increase difficulty - increase distance of step across line; take bigger steps; increase the walking speed Progressions of this task: Walking on a thin foam mat

Side stepping – participant stands on left side of room; he takes a step to the right with the right foot, followed by a step to the right (medially) with the left foot; the stepping continues until the edge of the room/available space is reached; then, starting from the right side of the room, he will walk in the opposite direction – left foot steps to left, followed by right foot stepping to left. Stepping continues until all perturbations are accomplished.

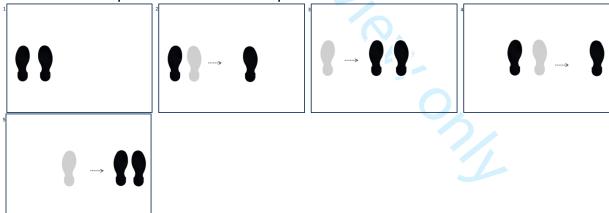


Figure 6.23. Side stepping

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps Progressions of this task: Stepping over obstacles –e.g. pool noodles

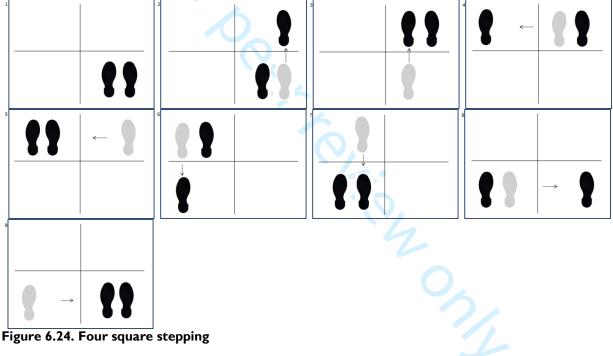
Walking on a thin foam mat

Turning on the spot, alternating to the right and left – participant takes steps to turn continuously in a clockwise direction. After a few turns (or 3 perturbations) the participant changes direction and turns counter-clockwise (until the final 3 perturbations are completed).

- Adaptation to reduce difficulty have participant turn slowly
- Adaptations to increase difficulty have participant turn quickly
 - Progressions of this task:

Eyes closed – if participant is unable, the lights in the room should be dimmed Cued direction – physiotherapist calls out 'right' or 'left' and the participant turns in the direction called; it may be the same direction or a change in direction Cued and Eyes closed – as written above but combined

Four square stepping – using tape, a cross is marked out on the floor creating 4 squares; participant stands in the bottom right-hand square facing forward; he is asked to step forward over the line with one foot then the other into the top right-hand square; then to step sideways, over the tape with the left foot and then the right into the top left-hand square; then to step backwards with one foot and then the other into the bottom left-hand square; and then finally, to step sideways with the right foot, then the left into the bottom right-hand square. He does that pattern a few times (or 3 perturbations) and then switches directions, moving in a clockwise pattern (until the final 3 perturbations are completed).



Adaptation to reduce difficulty – have participant take short steps over the lines Adaptation to increase difficulty – have participant take long steps over the lines Progressions of this task:

- Stepping on a thin foam mat
- Cued direction physiotherapist calls out 'change' or 'switch' and the participant begins moving in the opposite direction

Walking backward – participant takes steps to travel in a backward direction. Walking continues until all perturbations are accomplished.

Adaptation to reduce difficulty – have participant take short steps, or walk slowly Adaptation to increase difficulty – have participant take long steps; traffic light Progressions of this task:

Walking on a thin foam mat

Tandem walking forward - participant takes a step forward with the right foot and places the right heel ahead of the left toes; then he brings the left foot out and around the right foot, and places the left heel ahead of the right toes; then the process repeats until all perturbations are completed.



Figure 6.25. Tandem walking

Adaptations to reduce difficulty – participant takes longer steps (i.e. heel and toes don't touch) or participant places feet close to the line but not on the line

Adaptation to increase difficulty – traffic light

Progressions of this task:

Walking on a thin foam mat

Sideways braiding – participant stands at the right edge of the room; he is asked to walk to the left; he takes a step with the right foot that crosses over the left foot and lands lateral to, and slightly ahead of, the left foot, with part of his foot on the midline; then he brings the left foot out from behind the right and steps to the left, landing on the midline; then he takes a step with the right foot that crosses behind the left foot and lands lateral to, and slightly behind, the left foot, with part of his foot over the right foot and steps to the left; and then the process repeats until he walks as far as he possibly can within the available space. Then he is asked to do the opposite and walk to the right. This pattern continues until all perturbations are accomplished.

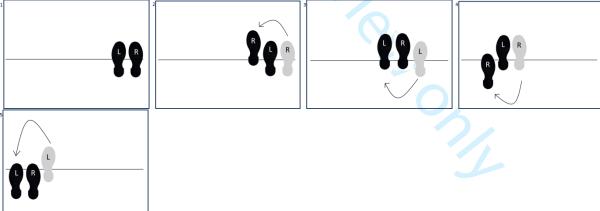


Figure 6.26. Sideways braiding

Adaptations to reduce difficulty – participant's foot does not fully cross over or behind the stance foot; or, participant's foot crosses but does not come into contact with midline Adaptation to increase difficulty – traffic light Progressions of this task:

Walking on a thin foam mat

Tandem walking backward - participant takes a step backward with the right foot and places the right toes behind the left heel; then he brings the left foot out and around the right foot, and places the left toes behind the right heel; then the process repeats until all perturbations are completed.

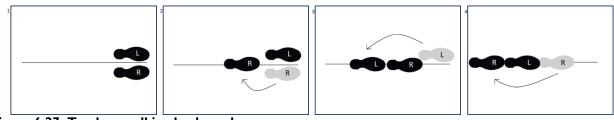


Figure 6.27. Tandem walking backward

Adaptations to reduce difficulty – participant takes longer steps (i.e. heel and toes don't touch) or participant places feet close to the line but not on the line

Adaptation to increase difficulty – traffic light

Progressions of this task:

Walking on a thin foam mat

Backward braiding – participant takes a step backward with the right foot that crosses the midline path and lands lateral to, and slightly behind, the left foot; then he brings the left foot out and around the right foot, taking a step backwards across the midline path that lands lateral to, and slightly behind, the right foot; then the process repeats until all perturbations are accomplished.

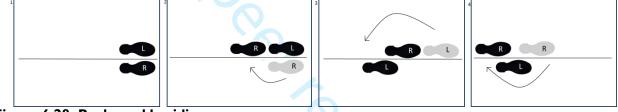


Figure 6.28. Backward braiding

Adaptation to reduce difficulty – walking on the line Adaptations to increase difficulty - increase distance of step across line; take longer steps; traffic light Progressions of this task:

Walking on a thin foam mat

Kicking a soccer ball against wall – participant stands at least 1 metre away from a wall; he kicks a soccer ball with enough force that it bounces back to him from the wall; he receives the ball and kicks it again. The task is repeated until all perturbations are accomplished.

Adaptation to reduce difficulty – none

Adaptations to increase difficulty – have participant stand further away from the wall; have participant kick it outside of his base of support; have participant alternate kicking with each foot

Progressions of this task:

- Standing on a thin foam mat
 - Kicking the ball to the physiotherapist and receiving it back; this may require moving to reach the ball
- Kicking the ball with the physiotherapist while standing on a thin foam mat

Throwing a handball against the wall – participant stands at least 1 metre away from a wall; he throws a hand ball with enough force that it bounces back to him from the wall; he receives the ball and throws it again. The task is repeated until all perturbations are accomplished.

Adaptation to reduce difficulty – have participant throw a large ball

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Adar	otations to increase difficulty – ha	ve participant throw a small ball; have	participant stand
		• •	
	<i>,</i> ,	icipant throw the ball with each arm	
Prog	ressions of this task:		
	Standing on a thin foam mat		
	Throwing the ball to the physi	otherapist and receiving it back; this I	may require moving
	to catch it		6
			f
	i nrowing the dail with the phy	ysiotherapist while standing on a thin	ioam mat
	ith suddon stone and change	s in direction – participant walks for	word and at any
•			,
	, , , ,	participant has to stop walking quickl	, , .
'left'), and t	he participant has to turn to the	right (left) and continue walking. The	task continues until
l perturbat	ions are accomplished.		
Adap	otation to reduce difficulty – have	participant walk slowly	
•	otation to increase difficulty – hav	,	
•	ressions of this task:		
FIOS			• haa 4aall. != +l
		ool noodles or steps – the participan	
	trame and manage the obstacle	es while also stopping or changing dir	ection on command
Move to di	fferent corners of the room -	 participant stands in the centre of the 	he room facing
		of the room (marked with different c	•
		rs in front of him, then backward to r	• •
,		rs behind him, then forward to return	
			i to the start
	e task continues until all perturba	· ·	
•	otation to reduce difficulty – have		
•	otation to increase difficulty – hav	e participant walk quickly	
Prog	ressions of this task:		
-	Stepping over obstacles, e.g. p	ool noodles or steps – the participan	t has to walk in the
		es while making his way to the correc	
			1
Jodgeball	- the participant must avoid hair	ng hit by the ball that is being thrown	at him by the
			at min by the
	bist. This requires transfer of wei		
•		iotherapist throws ball at upper body	
Adap	station to increase difficulty – phy	vsiotherapist throws ball rapidly at pa	rticipant's feet
Vancian datas ?	20 October 2017		Page 58 of 59

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6. RATING OF PERCEIVED CHALLENGE SCALE

NO CHALLENGE AT ALL		Ι
A LITTLE BIT OF CHALLENGE		2
SOME CHALLENGE		3
MUCH CHALLENGE		4
CAN NOT DO		5
APTED FROM: DARTHMOUTH COOP FUNCTIO nily Doctors) 1995	NAL ASSESSMENT CHARTS /	WONCO (World Organization

Section/Topic	ltem No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and	2a	Scientific background and explanation of rationale	
objectives	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
inal deelgn	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were	
		actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they	
		were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	
,		interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	
CONSORT 2010 checklist			Pag

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	assessing outcomes) and how	
11b	If relevant, description of the similarity of interventions	
12a	Statistical methods used to compare groups for primary and secondary outcomes	
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	
13b		
14a		
14b		
15		
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	
	by original assigned groups	
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	
	precision (such as 95% confidence interval)	
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	
	pre-specified from exploratory	
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
21		
22		
23	Begistration number and name of trial registry	
d reading	g this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, w	e also
NSORT e	extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragm	atic trials.
e forthco	ming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.	
	12a 12b 13a 13b 14a 14b 15 16 17a 17b 18 19 20 21 22 23 24 25 d reading	11b If relevant, description of the similarity of interventions 12a Statistical methods used to compare groups for primary and secondary outcomes 12b Methods for additional analyses, such as subgroup analyses and adjusted analyses 13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome 13b For each group, losses and exclusions after randomisation, together with reasons 14a Dates defining the periods of recruitment and follow-up 14b Why the trial ended or was stopped 15 A table showing baseline demographic and clinical characteristics for each group 16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 19 All important harms or unintended effects in each group (tor specific guidance see CONSORT for harms) 20 Trial limitations, addressing sources of potential bias, imprecision, and, if relev

CONSORT 2010 checklist

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ltem	Item	Where lo	Where located **		
number		Primary paper (page or appendix number)	Other [†] (details)		
1.	BRIEF NAME Provide the name or a phrase that describes the intervention. WHY				
2.	Describe any rationale, theory, or goal of the elements essential to the intervention. WHAT				
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).				
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. WHO PROVIDED				
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.				
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. WHERE				
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.				

TIDieR checklist

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	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including		
	the number of sessions, their schedule, and their duration, intensity or dose.		
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why,		
	when, and how.		
	MODIFICATIONS		
10. [‡]	If the intervention was modified during the course of the study, describe the changes (what, why,	n/a	
	when, and how).		
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any	8, 13	
	strategies were used to maintain or improve fidelity, describe them.		
12. [‡]	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the	13	
	intervention was delivered as planned.		
suffic † If the in or othe	brs - use N/A if an item is not applicable for the intervention being described. Reviewers – use '?' if information is intervented. Information is not provided in the primary paper, give details of where this information is available. This may inc er published papers (provide citation details) or a website (provide the URL). In pleting the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described	clude locations such	as a published protocol
* We stro	ongly recommend using this checklist in conjunction with the TIDieR guide (see BMJ 2014;348:g1687) which contains ar	n explanation and ela	boration for each item.
studies TIDieR (When a Statem	cus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. checklist should be used in conjunction with the CONSORT statement (see <u>www.consort-statement.org</u>) as an extension a clinical trial protocol is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as ent (see <u>www.spirit-statement.org</u>). For alternate study designs, TIDieR can be used in conjunction with the appropriate quator-network.org).	When a randomised of Item 5 of the CON s an extension of Iten	trial is being reported, the ISORT 2010 Statement. n 11 of the SPIRIT 2013
TIDieR	checklist For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml		

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Does perturbation-based balance training prevent falls among individuals with chronic stroke? A randomized controlled trial.

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Manuscript ID	bmjopen-2018-021510.R1
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Primary Subject Heading :	Rehabilitation medicine
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Keywords:	Stroke < NEUROLOGY, REHABILITATION MEDICINE, Exercise, Physiotherapy, Accidentaly falls, Postural balance

SCHOLARONE[™] Manuscripts Page 1 of 102

BMJ Open

1 2 3	1	Title: Does perturbation-based balance training prevent falls among individuals with chronic stroke? A
5 4 5	2	randomized controlled trial.
6 7	3	Authors: Avril Mansfield, PhD; ¹⁻³ Anthony Aqui, MSc; ¹ Cynthia J Danells, MSc; ^{1,3} Svetlana Knorr,
8 9	4	PhD; ¹ Andrew Centen, MSc; ² Vincent G DePaul, PhD; ⁴ Alison Schinkel-Ivy, PhD; ⁵ Dina Brooks,
10 11 12	5	PhD; ^{1,3} Elizabeth L Inness, PhD; ^{1,3} George Mochizuki, PhD ¹⁻³
13 14	6	Affiliations: ¹ Toronto Rehabilitation Institute, Toronto, ON, Canada; ² Evaluative Clinical Sciences,
15 16	7	Hurvitz Brain Sciences Research Program, Sunnybrook Research Institute, Toronto, ON, Canada;
17 18 19	8	³ Department of Physical Therapy, University of Toronto, Toronto, ON, Canada; ⁴ School of
20 21	9	Rehabilitation Therapy, Queen's University, Kingston, ON, Canada; ⁵ Schulich School of Education –
22 23	10	School of Physical and Health Education, Nipissing University, North Bay, ON, Canada
24 25 26	11	Corresponding author: Avril Mansfield; address: 550 University Ave, Toronto, ON, M5G 2A2; tel:
20 27 28	12	416-597-3422 ext 7831; e-mail: avril.mansfield@uhn.ca
29 30	13	Word count: 4,365
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33 34 35	15	authors also acknowledge the support of the Toronto Rehabilitation Institute; equipment and space
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40 41 42	18	Institutes of Health Research (MSH 141983). DB holds a Canada Research Chair. These funding
43 44	19	sources had no role in the design of this study and will not have any role during its execution, analyses,
45 46	20	interpretation of the data, or decision to submit results.
47 48 49	21	Acknowledgements: We thank the members of the Data Safety and Monitoring Committee (Kathryn
49 50 51	22	Sibley, Susan Marzolini, Parvin Eftekhar and Irene Antunes) who monitored the trial. We also
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54 55 56		
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59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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1 2	26	ABSTRACT (word count: 300; max: 300)
3		
4 5	27	Objectives: No intervention has been shown to prevent falls post-stroke. We aimed to determine if
6 7	28	perturbation-based balance training (PBT) can reduce falls in daily life among individuals with chronic
8 9 10	29	stroke.
11 12	30	Design: Assessor-blinded randomized controlled trial.
13 14	31	Setting: Two academic hospitals in an urban area.
15 16 17	32	Interventions: Participants were allocated using stratified blocked randomization to either 'traditional'
17 18 19	33	balance training (control) or PBT. PBT focused on improving responses to instability, whereas
20 21	34	traditional balance training focused on maintaining stability during functional tasks. Training sessions
22 23	35	were 1 hour twice/week for 6 weeks. Participants were also invited to complete 2 'booster' training
24 25 26	36	sessions during the follow-up.
27 28	37	Participants: Eighty-eight participants with chronic stroke (>6-months post-stroke) were recruited and
29 30	38	randomly allocated one of the two interventions. Five participants withdrew; 42 (control) and 41 (PBT
31 32 33	39	group) were included in the analysis.
33 34 35	40	Primary and secondary outcome measures: The primary outcome was rate of falls in the 12-months
36 37	41	post-training. Negative binomial regression was used to compare fall rates between groups. Secondary
38 39	42	outcomes were measures of balance, mobility, balance confidence, physical activity, and social
40 41 42	43	integration.
43 44	44	Results: PBT participants reported 53 falls (1.45 falls/person-year) and control participants reported 64
45 46	45	falls (1.72 falls/person-year; rate ratio: 0.85 [0.42, 1.69]; p=0.63). Per-protocol analysis included 32
47 48 49 50 51 52 53 54 55	46	PBT and 34 control participants who completed at least 10/12 initial training sessions and 1 booster
	47	session. Within this sub-set, PBT participants reported 32 falls (1.07 falls/person-year) and control
	48	participants reported 57 falls (1.75 falls/person-year; rate ratio: 0.62 [0.29, 1.30]; p=0.20). PBT
	49	participants had greater improvement in reactive balance control than the control group, and these
56 57		

improvements were sustained 12-months post-training. There were no intervention-related serious

adverse effects.

- Conclusions: The results are inconclusive. PBT may help to prevent falls in daily life post-stroke, but
- ongoing training may be required to maintain the benefits.
- Trial registration: ISRCTN05434601.
 - Funding: Canadian Institutes of Health Research.

Key words: Stroke; Rehabilitation; Exercise; Physiotherapy; Accidental Falls; Postural balance

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abilitation; Exercise; r...

1 2	57	STRE	NGHTS AND LIMITATIONS OF THE STUDY
3 4 5	58	٠	This study employed an assessor-blinded randomized controlled trial. As is typical of exercise
6 7	59		studies, participant blinding was not possible.
8 9 10	60	•	Attendance to the intervention was high (mean 87% of sessions attended), and rates of
11 12	61		withdrawal from the study were low (<6%).
13 14	62	•	The primary outcome (falls in daily life) was collected via self-report, which may have led to
15 16 17	63		under-reporting.
18 19	64	•	Inclusion and exclusion criteria were minimal so that results would be generalizable to a broad
20 21	65		population of individuals with chronic stroke. However, recruited participants were, on average,
22 23 24	66		high functioning; these results might not apply to more severely-affected individuals with
25 26	67		stroke.
$\begin{array}{c} 27\\ 28\\ 29\\ 30\\ 31\\ 32\\ 33\\ 34\\ 35\\ 36\\ 37\\ 38\\ 39\\ 40\\ 412\\ 43\\ 44\\ 45\\ 46\\ 47\\ 48\\ 9\\ 50\\ 51\\ 52\\ 53\\ 54\\ 55\\ 56\end{array}$	68		
57 58 59			5

INTRODUCTION

People with stroke have increased fall risk compared to age-matched individuals who have not had a stroke.¹ Impaired balance control, low balance confidence, and high rate of falls post-stroke are associated with reduced quality of life and reduced physical activity as a strategy to prevent falls.^{2,3} Physical exercise, particularly exercise that includes balance training, can reduce fall rates in older adults.⁴ However, studies including individuals with stroke have not demonstrated reduced fall rates following balance training.^{5,6}

Balance training programs typically include exercises that aim to improve the ability to maintain balance when keeping still (e.g., standing with reduced base of support) or during voluntary movement (e.g., sit-to-stand or step ups).⁷⁻¹¹ This type of balance training may prevent falls by reducing the risk of losing balance in daily life. However, occasional loss of balance may be an inevitable consequence of mobility, so the ability to react quickly after losing balance (i.e., reactive balance control) is essential to prevent falls.¹² Perturbation-based balance training (PBT) is a type of exercise where participants repeatedly experience loss of balance in order to practice and improve control of balance reactions.¹³ A review of small-sample randomized controlled trials suggests that PBT can prevent falls in older adults and individuals with Parkinson's disease.¹⁴

People with stroke have impaired reactive balance control,^{15,16} and impaired control of balance reactions is related to increased fall rates in daily life post-stroke.^{17,18} PBT can improve reactive balance control post-stroke.¹⁹ A non-randomized study found that those who completed PBT during inpatient stroke rehabilitation fell less frequently post-discharge than those who did not.²⁰

The main purpose of this study was to determine if PBT reduces fall rates in people with chronic stroke. A secondary purpose was to determine the effect of PBT on balance control, balance confidence, mobility, daily physical activity, and social integration. We hypothesized that, compared to a control group who completed 'traditional' balance training, those who completed PBT would

1 2	93	experience fewer falls in the year post-training and would have greater improvements in measures of
3 4 5 6 7 8 9	94	functional balance and mobility. Additionally, we expected that, due to reduced fall rates and improved
	95	balance confidence, participants who completed PBT would be less likely to restrict daily physical
	96	activities; therefore, we hypothesized that participants who completed PBT would show increased daily
10 11	97	physical activity and improved social integration compared to those in the control group.
12 13 14	98	
15 16	99	METHODS
17 18	100	Trial design
19 20 21	101	This assessor-blinded pragmatic randomized controlled trial took place at the Toronto Rehabilitation
	102	Institute (University Health Network) and Sunnybrook Health Sciences Centre. Individuals with
	103	chronic stroke were recruited and randomly assigned to either: 1) PBT or 2) 'traditional' balance
26 27	104	training (control group). The full study protocol is available elsewhere; ²¹ protocol modifications are
	105	detailed in the relevant sections below. The protocol and amendments were approved by the University
31 32	106	Health Network (study ID: 14-7428) and Sunnybrook Health Sciences Centre (study ID: 134-2014)
33 34	107	Research Ethics Boards. This manuscript was prepared following the CONSORT ²² and TIDieR ²³
35 36 37	108	checklists.
38	109	
40 41	110	Participants
42 43 44	111	Community-dwelling adults with chronic stroke (>6 months post-stroke) were recruited from research
	112	volunteer databases and advertisements in the community. Participants could stand independently
	113	without upper-limb support for >30s and tolerate at least 10 postural perturbations. Exclusion criteria
49 50 51	114	were: >2.1m tall and/or weighing >150kg; other neurological conditions; lower extremity amputation;
	115	unable to understand instructions in English; recent (last 6 months) significant illness, injury or
	116	surgery; severe osteoporosis (diagnosis of osteoporosis with fracture); poorly controlled diabetes or
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hypertension; contraindications to physical exercise;²⁴ receiving physiotherapy or supervised exercise 2 117 118 targeting balance and mobility between the time of recruiting and the post-training assessment; and/or 119 received PBT in the year before enrolment. Due to difficulty recruiting, the protocol was amended to allow individuals <50 years old to participate. Volunteers completed telephone screening and 120 11 121 subsequently attended an initial assessment where written informed consent was obtained and 122 eligibility was confirmed. To help alleviate barriers to participation, participants were compensated for 16 123 travel expenses (public transit fare or parking).

²⁰ 125 Interventions

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⁻⁻₂₃ 126 Participants completed 2 1-hour training sessions per week for 6 weeks, and 2 1-hour 'booster' training 24 sessions 3- and 9-months after the initial training period. Interventions were administered by a 25 127 26 ²⁷ 128 physiotherapist (CJD or SK) on a 1:1 basis (i.e., one physiotherapist per participant) in research 28 29 29 30 129 laboratories in academic hospitals. Both laboratories contained a 2.63 x 2.63m 4-post XY patient lift 31 gantry (Prism Medical Ltd, Concord, ON, Canada), and the Sunnybrook laboratory also contained a 32 130 33 34 131 8.5m long ceiling lift track, to which the safety harness was attached during PBT. Physiotherapists 35 ³⁶ 37 132 were trained in delivering the control intervention by reviewing the intervention developers' 38 documentation,²⁵ and in delivering the PBT intervention by study investigators (AM and VGD). 39 133 40 41 1 34 Interventions followed a general guide, but were tailored to participants' ability and balance 42 ⁴³ 135 impairments. Participants rated perceived level of challenge on a 5-point scale (see Supplementary 44 45 46 136 Material) after completing each exercise set. The physiotherapists documented activities in each 47 48 1 37 session, perceived level of challenge, adverse events, and deviations from prescribed activities. 49 ⁵⁰ 138 51 52 52 53 139 Control group 54

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The control group completed the Keep Moving with Stroke program.²⁵ This is an exercise program for community-dwelling individuals with stroke, based on balance and mobility interventions evaluated in clinical trials.⁹⁻¹¹ This program was designed to be delivered in a group, but was delivered 1:1 in this study to match attention received from the physiotherapist by the PBT group. Each session included a 5-10 minute warm-up, 40 minutes of mobility and balance exercises, and a 5-10 minute cool-down with stretching. Exercises included walking, sit-to-stand, heel raises, walking while carrying an object, tap-ups or step-ups (forward and sideways), reaching and weight shifting, and standing with reduced base of support.

149 PBT group

PBT sessions included a 5-10 minute warm-up, voluntary tasks intended to induce internal
perturbations, voluntary tasks combined with external perturbations, and a 5-10 minute cool-down.
Participants were supervised by the physiotherapist and wore a custom safety harness (ABG Concept
Médical Inc., Valcourt, QC, Canada) attached to the overhead support. Internal perturbations occurred
when participants failed to control balance during voluntary movement; 'agility' tasks, such as kicking
a soccer ball, were used to induce internal perturbations. External perturbations were caused by forces
outside participants' control (e.g., push or pull from the physiotherapist). We aimed for at least 60
postural perturbations per session, and set the task difficulty such that participants required an upper
extremity response, external assistance (i.e., from the overhead harness or physiotherapist), or a multistep response ~50% of the time. The progression in voluntary tasks occurred on a continuum from
stable to mobile, and from predictable to unpredictable.²⁶ Additionally, progression occurred by
increasing the magnitude of external perturbation, or imposing sensory or environmental challenges.
The full PBT program is available in the Supplementary Material.

2 164 3 4 165 5 6 166 7 8 167 9 10 11 168 12 13 169 14 15 16 170 17 18 171 19 ²⁰ 172 21 22 ⁻⁻₂₃ 173 24 25 174 26 ²⁷ 175 28 29 ²₃₀ 176 31 32 177 33 34 178 35 36 37 179 38 39 180 40 41 181 42 43 182 44 45 46 183 47 48 184 49 ⁵⁰ 185 51 52 186 53 54 55 187 56 57 58 59 60

4 Group allocation

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Participants were assigned using blocked stratified randomization with allocation concealment to either the control or PBT group by the principal investigator (AM), who was not involved in recruiting, assessments, or intervention administration. A variable block size of 4, 6 or 8 was used. There were four strata from two stratification factors: site (two levels), and frequency of 'failures' during baseline reactive balance control assessment¹⁷ (two levels). The random allocation sequence was computer generated and maintained in an electronic file by the principal investigator.

72 **Outcomes**

73 Cohort descriptors

Demographic and stroke information were recorded at study enrolment: age, sex, time since stroke,
lesion location, falls history, National Institutes of Health Stroke Scale (NIH-SS²⁷), and ChedokeMcMaster Stroke Assessment (CMSA) foot and leg scores.²⁸ Demographics and medical history were
obtained by self-report and, when possible, verified from participants' hospital charts.

79 Primary outcome – falls

A fall was defined as "an event that results in a person coming to rest unintentionally on the ground or other lower level".²⁹ Participants completed 12-months of falls reporting after the initial 6-week training period. Participants were provided stamped addressed postcards containing a 2-week calendar to record falls, which they completed daily, and returned to the research team fortnightly. If a postcard was not returned within 2 weeks the research assistant called the participant to ascertain if they fell. Participants who fell completed a short telephone questionnaire regarding the cause, circumstances, and consequences of the fall. Falls were excluded from analysis, by unanimous decision of two blinded research assistants, if they were caused by loss of consciousness or an overwhelming external force

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2 188 3	(i.e., if anyone would fall in that situation). If the research assistants could not agree that a fall should
4 189 5	be excluded, that fall was included in the analysis.
6 7 190	
8 9 191	Secondary outcomes
10 11 192 12	Balance and mobility and balance confidence were assessed immediately before, immediately after,
13 14 193	and 6- and 12-months after the end of the initial training period. Functional balance and mobility were
15 16 194 17	assessed using the Berg balance scale (BBS ³⁰), the mini-Balance Evaluation Systems test (mini-
18 195 19	BEST ³¹), and the Timed Up & Go (TUG ³²). The sub-scales of the mini-BEST were used to assess
²⁰ 196 21	different components of balance control (anticipatory balance control, reactive balance control, sensory
22 23 197 24	orientation, and gait). The Activities-specific Balance Confidence (ABC) questionnaire ³³ was used to
25 198 26	assess balance confidence in daily activities.
²⁷ 199 28	Physical activity and social integration were evaluated with the Physical Activity Scale for
²⁹ 30 ²⁰⁰	Individuals with Physical Disabilities (PASIPD ³⁴) and the Subjective Index of Physical and Social
31 32 201	Outcome (SIPSO ³⁵), respectively, at baseline and every 2 months during the 12-month follow-up.
33 34 202 35	
³⁶ 37203	Blinding
38 39 204	The research assistants (AA and AC) were blinded to group allocation and were responsible for
40 41 205 42	screening, recruiting, and collecting data. At the post-training, 6-month, and 12-month assessments, the
$\frac{43}{44}206$	research assistants guessed group allocation for each participant, rated their confidence in their guess of
45 46 207	group allocation, and noted if they had received any information to violate blinding. In cases where
47 48 208 49	blinding was violated, the balance measures were re-coded from video footage by another blinded
⁵⁰ 209 51	research assistant.
52 53 210	
54 55 211	Sample size
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212 The target sample size was estimated for the primary outcome (fall rate in the year post-training) using a formula for negative binomial regression.³⁶ Assuming the control group would report 1.75 per 213 person-year,¹⁷ a rate ratio of 0.54,¹⁴ mean follow-up time of 11 months per person, level of significance 214 of 0.05, and power of 0.8, we estimated that 37 participants per group would be required to show a 215 10 11 216 statistically significant between-group difference in fall rates. 12

15 16218 **Statistical analysis**

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18219 Wilcoxon-Mann-Whitney test (continuous/ordinal variables) and Fisher's exact test 19 ²⁰₂₁220 (categorical/frequency variables) were used to compare the two groups at baseline. Negative binomial 22 23 221 regression was used to compare fall rates and logistic regression was used to compare the proportion of 24 25 222 fallers between the two groups. Intent-to-treat analysis was used; that is, all participants with some 26 ²⁷ 223 28 falls-monitoring data were included in the analyses. To account for variable falls-monitoring duration ²⁹ 30 224 between participants (e.g., due to premature withdrawal from the study) the natural log of the 31 32 225 monitoring duration was included as an offset variable in negative binomial regression, and as a 33 34 2 2 6 covariate in logistic regression. Exploratory per-protocol analysis was also conducted, comparing 35 ³⁶ 37 227 proportion of fallers and fall rates between the two groups, including only those participants who 38 attended at least 10/12 of the initial training sessions and 1 booster session. We initially planned to 39 228 40 41 2 2 9 conduct repeated-measures analysis of variance, with group-by-time interaction, to evaluate the effect 42 ⁴³230 of the interventions on secondary outcome measures.²¹ However, because the variables were not 44 45 46 231 normally distributed we conducted analysis of co-variance (ANCOVA), comparing BBS, mini-BEST, 47 48 2 3 2 mini-BEST subscale scores, TUG, ABC, PASIPD, and SIPSO at each time point between groups, 49 ⁵⁰233 controlling for the value at baseline. Dependent variables were rank transformed prior to entry into the 51 ⁵² 53 234 ANCOVA to allow for non-parametric analysis.³⁷ Alpha was 0.05 for all analyses. 54

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1 2 236	Patient and public involvement
3	
5	Patients or the general public were not involved in the design of this study, development of research
⁶ ₇ 238	questions, or outcome measures. Some participants were recruited via referral from other participants.
8 9 239 10	Participants received a letter of appreciation at the end of the study, which included a summary of the
11 240 12	results. At the end of their involvement with the study, participants were invited to complete a short
13 14 241	questionnaire about their experiences, including whether they found data collection and the
15 16 242 17	intervention difficult.
18 243 19	
²⁰ 244	
22 23 245 24	Recruitment
25 246 26	Recruiting occurred between 24 April 2014 and 29 June 2016. Initially, we planned to recruit 46
²⁷ 247 28	
²⁹ 30 248 31	we had at least 37 participants per group who had returned at least one fall-reporting postcard. Any
32 249 33	participants who had started the intervention at this point continued with the study until they either
³⁴ 250 35	withdrew or completed all study elements. The trial ended when data collection for all recruited
³⁶ ₃₇ 251	participants was complete (August 2017). Forty-four participants were assigned to each group, with 42
38 39 252 40	(control) and 41 (PBT) returning at least 1 fall-reporting postcard (Figure 1); thus 42 control and 41
41 253 42	PBT participants were included in analysis of the primary outcome (falls in daily life). Baseline
43 44 254	characteristics for these participants are in Table 1; there were no significant differences between
45 46 255	groups on any baseline characteristics.
47 48 256 49	
⁵⁰ 257 51	Intervention adherence
52 53 258	During the initial 6-week training program, PBT participants attended a mean 10.5 sessions, with 34/41
54 55 259	participants attending at least 10 sessions (out of the prescribed 12). Participants experienced a mean of
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577 perturbations during all sessions (standard deviation: 195 perturbations; minimum: 42 perturbations), or a mean of 55 perturbations per session (standard deviation: 9 perturbations). For all PBT sessions combined, mean rate of balance recovery 'failures' was 57%, and mean rate of perceived challenge was 2.4 (on a five-point scale). In the initial 6-week training phase, control participants attended a mean of 11 sessions, with 38/42 participants attending at least 10 sessions (out of the prescribed 12). On average, control participants completed 87% of the prescribed exercises (standard deviation: 18%). For all control training sessions combined, mean rate of perceived challenge was 2.4.

- 68 **Outcomes and estimation**
- 69 Blinding

Blinding was violated for 9 participants (7 PBT and 2 control), who revealed their group allocation in conversation with the research assistant. The BBS and mini-BEST scores for these participants were recoded from video recordings by another blinded research assistant who had no interaction with participants. For the remaining participants, the research assistants correctly guessed group allocation 56% of the time; i.e., guesses were not correct more often than would be expected by random chance.

276 Missing data

Data were missing at assessment time points because participants: declined to complete the assessment (15 PBT and 21 control assessments); were unavailable due to acute illness (3 control assessments); were unavailable due vacation or other personal commitments (3 control assessments); or could not be contacted at the time of the assessment (6 control assessments). Some participants declined to come to the laboratories for the 6- and 12-month assessments, but were willing to complete the questionnaires (ABC, SIPSO, and PASIPD) over the telephone. Even when participants attended a study appointment,

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1 2 283	some declined to complete individual tests; the number of individuals included in analysis of each
3 4 284 5	variable at each time point is detailed in the Tables.
$\frac{6}{7}$ 285	
8 9 286	Falls
10 11 287	Data on number of individuals reporting 1 or more falls, and fall rates, are presented in Table 2. In
12 ¹³ 14 ²⁸⁸	intent-to-treat analysis, the between-group differences in odds of being a 'faller' (odds ratio: 0.71 [0.30,
14 15 16 289	1.70]; p=0.44) and fall rates (rate ratio: 0.85 [0.42, 1.69]; p=0.63) were not statistically significant.
17 18 290	Thirty-two PBT participants and 34 control participants completed at least 10/12 of the initial training
19 20 21 291	sessions and 1 booster session, and were included in per-protocol analysis. Within this sub-set, the
21 ²⁹¹ 22 23292	
24	between group differences in odds of being a 'faller' (odds ratio: 0.56 [0.21, 1.50]; p=0.25) and fall
25 293 26 27 20 4	rates (rate ratio: 0.62 [0.29, 1.30]; p=0.20) were not statistically significant.
27 294 28 29	
²⁹ 30295 31	Balance confidence, balance, mobility, physical activity, and social integration
32 296 33	Post-training, the PBT group had higher scores than the control group for the reactive sub-scale of the
34 297 35	mini-BEST (F _{1,74} =7.33, p=0.0084; Table 3), whereas the control group had higher scores than the PBT
³⁶ 37 38	group for the sensory subscale ($F_{1,74}$ =4.19, p=0.044). Scores for the reactive sub-scale of the mini-
39 299 40	BEST were higher for the PBT group than the control group at 6-months ($F_{1,57}$ =8.32, p=0.0055) and
41 300 42	12-months ($F_{1,53}$ =11.59, p=0.0013). Likewise, at 12-months, the PBT group had a higher score on the
43 44 301	total mini-BEST than the control group ($F_{1,53}$ =4.04, p=0.049). There were no other statistically
45 46 302	significant between-group differences for balance and mobility measures at any time point.
47 48 303 49	There were no significant between-group differences for the PASIPD at any time point (Table
⁵⁰ 304	4). SIPSO scores were significantly higher for the control group compared to the PBT group at 6-
⁵² 53 305	months ($F_{1,59}$ =6.73, p=0.012), 8-months ($F_{1,54}$ =4.25, p=0.044), 10-months ($F_{1,61}$ =4.89, p=0.031), and
54 55 306	12-months ($F_{1,59}$ =4.13, p=0.047).
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58 59	15 For peer review only - http://bmiopen.bmi.com/site/about/guidelines.xhtml

1 2 307	Data showing change in secondary outcomes over time are presented in the supplementary data
3	(Supplementary Tables S1 and S2). No analyses were conducted on these data.
5	(Supplementary Tables 51 and 52). No anaryses were conducted on these data.
7 309 8	
9 310 10	Ancillary analysis
11 311 12	Additional exploratory analysis compared causes, circumstances, and consequences of falls in daily life
$^{13}_{14}312$	between groups (Table 5). There was a significant between-group difference in motor activity at the
15 16 313	time of the fall (p=0.010). Falls in control participants were more likely to occur during transfers than
17 18 314 19	falls in PBT participants, whereas falls in PBT participants were more likely to occur during
²⁰ 315 21	reaching/bending than falls in control participants. Participants had something in their hands at the time
22 23 316 24	of 45% of control-group falls, compared to 23% of PBT-group falls (p=0.023). PBT participants
24 25 317 26	attempted to stop themselves from falling by using a step response for 21%, or a grasping response for
²⁷ 318 28	18% of falls, whereas control participants tried to prevent the fall by stepping for only 9% of falls, and
²⁹ 30 319	grasping for 30% of falls; however, this difference was not statistically significant (p=0.18). PBT
31 32 320 33	participants required assistance to get up after 48% of falls, compared to just 27% of falls for control
³⁴ 321 35	participants (p=0.040). Injuries resulted from 18 falls (39% of falls) in the PBT group and 20 falls
³⁶ 37 322	(34% of falls) in the control group (p=0.68). Most injuries were minor (e.g., cuts and bruises).
38 39 323 40	Participants sought medical attention after 3 falls (all control): visit to emergency room (2 falls), and
40 41 324 42	treatment from an unspecified healthcare professional (1 fall).
⁴³ ₄₄ 325	
45 46 326	Harms
47 48 327 49	Forty-eight adverse events were possibly, probably, or definitely related to study procedures or
50 328 51	interventions among the 88 randomized participants. Events were: fatigue with training (3 PBT, 1
⁵² 53 329	control); joint pain during or soon after training (14 PBT, 11 control); delayed onset muscle soreness (5
54 55 330	PBT, 8 control); seizure during training (1 PBT participant, with history of frequent seizures);
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59 60	16 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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abnormally elevated heart rate and low blood pressure during training (1 control; this participant was 331 332 withdrawn from the study). For all but this last event, medical attention was not necessary to treat 333 adverse events. In the case of fatigue or joint/muscle pain, the intensity and/or duration of training was reduced until the issue resolved. Additionally, four falls that occurred during the training portion of the 334 study were considered related to study procedures or interventions. In one case (control) the participant 336 fell outside the hospital while on the way to a study appointment. The other three falls were reported by a single PBT participant who noted that he felt more confident, and may have increased risk-taking behaviour, as a result of the intervention. Eight participants experienced serious adverse events unrelated to study procedures, but that resulted in study withdrawal: prolonged hospitalization (1 PBT, 1 control); another stroke (2 PBT, 3 control); death (1 control); and cancer diagnosis (1 control).

DISCUSSION

We hypothesized that PBT would reduce fall rates among individuals with stroke; this hypothesis was not supported. While the rate ratio comparing falls rates between the PBT and control groups was 0.85, this was not statistically significant. The pooled rate ratio estimating the effect of exercise on fall rates in community-dwelling older adults is 0.80,⁴ which is similar to that observed in the current study. Our sample size was based on a rate ratio of 0.54, which was estimated from a meta-analysis of PBT.¹⁴ that included studies among older adults and individuals with Parkinson's disease. Another non-randomized study reported a fall rate ratio of 0.32 when comparing individuals with sub-acute stroke who completed PBT during in-patient rehabilitation to those who did not.²⁰ The effect of PBT on fall rates in chronic stroke may be much lower than in other patient populations or individuals with sub-acute stroke and, therefore, the current study may not have had sufficient power to detect the true effect. 353 Conversely, the between-group difference in fall rates was much greater when only individuals who completed at least 80% of initial training sessions and 1 booster session were included in the analysis.

The booster sessions may have helped participants to retain the training benefits^{38,39} by providing

participants with opportunity to practice reactive balance skills throughout the 12-month follow-up period.

Importantly, the control group also completed balance training; previous studies using similar exercise programs found no effect of balance training on fall rates in people with chronic stroke when compared to a sham intervention⁷ or 'usual care'.⁴⁰ Thus, we expect that control participants did not have reduced fall risk as a result of completing this program. However, after the initial six week training period, both groups improved balance confidence (ABC), anticipatory balance control (BBS and mini-BEST anticipatory sub-scale sore), and mobility (mini-BEST gait sub-scale score), with no significant difference between groups on these measures post-training It is possible that improved balance and mobility led to reduced fall risk in the both groups compared to their pre-training fall risk.. Furthermore, it seems that PBT leads to similar improvements in anticipatory balance and mobility as a traditional balance training program that is primarily focused on improving anticipatory balance control.

Consistent with specificity of training, the PBT group improved reactive balance control (reactive sub-scale of the mini-BEST), but the control group did not;⁴¹ these improvements were retained at 6- and 12-months. This finding agrees with those of Bhatt *et al.*, who found that resistance to falling following a slip was retained up to 6-months after a single PBT session.³⁹ The mean betweengroup difference in the reactive sub-scale of the mini-BEST ranged from 0.6 (post-training) to 1.6 points (12-month follow-up). We are unaware of any study reporting minimal clinically important differences for the mini-BEST sub-scales; however, these between group differences represent 10-27% of the maximum score for this sub-scale (6 points) and, therefore, we interpret these differences as clinically meaningful. Despite these retained improvements in reactive balance control, PBT participants did not have a significantly reduced fall risk than control participants. Falls occur when

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2 379 3	there is a loss of balance and subsequent failure to recover. ⁴² Improved reactive balance control
4 380 5	following PBT should help to prevent falls by improving the ability to recover from a loss of balance.
6 7 381	Loss of balance can occur due to an external force or failure of anticipatory balance control. Thus, it is
8 9 382	possible that effective fall prevention post-stroke requires sustained improvements in both anticipatory
10 11 383 12	and reactive balance control; home exercise may help participants to retain improvements in
$^{13}_{14}384$	anticipatory balance control. ⁴⁰
15 16 385	Contrary to our hypothesis, control participants reported greater social integration 6-12 months
17 18 386 19	post-training than the PBT group. Individual-item SIPSO scores suggest that this finding was primarily
²⁰ 387	driven by control participants reporting increased independence in moving around their local
22 23 388	neighbourhoods. The control training program included walking practice during every session, whereas
24 25 389 26	the PBT program only included short bouts of walking in later sessions. This walking practice may
27 27 28 28	have increased control participants' confidence with community mobility. While increased social
²⁹ 30 391	integration at 6-12 months was not associated with improved physical function, it is likely that the tests
31 32 392	used in the current study do not correlate highly with community mobility. ⁴³ Training-related
33 34 393 35	improvements in balance and mobility in both groups, and increased self-reported participation in the
³⁶ 37 394	control group, were not associated with increased physical activity post-training. While impaired
38 39 395	balance and mobility post-stroke may be a barrier to physical activity, ⁴⁴ improved balance and mobility
40 41 396 42	alone is not sufficient to increase activity. ^{7,45} It is likely that an intervention that combines behaviour
⁴³ 44 397	change techniques with physical exercise is required to increase long-term participation in physical
45 46 398	activity. ⁴⁶
47 48 399	Examining fall characteristics can provide further insight into intervention effects on falls. ²⁰

Examining fall characteristics can provide further insight into intervention effects on falls. ⁵⁰ 400 Individuals with stroke seem to be reliant upon upper-extremity reactions to prevent falls in daily life.²⁹ In the current study, participants had something in their hands at the time of the fall for more control group falls than PBT falls, which may have prevented these individuals from using an upper-extremity 55 402

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reaction to prevent the fall.⁴⁷ Conversely, training, with a specific focus on reactive stepping, may have made PBT participants less reliant on upper extremity reactions to prevent falls. In agreement with a previous study,²⁰ control participants were more likely than PBT participants to fall during transfers; this finding may support the idea that PBT helps to prevent falls in routine situations, but not falls in more challenging situations. Participants required assistance to get up from the ground after more PBT group than control group falls; this finding could suggest that those PBT participants who fell were more impaired than PBT participants who did not fall or than those in the control group who fell.

11 Limitations

The primary outcome (falls in daily life) was obtained via self-report. While the method of prospective falls reporting used in the current study is the best available,⁴⁸ falls may have been under-reported. The cohort was, on average, relatively high functioning (e.g., median BBS score ~50/56), but had a wide range of physical function (minimum scores for CMSA leg: 3, CMSA foot: 2, BBS: 23, mini-BEST: 5; maximum NIH-SS score: 13; highest TUG time: 119s). This study's findings apply to communitydwelling individuals with chronic stroke who can stand independently for at least 30s. Group allocation blinding was violated for 9 participants. Balance measures for these participants were re-scored by a truly blinded research assistant; however, knowledge of group allocation may have sub-consciously influenced how other data were collected for these participants.

PASIPD scores were higher at the time points when the questionnaire was administered inperson compared to over the telephone. Physical activity questionnaires, including the PASIPD,³⁴ are often designed to have several methods of administration (e.g., self-administered via in-person or telephone interview),⁴⁹ and investigators seem to treat administration methods as equivalent.⁵⁰ We are not aware of any study that directly compared scores from the PASIPD or any other physical activity questionnaire when administered using different methods. It is possible that scores are higher when

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427 administered in-person versus over the telephone as participants' desire for social acceptance was 428 higher when they interacted directly with the research assistant. Alternatively, in-person administration 429 may have led to more accurate scores than telephone administration within this population, who may 430 have subtle cognitive-communication deficits, as the research assistant and participant could avail of 431 non-verbal communication to facilitate completing the questionnaire. However, SIPSO scores did not 432 differ between telephone versus in-person administration. Finally, participants in the current study may 433 have truly been more active in the week prior to the in-person interview compared to the telephone 434 interview to prepare for the tests of physical function. Future studies should investigate the potential 435 influence of administration methods on physical activity questionnaire scores.

37 Clinical implications

While this study found that PBT did not reduce fall rates among the entire cohort, PBT participants improved on measures of balance and mobility, and retained the improvements in reactive balance control up to 12-months post-training. Combined with results of previous studies reporting reduced fall rates following PBT among individuals with sub-acute stroke,²⁰ chronic stroke with a history of falling,⁵¹ and without stroke,¹⁴ and showing that PBT is the only intervention with capacity to improve reactive balance control,^{41,52} these results suggest that PBT may be a useful addition to existing balance training post-stroke. The PBT program developed for this study used existing resources available in many clinical settings and, therefore, could be relatively easily implemented in clinical practice. Joint pain was the most common adverse event related to PBT, which appeared to be most prevalent among those with lower-extremity arthritis; these participants were able to complete training with modifications to avoid exacerbating pain (e.g., temporarily reducing perturbation intensity). Therefore, modifications to PBT may be required for those with lower-extremity arthritis. Regular 'booster' PBT training sessions may be necessary to prevent falls long-term.

1 2 451	
3 4 452 5	Contributorship statement: AM conceived of the study, is the grant holder, performed statistical
6 7 453	analysis and drafted the manuscript. AM, VGD, ASI, DB, ELI, and GM developed the study protocol.
8 9 454	AM and GM led implementation of the study at each site. AM, VGD, and ELI developed the
10 11 455 12	intervention. AA, AC and ASI collected data. CJD and SK delivered the interventions. All authors
$^{13}_{14}456$	approved the final manuscript.
15 16 457	Competing interests statement: The authors declare that they have no competing interests.
17 18 458 19	Data sharing statement: Due to research ethics and privacy restrictions, raw data for this study are
²⁰ 459	Data sharing statement: Due to research ethics and privacy restrictions, raw data for this study are currently not available publicly.
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60	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2 460	REFE	CRENCES	
3 4 461 5	1.	Batchelor FA, Mackintosh SF, Said CM, Hill KD. Falls after stroke. Int J Stroke.	
6 7 462		2012;7(6):482-490.	
8 9 463	2.	Andersson ÅG, Kamwendo K, Apperlros P. Fear of falling in stroke patients: relationship with	
10 11 464		previous falls and functional characteristics. Int J Rehabil Res. 2008;31:261-264.	
12 ¹³ 14 465	3.	Schmid AA, Van Puymbroeck M, Altenburger PA, et al. Balance and balance self-efficacy are	
14 15 16 466		associated with activity and participation after stroke: a cross-sectional study in people with	
17 18 467		chronic stroke. <i>Arch Phys Med Rehabil.</i> 2012;93:1101-1107.	
19			
²⁰ 468 21 22	4.	Sherrington C, Michaleff ZA, Fairhall N, et al. Exercise to prevent falls in older adults: an	
22 23 469		updated systematic review and meta-analysis. Br J Sports Med. 2016;doi:10.1136/bjsports-	
24 25 470 26		2016-096547.	
²⁷ 471 28	5.	Verheyden GS, Weerdesteyn V, Pickering RM, et al. Interventions for preventing falls in	
²⁹ 30472		people after stroke. Cochrane Database Syst Rev. 2013;31(5):CD008728.	
31 32 473	6.	Batchelor F, Hill K, Mackintosh S, Said C. What works in falls prevention after stroke? a	
33 34 474		systematic review and meta-analysis. Stroke. 2010;41(8):1715-1722.	
35 36 37 475	7.	Dean CM, Rissel C, Sherrington C, et al. Exercise to enhance mobility and prevent falls after	
37 38 39 476		stroke: the community stroke club randomized trial. <i>Neurorehabil Neural Repair</i> .	
40			
41 477 42		2012;26(9):1046-1057.	
43 44 478	8.	Gardner MM, Buchner DM, Robertson MC, Campbell AJ. Practical implementation of an	
45 46 479		exercise-based falls prevention programme. Age Ageing. 2001;30:77-83.	
47 48 480 49	9.	Dean CM, Richards CL, Malouin F. Task-related circuit training improves performance of	
⁵⁰ 481 51		locomotor tasks in chronic stroke: a randomized controlled pilot trial. Arch Phys Med Rehabil.	
52 53 482		2000;81:409-417.	
54 55			
56			
57 58		2	3
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1 2 483	10.	Eng JJ, Chu KS, Kim CM, Dawson AS, Carswell A, Hepburn KE. A community-based group	
3 4 484 5		exericse program for persons with chronic stroke. Med Sci Sports Exerc. 2003;35(8):1271-1278	-
6 7 485	11.	Salbach NM, Mayo NE, Wood-Dauphinee S, Hanley JA, Richards CL, Côté R. A task-oriented	
8 9 486		intervention enhances walking distance and speed in the first year post stroke: a randomized	
10 11 487 12		controlled trial. Clin Rehabil. 2004;18:509-519.	
¹³ 14 ⁴⁸⁸	12.	Maki BE, McIlroy WE. The role of limb movements in maintaining upright stance: the	
15 16 489		"change-in-support" strategy. Phys Ther. 1997;77:488-507.	
17 18 490 19	13.	Gerards MHG, McCrum C, Mansfield A, Meijer K. Perturbation-based balance training for falls	S
²⁰ 491		reduction among older adults: current evidence and implications for clinical practice. Geriatr	
22 23 492		Gerontol Int. 2017;17(12):2294-2303.	
24 25 493	14.	Mansfield A, Wong JS, Bryce J, Knorr S, Patterson KK. Does perturbation-based balance	
26 27 494 28		training prevent falls? A review and meta-analysis of preliminary randomized controlled trials.	
²⁹ 30 495		<i>Phys Ther</i> . 2015;95(5):700-709.	
31 32 496	15.	Mansfield A, Inness EL, Lakhani B, McIlroy WE. Determinants of limb preference for	
33 34 497 35		initiating compensatory stepping post-stroke. Arch Phys Med Rehabil. 2012;93:1179-1184.	
³⁶ 37498	16.	de Kam D, Roelofs JMB, Bruijnes AKBD, Geurts ACH, Weerdesteyn V. The next step in	
38 39 499		understanding impaired reactive balance control in people with stroke: the role of defective	
40 41 500 42		early automatic postural responses. Neurorehabil Neural Repair. 2017;31(8):708-716.	
$\frac{43}{44}$ 501	17.	Mansfield A, Wong JS, McIlroy WE, et al. Do measures of reactive balance control predict falls	S
45 46 502		in people with stroke returning to the community? <i>Physiotherapy</i> . 2015;101(4):373-380.	
47 48 503	18.	Mansfield A, Inness EL, Wong JS, Fraser JE, McIlroy WE. Is impaired control of reactive	
49 50 504 51		stepping related to falls during inpatient stroke rehabilitation? Neurorehabil Neural Repair.	
⁵² 53 505		2013;27(6):526-533.	
54 55			
56 57 58		24	1

59

1 2 506	19.	Mansfield A, Inness EL, Komar J, et al. Training rapid stepping responses in an individual with
3 4 507 5		stroke. Phys Ther. 2011;91(6):958-969.
6 7 508	20.	Mansfield A, Schinkel-Ivy A, Danells CJ, et al. Does perturbation training prevent falls after
8 9 509		discharge from stroke rehabilitation? A prospective cohort study with historical control. J
10 11 510		Stroke Cerebrovasc Dis. 2017;26(10):2174-2180.
12 13 14 511	21.	Mansfield A, Aqui A, Centen A, et al. Perturbation training to promote safe independent
14 15 16 512		mobility post-stroke: study protocol for a randomized controlled trial. <i>BMC Neurol</i> . 2015;15:87.
17 18 513	22.	Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting
19	22.	
²⁰ 514 21 22		parallel group randomised trials. Br Med J. 2010;340:c332.
22 23 515 24	23.	Hoffman TC, Glasziou PP, Milne R, et al. Better reporting of interventions: template for
24 25 516 26		intervention desription and replication (TIDieR) checklist and guide. Br Med J. 2014;345:1687.
²⁷ 517 28	24.	Thomas S, Reading J, Shephard RI. Revision of the Physical Activity Readiness Questionnaire
²⁹ 30 518		(PAR-Q). Can J Sport Sci. 1992;174:338-345.
31 32 519	25.	French E, Reinikka K, MacLeod A. Community-based exercise for people living with stroke.
33 34 520 35		http://www.tbrhsc.net/clinical_partners/regional_stroke_program/video_resources/community_
³⁶ 37 521		based_exercise.asp. Accessed 1 Aug, 2013.
38 39 522	26.	Shumway-Cook A, Woollacott MH. Motor control: translating research into clinical practice.
40 41 523		3rd ed. Philadelphia: Lippincott Williams & Wilkins; 2007.
42 43 44 524	27.	Goldstein LB, Bertels C, Davis JN. Interrater reliability of the NIH Stroke Scale. Arch Neurol.
45 46 525		1989;46(6):660-662.
47 48 526	28.	Gowland C, Stratford P, Ward M, et al. Measuring physical impairment and disability with the
49 50 527 51		Chedoke-McMaster Stroke Assessment. Stroke. 1993;24:58-63.
52 53		
54		
55 56		
57 58		
59		25 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
60		rorpeer events maps/smjopen.smj.com/sne/about/guidelines.nitim

1 2 528	29.	Hyndman D, Ashburn A, Stack E. Fall events among people with stroke living in the
3 4 529 5		community: circumstances of falls and characteristics of fallers. Arch Phys Med Rehabil.
6 7 530		2002;83:165-170.
8 9 531	30.	Berg K, Wood-Dauphinée S, Williams JI, Gayton D. Measuring balance in the elderly:
10 11 532 12		preliminary development of an instrument. Physiother Can. 1989;41:304-311.
¹³ 14 533	31.	Frachignoni F, Horak F, Godi M, Nardone A, Giordani A. Using psychometric techniques to
15 16 534		improve the balance evaulation systems test: the mini-BES test. J Rehabil Med.
17 18 535		2010;42(4):323-331.
19 20 21 536	32.	Podsiadlo D, Richardson S. The Timed "Up & Go": A test of basic functional mobility for frail
22 23 537		elderly persons. J Am Geriatr Soc. 1991;39:142-148.
24 25 538	33.	Powell LE, Myers AM. The Activities-specific Balance Confidence (ABC) Scale. J Gerontol A
26 27 539 28		<i>Biol Sci Med Sci.</i> 1995;50A(1):M28-34.
²⁹ 30 540	34.	Washburn RA, Zhu W, McAuley E, Frogley M, Figoni SF. The Physical Activity Scale for
31 32 541		Individuals with Physical Disabilities: development and evaluation. Arch Phys Med Rehabil.
33 34 542 35		2002;83:193-200.
³⁶ 37 543	35.	Trigg R, Wood VA. The Subjective Index of Physical and Social Outcome (SIPSO): a new
38 39 544		measure for use with stroke patients. Clin Rehabil. 2000;14(3):288-299.
40 41 545 42	36.	Tang Y. Sample size estimation for negative binomial regression comparing rates of recurrent
$\frac{43}{44}$ 546		events with unequal follow-up time. J Biopharm Stat. 2015;25(5):1100-1113.
45 46 547	37.	Conover WJ, Iman RL. Analysis of variance using the rank transform. <i>Biometrics</i> .
47 48 548 49		1982;38(3):715-724.
50 549 51	38.	van Duijnhoven HJR, De Kam D, Hellebrand W, Smulders E, Geurts ACH, Weerdesteyn V.
⁵² 53 550		Development and process evaluation of a 5-week exercise program to prevent falls in people
54 55 551		after stroke: the FALLS program. Stroke Res Treat. 2012;2012:407693.
56 57 58		26
59 60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2 552	39.	Bhatt T, Yang F, Pai Y-C. Learning to resist gait-slip falls: long-term retention in community	/_
3	071		
4 553 5		dwelling older adults. Arch Phys Med Rehabil. 2012;93:557-564.	
6 7 554	40.	Batchelor FA, Hill KD, Mackintosh SF, Said CM, Whitehead CH. Effects of a multifactorial	
8 9 555 10		falls prevention program for people with stroke returning home after rehabilitation: a	
11 556 12		randomized controlled trial. Arch Phys Med Rehabil. 2012;93(9):1648-1655.	
¹³ 14 557	41.	Mansfield A, Peters AL, Liu BA, Maki BE. Effect of a perturbation-based balance-training	
15 16 558		program on compensatory stepping and grasping reactions in older adults: a randomized	
17 18 559		controlled trial. Phys Ther. 2010;90(4):476-491.	
19 20 21 560	42.	Maki BE, McIlroy WE. Postural control in the older adult. Clin Geriatr Med. 1996;12(4):635	, -
22 23 561		658.	
24 25 562	43.	Robinson CA, Shumway-Cook A, Matsuda PN, Ciol MA. Understanding physical factors	
26 27 563 28		associated with participation in community ambulation following stroke. Disabil Rehabil.	
²⁹ 30 564		2011;33(12):1033-1042.	
31 32 565	44.	Nicholson S, Sniehotta FF, van Wijck F, et al. A systematic review of perceived barriers and	
33 34 566 35		motivators to physical activity after stroke. Int J Stroke. 2013;8:357-364.	
³⁶ 37 567	45.	Mudge S, Barber PA, Stott S. Circuit-based rehabilitation improves gait endurance but not us	ual
38 39 568		walking activity in chronic stroke: a randomized controlled trial. Arch Phys Med Rehabil.	
40 41 569 42		2009;90:1989-1996.	
$43 \\ 44 570$	46.	Morris JH, MacGillivray S, Mcfarlane S. Interventions to promote long-term participation in	
45 46 571		physical activity after stroke: a systematic review of the literature. Arch Phys Med Rehabil.	
47 48 572		2014;95:956-967.	
49 50 573 51	47.	Bateni H, Zecevic A, McIlroy WE, Maki BE. Resolving conflicts in task demands during	
52 53 574		balance recovery: does holding an object inhibit compensatory grasping? Exp Brain Res.	
54 55 575		2004;157:49-58.	
56 57			
58 59			27
60		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

1	10	
2 576 3	48.	Lamb SE, Jørstad-Stein EC, Hauer K, Becker C. Development of a common outcome data set
4 577 5		for fall injury prevention trials: The Prevention of Falls Network Europe consensus. J Am
6 7 578		<i>Geriatr Soc.</i> 2005;53(9):1618-1622.
8 9 579	49.	Strath SJ, Kaminsky LA, Ainsworth BE, et al. Guide to the assessment of physical activity:
10 11 580 12		clinical and research applications. A scientific statement from the American Heart Association.
¹³ 14 581		Circulation. 2013;128:2259-2279.
15 16 582 17	50.	Craig CL, Marshall AL, Sjöström M, et al. International physical activity questionnaire: 12-
18 583 19		country reliability and validity. Med Sci Sports Exerc. 2003;35(8):1381-1395.
²⁰ 584	51.	Marigold DS, Eng JJ, Dawson AS, Inglis JT, Harris JE, Gylfadóttir S. Exercise leads to faster
22 23 585		postural reflexes, improved balance and mobility, and fewer falls in older persons with chronic
24 25 586 26		stroke. J Am Geriatr Soc. 2005;53:416-423.
27 27 28 28	52.	Smith GV, Forrester LW, Silver KHC, Macko RF. Effects of treadmill training on translational
²⁹ 30 588		balance perturbation responses in chronic hemiparetic stroke patients. J Stroke Cerebrovasc
31 32 589		Dis. 2000;9:238-245.
33 34 590 35	53.	Robinovitch SN, Feldman F, Yang Y, et al. Video capture of the circumstances of falls in
³⁶ 37 591		elderly people residing in long-term care: an observational study. Lancet. 2013;381(9860):47-
38 39 592		54.
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2	596	TABLES
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Table 1: Participant characteristics at study enrolment. Values presented are medians with interquartile range in parentheses (for continuous/ordinal variables) or number with percentage in parentheses (for count/frequency variables). The p-value is for the Wilcoxon-Mann-Whitney test 11 600 (continuous/ordinal variables) or Fisher's exact test (count/frequency variables).

	PBT (n=41)	Control (n=42)	p-value
Age (years)	<u>66 (17)</u>	<u>67 (13)</u>	0.84
Sex (number, %)	00(17)	07 (15)	0.04
Female	15 (36.6)	12 (28.6)	0.49
Male		· · · ·	0.49
	26 (63.4)	30(71.4)	0.000
Time post-stroke (years)	2.0 (3.3)	3.2 (4.5)	0.086
More affected side (number, %)			
Left	22 (53.7)	22 (52.4)	>0.99
Right	19 (46.3)	20 (47.6)	
NIH-SS (score)	3 (4)	3 (5)	0.57
CMSA leg (score)	5 (1)	5(1)	0.54
CMSA foot (score)	5 (3)	5 (1)	0.45
ABC scale (%)	65.6 (26.3)	79.1 (33.8)	0.42
BBS (score)	50 (10)	51(7)	0.94
Mini-BEST (score)	18(7)	18 (5)	0.95
TUG (s)	14.4 (12.3)	13.0 (7.6)	0.62
PASIPD (score)	8.4 (9.5)	11.6 (10.9)	0.48
SIPSO (score)	30 (9)	31 (13)	0.74
Fall in the past year (number, %)			
Yes	17 (41.5)	18 (42.9)	>0.99
No	24 (58.5)	24 (57.1)	
ABC=Activities-specific Balance	· /	· /	g Balanc
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cale, mini-BEST=mini-

42⁶⁰² Balance Evaluation Systems Test, CMSA=Chedoke-McMaster Stroke Assessment, NIH-SS=National

44 603 Institutes of Health Stroke Scale; PASIPD=Physical Activity Scale for Individuals with Physical

Disabilities, SIPSO=Subjective Index of Physical and Social Outcome. 46 604

- ⁴⁸ 605

2 606 **Table 2: Falls between groups.** Values presented are absolute number of participants, or rate of falls

607 per person-year. The p-value is for the difference in falls or fall rates from logistic regression or

 $\frac{6}{7}$ 608 negative binomial regression, respectively.

	PBT	Control	p-valu
Intent-to-treat analysis			
Participants (number)	41	42	
Participants reporting ≥ 1 fall (number	r) 19	23	0.44
Falls (total number)	53	64	
Falls (number per person-year)	1.45	1.72	0.6.
Per-protocol analysis			
Participants (number)	32	34	
Participants reporting ≥ 1 fall (number)		20	0.2
Falls (total number)	32	2 0 57	0.2
Falls (number per person-year)	1.07	1.75	0.2
r uns (number per person-year)	1.07	1.75	0.2
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2 611 Table 3: Balance and mobility measures between groups. Values presented are least-square means

612 with 95% confidence intervals in brackets. The p-value is for the ANCOVA comparing groups at each

6 7 613 time point, controlling for the baseline value.

	PBT	Control	p-value
Post-training			
Ν	39	38	
ABC (%)	75.6 [71.6, 79.7]	78.2 [74.1, 82.2]	0.97
BBS (score)	50.8 [50.0, 51.7]	51.2 [50.3, 52.1]	0.99
Mini-BEST (score)	20.3 [19.6, 21.0]	20.1 [19.3, 20.8]	0.96
BEST-anticipatory (score)	4.4 [4.2, 4.6]	4.4 [4.2, 4.6]	0.94
BEST-reactive (score)	4.2 [3.7, 4.7]	3.6 [3.0, 4.1]	0.044
BEST-sensory (score)	5.3 [5.2, 5.5]	5.6 [5.4, 5.7]	0.0084
BEST-gait (score)	6.4 [6.0, 6.7]	6.6 [6.2, 7.0]	0.44
TUG (s)	17.5 [15.8, 19.2]	17.4 [15.7, 19.1]	0.30
6-month follow-up			
N	30*	30^{*}	
ABC (%)	75.4 [70.1, 80.8]	74.1 [68.6, 79.5]	0.70
BBS (score)	50.2 [49.2, 51.2]	51.3 [50.3, 52.4]	0.11
Mini-BEST (score)	19.8 [18.9, 20.7]	19.1 [18.2, 20.0]	0.81
BEST-anticipatory (score)	4.3 [4.0, 4.6]	4.3 [4.0, 4.6]	0.99
BEST-reactive (score)	4.0 [3.4, 4.5]	2.9 [2.3, 3.4]	0.0055
BEST-sensory (score)	5.4 [5.1, 5.7]	5.4 [5.2, 5.7]	0.44
BEST-gait (score)	6.2 [5.6, 6.7]	6.5 [6.0, 7.1]	0.25
TUG (s)	16.8 [15.3, 18.2]	15.4 [13.9, 16.9]	0.32
12-month follow-up			
N	27^{\dagger}	29 [†]	
ABC (%)	75.2 [69.3, 81.1]	78.1 [72.1, 84.0]	0.95
BBS (score)	50.6 49.5, 51.6	51.1 50.0, 52.1	0.27
Mini-BEST (score)	20.6 [19.4, 21.8]	18.7 [17.5, 19.8]	0.049
BEST-anticipatory (score)	4.3 [4.0, 4.6]	4.3 [3.9, 4.6]	0.45
BEST-reactive (score)	4.2 [3.6, 4.9]	2.6 [2.0, 3.2]	0.0013
BEST-sensory (score)	5.4 5.1, 5.7	5.4 5.1. 5.6	0.64
BEST-gait (score)	6.6 [6.0, 7.3]	6.5 [5.9, 7.1]	0.90
TUG (s)	15.7 [14.3, 17.2]	17.3 [15.9, 18.7]	0.79
ABC=activities-specific balance			
systems test.			
5			
*N=32 PBT and 31 control for t	he ABC at 6-month	follow-up. [†] N=31 PB	T and 31 control fo
at 12-month follow-up.			
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Table 4: Physical activity and social integration between groups. Values presented are least-square 2 618

means with 95% confidence intervals in brackets The p-value is for the ANCOVA comparing groups at

each time point, controlling for the baseline value.

	PBT	Control	p-value
Post-training			
N	39	38	
PASIPD (score)	12.3 [10.0, 14.6]	11.2 [8.8, 13.6]	0.92
SIPSO (score)	29.8 [28.1, 31.4]	31.2 [29.5, 32.9]	0.29
2-month follow-up			
N	38	31	
PASIPD (score)	8.6 [6.4, 10.8]	9.5 [7.1, 11.9]	0.51
SIPSO (score)	29.7 [28.2, 31.2]	31.5 [29.8, 33.21]	0.23
4-month follow-up		L / J	
N	33	34	
PASIPD (score)	9.2 [7.3, 11.2]	7.8 [5.9, 9.8]	0.34
SIPSO (score)	30.0 [28.2, 31.9]	30.2 [28.4, 32.0]	0.62
6-month follow-up			
N	32	31*	
PASIPD (score)	11.3 [7.3, 15.3]	10.9 [6.8, 15.0]	0.21
SIPSO (score)	30.3 [29.0, 31.6]	32.6 [31.3, 33.9]	0.012
8-month follow-up			
N	31	26	
PASIPD (score)	7.0 [5.6, 8.4]	6.9 [5.4, 8.5]	0.61
SIPSO (score)	30.5 [29.3, 31.7]	32.3 [31.0, 33.6]	0.037
10-month follow-up			
N	32	32	
PASIPD (score)	7.0 [5.5, 8.5]	8.2 [6.7, 9.7]	0.16
SIPSO (score)	29.9 [28.4, 31.3]	32.3 [30.9, 33.8]	0.031
12-month follow-up			
N	31	31	
PASIPD (score)	11.1 [7.4, 14.8]	10.1 [6.4, 13.9]	0.27
SIPSO (score)	30.6 [29.1, 32.0]	32.6 [31.1, 34.0]	0.047

⁴⁵ 622 physical and social outcome

., 48⁶²³ *N=30 control for the SIPSO

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2 624 Table 5: Between-group comparison of fall circumstances. Values are the number of falls in each category, with the percentage of falls in parentheses. The percentage was calculated from the total number of falls for which information was available (i.e., "do not recall" responses were excluded from the denominator). Percentages might not sum to 100 due to rounding error. The p-value is for Fisher's 11 628 exact test comparing the two groups, excluding "do not recall" responses from analysis.

		PBT (53 falls)	Control (64 falls)	p-value
	Cause of fall			
	Do not recall	8	6	
	Slip	16 (35.6)	22 (37.9)	0.26
	Trip	11 (24.4)	6 (10.3)	
	Push/external force	1 (2.2)	3 (5.2)	
	Incorrect weight transfer ⁵³	17 (37.8)	27 (46.6)	
	Posture at the time of the fall	()		
	Do not recall	7	4	
	Lying	1 (2.2)	0 (0)	0.33
	Sitting	4(8.9)	7 (12.1)	0.55
	Standing	9 (20.0)	6 (10.3)	
	Walking	32 (68.9)	47 (77.6)	
	Motor activity at the time of the fall	52 (00.7)	47 (77.0)	
	Do not recall	7	1	
			2(25)	0.010
	Not moving Transforming	4(8.9)	2(3.5)	0.010
	Transferring	2(4.4)		
	Turning/reaching/bending	10 (22.2)	4 (5.2)	
	Walking on level surface	18 (37.8)	· · · · · · · · · · · · · · · · · · ·	
	Walking on ramp/stairs/uneven surface	12 (26.7)	22 (36.2)	
	Cognitive activity at the time of the fall	1.0		
	Do not recall	10	9	0.00
	None	34 (78.6)	44 (81.1)	0.80
	Distracted	9 (21.4)	11 (18.9)	
	Where did the fall occur			
	Outdoors	19 (35.8)	22 (34.4)	>0.99
	Indoors	34 (64.2)	42 (65.6)	
	Using an assistive device			
	Do not recall	7	5	
	Never use one	11	23	
	No	16 (45.7)	24 (66.7)	0.096
	Yes	19 (54.3)	12 (33.3)	
	Holding onto a handrail	× ,	× /	
	Do not recall	7	6	
	No	41 (89.1)	48 (82.8)	0.41
	Yes	5 (10.9)	10 (17.2)	
29		2 (10.9)	·· (·····)	

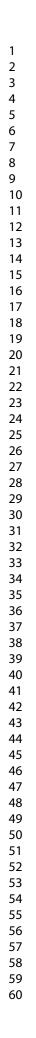
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2 3		PBT (53 falls)	Control (64 falls)	p-value
4 5	Anything in hands			
6	Do not recall	9	6	
7	No	34 (77.3)	32 (55.2)	0.023
8	Yes (one or both hands)	10 (22.7)	26 (44.8)	
9	Action to try to prevent the fall			
10	Do not recall	9	18	
11	None	27 (61.4)	28 (60.9)	0.18
12 13	Grasp	8 (18.2)	14 (30.4)	
13	Step or step + grasp	9 (20.5)	4 (8.7)	
15	Length of lie on floor or ground	~ /	~ /	
16	Do not recall	7	4	
17	A few minutes or less	39 (84.8)	57 (95.0)	0.098
18	More than a few minutes but less than an hour	7 (15.2)	3 (5.0)	
19	Assistance required to get up from fall			
20	Do not recall	7	4	
21 22	No	24 (52.2)	44 (73.3)	0.040
22	Yes	22 (47.8)	16 (26.7)	0.070
24	Injuries	(1110)	10 (2017)	
25	Do not recall	7	5	
26	None	28 (60.9)	39 (66.1)	0.68^{*}
27	Cuts or bruises	17 (37.0)	19 (32.2)	0.00
28	Joint sprain or dislocation	1(2.2)	1 (1.7)	
29 30	Medical assistance required after fall	1 (2.2)	1 (1.7)	
30 31	Do not recall	7	5	
32	No injuries	30	42	
33	Injured but did not seek treatment	16 (100)	14 (82.4)	0.23^{\dagger}
34	Saw other healthcare professional	0(0)	1 (5.9)	0.25
35	Treated in hospital emergency room	0(0) 0(0)	2(11.8)	
36		0(0)	2 (11.0)	
37 630	*Analysis compared injury vs no injury			
38 39 63 1	[†] Analysis compared sought treatment vs did not s	aalt traatmant		
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FIGURE CAPTIONS

Figure 1: Participant flow through the study. Eight participants who consented to participate in the study were excluded on the initial assessment because they could not tolerate the lean-and-release postural perturbations. Participants were withdrawn after randomization because it became apparent that they did not meet the study criteria (1 PBT participant had osteoporosis with history of fracture, and 1 control participant had uncontrolled hypertension), or because they had a significant decline in health during the training portion of the study (1 PBT and 1 control participant). One PBT participant was withdrew from the study because she did not like the group allocation. Therefore, there were 42 control participants and 41 PBT participants available for analysis of the primary outcome (falls in daily life). Participants withdrew during the 12-month follow-up period because they: no longer wished to be in the study (2 PBT, 1 control); experienced a serious adverse event (2 PBT, 5 control); were lost to follow-up (2 PBT, 3 control); or enrolled in a conflicting study (2 PBT). in a c.



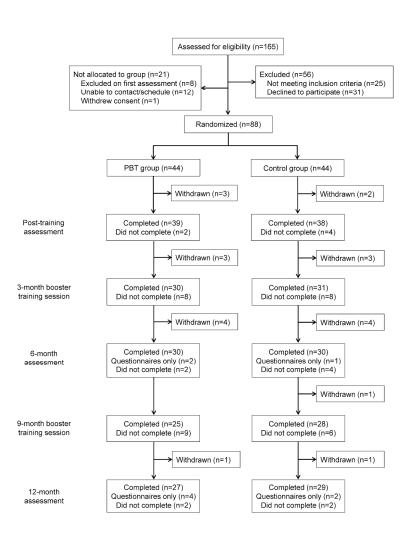


Figure 1: Participant flow through the study. Eight participants who consented to participate in the study were excluded on the initial assessment because they could not tolerate the lean-and-release postural perturbations. Participants were withdrawn after randomization because it became apparent that they did not meet the study criteria (1 PBT participant had osteoporosis with history of fracture, and 1 control participant had uncontrolled hypertension), or because they had a significant decline in health during the training portion of the study (1 PBT and 1 control participant). One PBT participant was withdrew from the study because she did not like the group allocation. Therefore, there were 42 control participants and 41 PBT participants available for analysis of the primary outcome (falls in daily life). Participants withdrew during the 12-month follow-up period because they: no longer wished to be in the study (2 PBT, 1 control); experienced a serious adverse event (2 PBT, 5 control); were lost to follow-up (2 PBT, 3 control); or enrolled in a conflicting study (2 PBT).

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SUPPLEMENTARY TABLES

Table S1: Balance and mobility measures, change over time. Values presented are the differences from pre-training with 95% confidence intervals in brackets. A positive difference value indicates an improvement for all variables except the TUG, where a negative value indicates an improvement (i.e., faster TUG time compared to baseline).

	PBT	Control
ost-training		
N	39	38
ABC (%)	5.2 [0.7, 9.8]	6.6 [1.5, 11.6]
BBS (score)	1.8 [0.7, 2.9]	1.9 [1.0, 2.9]
Mini-BEST (score)	2.6 [1.8, 3.4]	2.2 [1.5, 3.0]
BEST-anticipatory (score)	0.5 [0.2, 0.8]	0.5 [0.2, 0.8]
BEST-reactive (score)	1.5 [0.9, 2.1]	0.8 [0.3, 1.2]
BEST-sensory (score)	0 [-0.2, 0.2]	0.3 [0.0, 0.5]
BEST-gait (score)	0.6 [0.1, 1.0]	0.7 [0.3, 1.1]
TUG (s)	-1.0 [-2.9, 0.8]	-1.1 [-2.8, 0.5]
6-month follow-up		- , -
N	30*	30^{*}
ABC (%)	3.5 [-2.3, 9.2]	0.6 [-5.2, 6.3]
BBS (score)	0.3 [-0.8, 1.4]	1.3 [0.2, 2.4]
Mini-BEST (score)	1.6 [0.6, 2.6]	0.8 [-0.1, 1.7]
BEST-anticipatory (score)	0.3 [-0.1, 0.6]	0.3 [-0.1, 0.7]
BEST-reactive (score)	1.2 [0.5, 1.8]	0.0 [-0.5, 0.5]
BEST-sensory (score)	0.1 [-0.2, 0.3]	
BEST-gait (score)	0.1 [-0.6, 0.8]	0.3 [-0.1, 0.8]
TUG (s)	1.0 [-1.0, 2.9]	-0.5 [-1.4, 0.5]
12-month follow-up		
N	27^{\dagger}	29^{\dagger}
ABC (%)	3.5 [-3.1, 10.2]	3.8 [-2.7, 10.3]
BBS (score)	0.6 [-0.7, 1.8]	0.8 [-0.3, 2.0]
Mini-BEST (score)	2.2 [0.9, 3.4]	0.1 [-1.1, 1.4]
BEST-anticipatory (score)	0.2 [-0.1, 0.5]	0.2 [-0.2, 0.7]
BEST-reactive (score)	1.4 [0.5, 2.3]	-0.4 [-1.0, 0.2]
BEST-sensory (score)	0.1 [-0.2, 0.4]	0.1 [-0.1, 0.4]
BEST-gait (score)	0.4 [-0.3, 1.2]	0.2 [-0.4, 0.8]
TUG (s)	0.1 [-1.0, 1.2]	1.6 [-0.4, 3.6]

systems test.

^{*}N=32 PBT and 31 control for the ABC at 6-month follow-up. [†]N=31 PBT and 31 control for the ABC at 12-month follow-up.

Table S2: Physical activity and social integration, change over time. Values presented are the
difference from pre-training with 95% confidence intervals in brackets. A positive difference value
indicates an improvement.

	ming with 5570 com	indence intervals in	brackets. A positive difference va
indicates an improveme			
	PBT	Control	
Post-training			
Ν	39	38	
PASIPD (score)	1.1 [-2.0, 4.2]	-1.0 [-3.1, 1.0]	
SIPSO (score)	0.5 [-1.4, 2.5]	1.8 [0.0, 3.7]	
2-month follow-up			
Ν	38	31	
PASIPD (score)	-2.1 [-5.1, 0.8]	-2.8 [-5.8, 0.3]	
SIPSO (score)	-0.1 [-1.7, 1.6]	1.5 [-0.4, 3.4]	
4-month follow-up			
N	33	34	
PASIPD (score)	-1.7 [-4.2, 0.8]	-4.1 [-6.6, -1.5]	
SIPSO (score)	0.5 [-1.2, 2.2]	0.7 [-1.3, 2.7]	
6-month follow-up	6		
N	32	31*	
PASIPD (score)	0.4 [-5.3, 6.2]	-2.2 [-5.6, 1.1]	
SIPSO (score)	0.3 [-1.0, 1.7]	2.5 [0.8, 4.2]	
8-month follow-up			
N	31	26	
PASIPD (score)	-4.5 [-7.3, -1.6]	-5.7 [-9.7, -1.6]	
SIPSO (score)	0.2 [-1.1, 1.5]	1.8 [0.4, 3.3]	
10-month follow-up			
N	32	32	
PASIPD (score)	-4.1 [-6.6, -1.7]	-3.5 [-6.7, -0.4]	
SIPSO (score)	-0.3 [-1.6, 1.0]	2.2 [0.4, 3.9]	
12-month follow-up			
N	31	31	
PASIPD (score)	0.4 [-4.6, 5.4]	-2.9 [-6.0, 0.2]	
SIPSO (score)	0.8 [-0.7, 2.3]	2.7 [0.9, 4.4]	

PASIPD=physical activity scale for individuals with physical disabilities; SIPSO=subjective index of vity scale for individuals with physical disa come SIPSO physical and social outcome

^{*}N=30 control for the SIPSO

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Program developed and manual written by: Avril Mansfield, Vincent DePaul, Cynthia Danells, Elizabeth Inness, Louis Biasin, Vivien Poon, and Svetlana Knorr

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5. Task descriptions	

Version date: 20 October 2017

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- LIST OF ABBREVIATIONS
- AFO = ankle-foot orthosis
- BOS = base of support
- BP = blood pressure
- CMSA = Chedoke-McMaster Stroke Assessment
- DF = dorsiflexion
- EV = eversion
- HR = heart rate
- INV = inversion
- Mini-BES = Mini Balance Evaluation Systems (test)
- PBT = perturbation-based balance training
- PF = plantar flexion
- i challenge RPC = rating of perceived challenge
- TUG = timed-up and go

INTRODUCTION

The goal of PBT is to improve reactive balance control in order to optimize safe independent mobility. The program requires that individuals repeatedly experience loss of balance (i.e., internal or As par, be increase, n, adding mor, feedback, and cha. c, and masculine pronouns to the feedback and charter the feedback and the feedback and ch manual postural perturbations) and are provided the opportunity to practice stepping reactions to regain balance following this instability. As participants adapt to the challenge and improve their balance control, the challenge should be increased. Challenge can be increased by increasing the magnitude of the manual perturbation, adding more challenging secondary movement and cognitive tasks, removing or altering sensory feedback, and changing the environment.

Note, for convenience and clarity of expression in this document, we use feminine pronouns to refer to the treating physiotherapist, and masculine pronouns to refer to the participant.

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I. SCREENING AND ASSESSMENT

I.I An initial assessment is required to inform and guide treatment, and ensure patient safety.

Information regarding significant medical history is obtained; specifically, does the participant:

- Have arthritis in the lower extremities or any other joint pain;
- Normally wear glasses or contact lenses;
- Normally use a cane, a rollator, or any other mobility aid;
- Normally wear an orthotic (brace) around the ankle and/or knee;
- Normally wear a sling around the arm/shoulder;
- Have diabetes;
- Take any medication on an "as needed" basis (i.e., PRN medication);
- Report any recent falls; and
- Have fear of falling?

Modifications to the manner in which the program is provided may be made based on responses to the questions above. For example, some activities might be avoided to prevent exacerbation of a previous injury.

The initial assessment includes:

- Assessment of reactive stepping using
 - Forward-fall lean-and-release perturbations under two conditions: usual response and encouraged use (5 trials per condition); and
 - Observation of reactions in the 'Reactive' component of the mini-Balance Evaluation Systems (mini-BES) test.
- Consideration of some of the contributors to impaired reactive stepping:
 - Stroke severity/stroke symptoms e.g., using the National Institutes of Health Stroke Scale;
 - Stage of motor recovery e.g., using the Chedoke McMaster Stroke Assessment (CMSA);
 - Balance confidence e.g., using the Activity-specific Balance Confidence scale; and
 - Sensation (see Sections 1.4 and 1.5).

I.2 Lean and release assessment instructions.

Control of reactive stepping following a postural perturbation is assessed using a lean-and-release system. Participants wear a safety harness attached to an overhead support system. The harness is also connected at the back to a beam via a quick-release mechanism (i.e., a modified crossbow trigger). The participant must lean forward from the ankles far such that approximately 10% of his body weight supported by the cable. Once achieved, the cable is released creating a forward fall from which the participant needs to recover. He is instructed step as quickly as possible to regain balance and come to stable stance. If he cannot regain stability independently, then the assessor can aid in the recovery and prevent a 'fall' (i.e., being caught by the safety harness).

Two conditions are assessed and recorded on the score sheet (see Section 1.3) – the 'usual response' and the 'encouraged use'. The first five trials are completed as described above and the limb that

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responds first to the release is recorded. This is the **'usual response'**. If the same limb responds $\geq 4/5$ times, this is considered to be the 'preferred limb'. In the **'encouraged use'** condition, five trials are completed with the preferred limb blocked and the participant is instructed to attempt to react with the non-preferred limb. The blocking is accomplished with the hand or foot of the physiotherapist/assessor. If it appears that the participant is going to step with the blocked limb, the hand/foot can be removed quickly, but the participant is not told that the block will be removed. If there is no obvious preferred limb (i.e., participant stepped 3 times with one leg and 2 with the other), then the limb that is blocked should alternate 2 times for one limb and 3 for the other.

The lean-and-release assessment is video-recorded and the video is reviewed later to observe any participant-specific impairments in reactive stepping (see also Section 4). While it might be possible to observe some obvious impairments in 'real time', often the reaction happens so quickly that this is not possible.





Figure 1.1: The lean-andrelease system. Panel A (left) shows the usual response condition. Panel B (right) shows the encouraged-use condition. Figure taken from Mansfield et al., BMC Neurol. 2015;15:87



1.3 Lean and release collection sheet.

Usual response

- Participant wearing harness
- Aim for 10% body weight on the cable
- □ Random delay between 'ready' signal and perturbation
- □ Review video to determine preferred limb & assists (if not clear during testing)
- Record limb for first step

Test	Trial #	Comments	Limb	Assist
			🛛 Right	🛛 No
			Left	Yes
2			🛛 Right	🛛 No
			🗖 Left	Yes
3		O.	🛛 Right	🛛 No
			🗖 Left	Yes
4		6	🛛 Right	🛛 No
			Left	🛛 Yes
5			🛛 Right	🛛 No
			🗖 Left	Yes

Preferred limb (initiated stepping in $\geq 4/5$ trials with this limb):

- 🛛 Right
- Left
- □ No clear preference

Encouraged use

- Block preferred limb with researchers hand/foot; if no limb preference do two trials blocking one limb and three blocking the other
- □ Aim for 10% body weight on the cable
- Random delay between 'ready' signal and perturbation
- □ Review video to determine preferred limb & assists (if not clear during testing)
- □ Record limb for first step

Test	Trial #	Comments	Limb	Assist
6			🛛 🛛 Right	🛛 No
			🖵 Left	Yes
7			🛛 Right	🛛 No
			🖵 Left	Yes
8			🛛 Right	🛛 No
			🖵 Left	Yes
9			🛛 Right	🛛 No
			🖵 Left	Yes
10			🛛 Right	🛛 No
			Left	Yes

I.4 Sensation assessment instructions.

Exteroceptive and proprioceptive sensation are assessed in the affected foot and ankle. It is necessary to know if the participant appreciates light touch and movement of the ankle and foot. If these are absent or decreased, steps should be taken to accommodate the deficits in order to minimize potential injury due to PBT.

Sensation is assessed with the participant sitting on a raised plinth, feet dangling, with shoes and socks removed. Demonstration of the test should be done with the participant's eyes open and administered to the less-affected foot/ankle. The actual test should be administered to the more-affected foot/ankle following the demonstration with the participant's eyes closed.

Light touch is assessed using a cotton ball; the cotton ball should lightly touch but not brush the sole of the participant's foot. The foot is touched 5 times and the participant is instructed to respond when the touch is felt. Responses are recorded on the score sheet (see Section 1.5). If there is no response (and you are certain that the participant understood the instructions) this is recorded as a negative response.

The **perception of joint movement** is assessed in the ankle (dorsiflexion and plantar flexion) and in the foot (inversion and eversion). The participant's foot is held in two places: the bony prominences of the first and fifth meta-tarsal phalangeal joints and at the medial and lateral malleoli. Movements of the ankle should be demonstrated on the less-affected side as "up" for dorsiflexion and "down" for plantar flexion and, of the foot, as "in" for inversion and "out" for eversion. Care should be taken not to change the pressure of the hold during the movement. When being tested, movements should be through small ranges and time should be allowed for the participant to respond. If the participant is unsure of the direction of the movement, the range should be increased. If the participant is still unsure, then this is a negative response for the test. Five movements should be tested at the ankle and five at the foot.

Each correct, incorrect, or absent response is recorded on the score sheet (Section 1.5). If the participant scores <4/5 for light touch appreciation, and/or <8/10 for joint movement perception, then consideration is made for use of an Aircast Airsport Ankle Brace during training.

1.5 Sensation assessment collection sheet.

Position recognition

Position	Correct response?
Dorsiflexion	☐ Yes
	🛛 No
Plantarflexion	☐ Yes
	🛛 No
Dorsiflexion	☐ Yes
	🛛 No
Dorsiflexion	☐ Yes
	🛛 No
Plantarflexion	☐ Yes
	🛛 No
Number	
correct	

Position	Correct response?
Inversion	☐ Yes
	🛛 No
Eversion	Yes
	🛛 No
Inversion	Yes
	🛛 No
Eversion	Yes
	🛛 No
Eversion	Yes
	🛛 No
Number correct	

If number correct is <8/10, an AirSport ankle brace should be used to prevent injury during PBT.

Light touch sensation

_ight touch sen	sation	
Frial	Correct response?	
Trial I	□ Yes	
	🛛 No	
Trial 2	Yes	
	🛛 No	
Trial 3	☐ Yes	
	🛛 No	
Trial 4	☐ Yes	
	🛛 No	
rial 5	☐ Yes	
	🛛 No	
Number correct		

If number correct is <4/5, an AirSport ankle brace should be used to prevent injury during PBT.

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2. PLANNING THE PROGRAM

2.1 The program is individualized to the participant's specific impairments in reactive balance control

In order to create an effective training program, consideration is made of the participant's unique areas of dyscontrol (identified on initial assessment; see Section 1). Section 4 (Perturbation Training Log) outlines areas of dyscontrol and suggested treatment approaches for each problem. The principle of individual differences considers an individual's response to exercise. Therefore, progression should be gradual and systematic and occur at the individual participant's rate of improvement. Task difficulty is not absolute and could vary from participant-to-participant depending on specific control problems and other deficits.

2.2 List of equipment

The following equipment is required for this specific program:

- Overhead harness support track;
- Fall-arrest approved safety harness;
- Equipment for task-specific activities:
 - Thin foam mat (e.g., thickness of yoga mat or 2.5 cm gym mat);
 - Thick foam pad (dense blue foam);
 - Hand ball (2 sizes; e.g., 10 cm diameter and tennis ball);
 - Soccer ball;
 - $\circ~$ Steps (10 cm and 20 cm high);
 - Stop watch;
 - Unstable 'step' (if an unstable step is not available, place a regular step on a thin foam mat);
 - Cross marked out in tape on the floor (2 pieces of tape each at least 60 cm long placed to intersect at right angles (see Figure 6.24);
 - Set of 6 23 cm diameter multi-colored Agility Dots;
 - Foam obstacles (e.g., pool noodles or half-round foam rollers); and
- Participant-specific equipment (e.g., walking aid, ankle brace/orthosis, helmet, arm sling).

2.3 Ensuring safety during training

2.3.1 Safety harness

Participants wear a safety harness attached to an overhead track at all times to prevent a fall to the ground. However, the harness system should be used as a back-up; the supervising physiotherapist still intervenes and provides physical assistance to 'brake the fall' when she feels the individual will not be able to recover balance. (Note, to allow participants the opportunity to practice stepping reactions, the physiotherapist **only** provides hands-on assistance if the participant is unable to regain stability alone.) The harness can prevent a fall to the floor but cannot prevent all possible injuries. Appropriate selection of participants, consideration of their underlying impairments, and appropriate supervision is still required. For example, it is possible that an individual could experience an ankle sprain while stepping in response to a perturbation (see Section 2.3.2). It is also possible that a frail individual who falls completely into the harness will experience an injury (e.g., bruise) because he is caught by the safety harness; a fracture could also be possible with a participant who has very low Version date: 20 October 2017 Page 10 of 59

bone mineral density. Participants should not be left 'dangling' in the safety harness as the straps can restrict circulation.

2.3.2 Protective equipment for ankle

An ankle-foot orthosis (AFO; if prescribed) or an Aircast AirSport Ankle Brace is used during PBT if the participant meets one or more of the following criteria:

- Participant typically uses an AFO during home and/or community walking;
- CMSA foot score is stage 3 or lower;
- Ankle joint position sense score is <8/10 (see Section 1.4 and 1.5);
- Light touch sensation of the plantar surface of the foot score is <4/5 (see Section 1.4 and 1.5); and/or
- The treating physiotherapist feels this is necessary to preserve stability of the ankle joint and prevent injury.

Use of the AirSport Ankle Brace, AFO, or any other assistive devices should be documented in the Perturbation Training Log (Section 4).

2.3.3 Monitoring heart rate and blood pressure

Heart rate (HR) and blood pressure (BP) are taken from the less affected arm using an automatic BP cuff. The less-affected arm is repositioned in an extended position resting on a table slightly below the level of the heart. If BP and/or HR fall outside of an 'acceptable' range (systolic BP is outside 90-140 mmHg; diastolic BP is outside 60-90 mmHg; or, HR is outside 60-100 bpm), a second measure is obtained. If the values continue to be outside of the range, the participant is asked to sit quietly for 5 minutes and perhaps, take a few deep breaths or drink a glass of water, before taking a third measurement. Participants with HR/BP measurements outside of the acceptable range are also questioned regarding recent medications (what they have taken and when, or if they have not taken their usual medications), when they last had something to eat/drink, and if the recently took caffeine, exercised, or smoked. The decision to continue or terminate the session is made by the physiotherapist considering factors such as the participants' usual resting HR/BP, how far the measured values are outside of the acceptable range, the participants' usual medication (e.g., betablockers), and the participants' perception of how they are feeling. If the visit is terminated, the physiotherapist may advise that the participant follow-up with his primary care physician. If the visit continues, the physiotherapist may choose to monitor HR and BP regularly throughout the visit and observe cardiovascular responses to exercise.

3. THE PROGRAM

3.1 Overview

The PBT program involves 12 1-hour training sessions provided 2 times per week for 6 weeks. Each session is 60 minutes in length and is provided in a one-to-one format. This core program is modified to fit with delivery of in-patient rehabilitation to allow for evaluation among individuals with sub-acute stroke.

Sessions begin with a 10-minute warm-up and end with a 10-minute cool-down following the warmup and cool-down from the Keep Moving with Stroke program. Each session involves a minimum of ten 'voluntary' tasks that are each practiced for about 2 minutes. Once the participant is comfortable doing the task, the physiotherapist provides a manual perturbation to cause the participant to lose balance with the intent of evoking a reactive step (see Section 3.3). Six external perturbations are provided per task such that there are 60 external perturbations per session; however, fewer perturbations may be performed if participant tolerance is low. Participants might also experience a loss of balance (i.e., internal perturbation) due to failure to properly control balance during the voluntary task. Intensity of the session is determined by participant response; the participant should successfully regain stability with 1 or 2 steps and no assistance from the physiotherapist or safety harness 50% of the time. If the participant is too 'successful', the level of challenge is increased, or vice versa.

3.2 Voluntary Tasks

Each session involves 'voluntary' tasks that progress along a mobility continuum to evoke internal perturbations (i.e., loss of balance or self-destabilization):

- a) 'Stable' the voluntary task is to maintain a static base of support;
- b) 'Quasi-mobile' the voluntary task is to move the feet (e.g., stepping forward with alternate feet); however, the participant remains in place;
- c) 'Mobile' the voluntary task is to move from one location to another (e.g., walking, sidestepping); and
- d) 'Unpredictably mobile' the voluntary task is to move from one location to another in an unpredictable manner (e.g., kicking a soccer ball).

The challenge of each voluntary task can be influenced by manipulating other factors, such as:

- a) The sensory condition (e.g., firm to compliant surfaces, eyes open to eyes closed).
- b) The cognitive requirements (e.g. single task to multi-task, counting backwards, moving on cue).
- c) The environment (e.g., walking on even surface to walking over obstacles).

See "Description of Voluntary Tasks" in Section 5 for further information.

3.3 Methods of Perturbation

Internal perturbations are evoked when the participant attempts to perform a task that causes instability. Various voluntary tasks, including rapid 'agility' tasks (e.g., rapid step-ups) are used to evoke internal perturbations. A task that appears as easy as standing with eyes closed may cause an internal perturbation for a participant with poor balance control. However, some participants do not put themselves in situations causing a loss of balance or necessitating a stepping reaction (i.e., they will

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perform agility tasks slowly); therefore, external perturbations are also included in every session to ensure a sufficient training dose.

External perturbations are caused by a force outside of the participant's control. Small-magnitude external perturbations may be used with participants who have lower functional abilities. It is usually easiest to start with perturbations that cause a fall towards the physiotherapist (i.e., pull or lean-and-release) so that the physiotherapist can control the outcome and alleviate participants' anxiety and facilitate participants' perceptions of safety. There are three methods for evoking external perturbations: 1) lean-and-release (predictable direction/magnitude; 2) push/pull (can be unpredictable in terms of direction and magnitude; or 3) trip during walking (see Section 5 for details).

3.4 Measurement

Measures are taken throughout the training to ensure: 1) focus on participant-specific problems; 2) ongoing progression; and 3) participant safety. The Perturbation Training Log (Section 4) is used to document the following:

- Performance on reactive stepping linked to key areas of focus (e.g., if a goal is to reduce frequency of multiple stepping then frequency of multiple stepping should be documented);
- Number of repetitions (i.e., number of times the participant experiences a loss of balance): '0'
 = balance recovered using 2 steps or fewer; '1' = balance recovered using more than 2 steps; and, 'X' = assistance provided by the safety harness or physiotherapist to recover balance;

ien

- Additional tasks/conditions;
- Number of rest breaks;
- 'Rating of perceived challenge' (RPC) (Section 6);
- HR and/or BP (if indicated);

3.5 Format of training session

- I) Participant arrives.
- 2) HR and BP are taken.
- 3) Warm-up is completed.
- 4) Harness is donned.
- 5) Tasks, as outlined in the Perturbation Training Log (Section 4), are performed for that particular session. Detailed descriptions of each task can be found in Section 5.
- 6) Documentation about and scoring of each task are completed before moving on to the next task.
- 7) Rest is taken as required, or after each task.
- 8) Cool-down and stretching are completed.

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4. PERTURBATION TRAINING LOG					
Participant ID:					
Affected side of body:	Does HR &/or BP need r	monitor	ring throug	h session? Y	Ń
Harness size:	Participant Equipment:	AFO	AirsSport	Arm Sling	Other
Participant Goal(s):					
Highlights of Assessment Findings:	9				
CMSA stage (/7): Leg Foot					
Position Recognition (#correct/5): DF/PF IN					
Light touch (#correct/5):					
Berg balance scale (/56):					
Mini-BES - Reactive Postural Control (/12):					
TUG (sec):					
Lean & Release – Preferred trials (#): Right	Left				
Lean & Release – Encouraged use trials (#): Right .	Left				
Comments:					
					· · · · · · · · · · · · · · · · · · ·
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Participant ID: _____

Date: _____

Treatment planning:

Area of dyscontrol	Treatment suggestions	Additional treatment strategies/comments
Requires external assist to regain stability	 Start with low-magnitude perturbation, increase magnitude as tolerated Consider other problems that contribute, like delayed stepping or no stepping 	
Does not step when magnitude of perturbation requires a step	 Instruct participant to step when s/he feels unstable Start with low-magnitude perturbations Start with predictable time/direction of perturbation Practice the step prior to perturbation Consider other problems that contribute, like unwillingness to step with paretic limb 	
Has low foot clearance during step: foot 'slides', or shuffles	Use obstacles to 'force' a step-over	0 D
Demonstrates delayed stepping reaction	 Instruct participant to step as quickly as possible Start with predictable time/direction of perturbation If delay is with non-paretic limb, have participant weight-shift to paretic limb prior to perturbation 	<u>J</u>

Area of dyscontrol	Treatment suggestions	Additional treatment strategies/comments
Is unwilling to step with paretic limb	Block the non-paretic limb with obstacles, or hand/ foot of physiotherapist Instruct participant to step with paretic limb Start with predictable time/direction of perturbation Time perturbation to coincide with paretic leg/foot being un-weighted	
Demonstrates multi-step reactions	Instruct participant to take as few steps as possible Instruct participant to take long(er) steps	
Stands asymmetrically prior to perturbation	Instruct participant to increase loading on the less-loaded limb Consider using video or feedback of stance symmetry	
Takes short steps	Instruct participant to take longer steps Step to targets Step over obstacles	
Attempts to use upper extremity to regain stability	Physiotherapist should stand as far away as safely possible Instruct to not use reach-to-grasp reactions Have participant hold object to prevent grasping	J.

A	Area of dyscontrol	Treatment suggestions	Additional treatment strategies/comments
Falls late	erally on step termination	 Instruct participant to take as few steps as possible Start with low-magnitude perturbation Try forward/backward perturbations initially with a narrow base of support 	
	rossover' steps to respond to perturbations	 Instruct participant to use side- stepping strategy Place large obstacles in front and behind participant to deter cross- overs 	
Is unabl directio	e to step equally well in all ons	 Use multi-directional perturbations Do more perturbations in the most challenging direction 	

'Stable' tasks: session 1

Voluntary task	ary task to reduce to		Adaptation to increase Perturbation (0= difficulty		Outcome (0=≤2 steps, I=multi step, X=loss of balance) RPC		# Rests during task	Rest after task (Y/N)
Standing still with feet hip- width apart	U Wide BOS	Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, eyes closed	G Wide BOS	□ Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, on a thin foam mat	G Wide BOS	□ Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, on a thick foam pad	Given Wide BOS	□ Feet together	6 multi-directional lean-and-release	04				
Standing still with feet hip- width apart, turning head left and right	Generation Wide BOS	□ Feet together	6 multi-directional lean-and-release	(0 ₀			
Standing still with feet hip- width apart, looking up and down	Generation Wide BOS	□ Feet together	6 multi-directional lean-and-release					
Standing with feet hip- width apart, counting backwards by 3's	G Wide BOS	□ Feet together	6 multi-directional lean-and-release					

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Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Standing with feet hip- width apart, eyes closed & counting backwards by 3's	U Wide BOS	☐ Feet together	6 multi-directional lean-and-release				
Standing with feet hip- width apart, rapid weight- shifting left and right	U Wide BOS	□ Feet together	6 multi-directional push/pull				
Standing with feet hip- width apart, or in stride position, rapid weight- shifting forward and backward	Wide BOS	□ Feet together	6 multi-directional push/pull				
Standing with feet hip- width apart, throwing & catching a ball	Wide BOS	☐ Feet together	internal				
Standing with feet hip- width apart, rapid arm raises forward and to the sides	U Wide BOS	Given Feet together	internal	en.			
HR:	BP:	<u></u>		Overall rating of	perceiv	ed challeı	nge:
TOTALS/AVERAGE	S			0= = X=			
Overall comments for	• the session:						
							_
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'Stable' tasks: Session 2

Initial - HR: E	BP:	Repeat I	- HR: BP:		Repeat	: 2 - HR	:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, I=r X=loss of ba	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Standing still with feet hip- width apart	U Wide BOS	□ Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, eyes closed	U Wide BOS	□ Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, on a thin foam mat	Wide BOS	Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, on a thick foam pad	U Wide BOS	□ Feet together	6 multi-directional lean-and-release					
Standing still with feet hip- width apart, turning head left and right	U Wide BOS	Given Feet together	6 multi-directional lean-and-release	-h				
Standing still with feet hip- width apart, looking up and down	U Wide BOS	□ Feet together	6 multi-directional lean-and-release	C	5			
Standing with feet hip- width apart, counting backwards by 3's	Wide BOS	☐ Feet together	6 multi-directional lean-and-release					
Standing with feet hip- width apart, eyes closed & counting backwards by 3's	Wide BOS	Given Feet together	6 multi-directional lean-and-release					
Standing with feet hip- width apart, rapid weight- shifting left and right	U Wide BOS	□ Feet together	6 multi-directional push/pull					

Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, 1=multi step, X=loss of balance)	RPC	# Rests During task	Rest After task (Y/N)
Standing with feet hip-width apart, or in stride position, rapid weight-shifting forward and backward	Wide BOS	□ Feet together	6 multi-directional push/pull				
Standing with feet hip-width apart, throwing & catching a ball	U Wide BOS	Feet together	internal				
Standing with feet hip-width apart, rapid arm raises forward and to the sides	Wide BOS	Given Feet together	internal				
Rapid stepping forward with alternate feet	□ Short steps	Long steps	internal				
Rapid stepping backward with alternate feet	Short steps	Long steps	internal				
Rapid stepping to the right (right foot)	□ Short steps	Long steps	internal				
Rapid stepping to the left (left foot)	Short steps	Long steps	internal	W.			
HR:	BP:		Ove	rall rating of perce	ived cho	ıllenge:	
TOTALS/AVERAGES				0= = X=			
Overall comments for th	e session:						

'Quasi-mobile' tasks: Session 3

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	k:	BP:	
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation Outco (0=≤2 steps, X=loss or		multi step, RPC		# Rests during task	Rest after task (Y/N)
Rapid stepping forward with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull					
Rapid stepping backward with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull					
Rapid stepping to alternate sides	□ Short steps	Long steps	6 multi-directional push/pull	•				
Rapid tap-ups forward with alternate feet	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull	Ch.				
Walking in place	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull	C	5			
Rapid stepping forward with alternate feet, on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull					
Rapid stepping backward with alternate feet, on a thin foam mat	Short steps	Long steps	6 multi-directional push/pull					

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Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Rapid stepping to alternate sides, on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull				
Rapid tap-ups forward with alternate feet, on a thin foam mat	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull				
Walking in place, on a thin foam mat	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull				
HR:	BP:		Ov	verall rating of perceiv	ved cha	llenge:	
TOTALS/AVERAGE	S		(0)	0=			
				1= X=			
	• the session:		- 4				
Overall comments for	the session:		- 4				
	the session:						
	the session:						
	the session:						
	the session:						

'Quasi-mobile' tasks: Session 4

Initial - HR:	BP:	Repeat I - HR: BP:			Repeat	•	BP:	
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, 1=n X=loss of bal	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Rapid stepping forward and backward with right foot	Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid stepping forward and backward with left foot	Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid tap-ups forward with alternate feet	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull	• (
Rapid step-ups with alternate feet	Low step Step Height:	Unstable surface (e.g. dense foam)	6 multi-directional push/pull	Ch,				
Rapid tap-ups to alternate sides	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull	U	5/			
Rapid stepping forward and backward with right foot, on a thin foam mat	Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid stepping forward and backward with left foot, on a thin foam mat	Short steps; rest in stance	Long steps	6 multi-directional push/pull					

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with alternate feet, on a thin foam mat Step Height:	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
alternate feet, on a thin foam mat I Low step Surface (e.g. dense foam) 6 multi-directional push/pull Rapid tap-ups to alternate sides, on a thin foam mat I Low step Unstable surface (e.g. soccer ball) 6 multi-directional push/pull HR: BP: BP: Overall rating of perceived challenge: 0= TOTALS/AVERAGES 0= 1= 0=	Rapid tap-ups forward with alternate feet, on a thin foam mat		surface (e.g.					
Rapid tap-ups to alternate sides, on a thin foam mat I Low step Step Height:	alternate feet, on a thin		surface (e.g.					
TOTALS/AVERAGES 0= 1= X= 0			surface (e.g.					
1= X=	HR:	BP:		Ov	verall rating of perceiv	ved cha	llenge:	
Overall comments for the session:	TOTALS/AVERAGE	ES		(er	1=			
	Overall comments fo	r the session ·			ch .			
					0			

'Quasi-mobile' tasks: Session 5

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	:	BP:	
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	increase Perturbation (0=≤2 step		Outcome 2 steps, I=multi step, =loss of balance)		# Rests during task	Rest after task (Y/N)
Rapid stepping forward and backward with right foot	Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid stepping forward and backward with left foot	Short steps; rest in stance	Long steps	6 multi-directional push/pull					
Rapid stepping to alternate sides	□ Short steps	Long steps	6 multi-directional push/pull					
Rapid diagonal forward stepping with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull	Ch,				
Walking in place	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull	C	5/			
Walking in place, eyes closed	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull					
Rapid stepping with alternate feet in random cued direction	Short steps	Long steps	6 multi-directional push/pull					

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Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Rapid step-ups with alternate feet	Low step Step Height:	 Unstable surface (e.g. dense foam) 	6 multi-directional push/pull				
Rapid tap-ups forward with alternate feet	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull				
Rapid tap-ups to alternate sides	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull				
HR:	BP:		Ον	verall rating of perceiv	ved cha	llenge:	
TOTALS/AVERAGE	ES		er,	0= = X=			
Overall comments for	r the session:			The second secon			

'Quasi-mobile' tasks: Session 6

Initial - HR: I	BP:	Repeat I -	Repeat I - HR: BP:			Repeat 2 - HR:			
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, 1=multi step, X=loss of balance)		RPC	# Rests during task	Rest after task (Y/N)	
Rapid stepping forward with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull						
Rapid stepping backward with alternate feet	□ Short steps	Long steps	6 multi-directional push/pull						
Rapid stepping to alternate sides	Short steps	Long steps	6 multi-directional push/pull						
Walking in place, eyes closed	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull	EN,					
'Jogging' (or fast walking) in place	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull	C	5/				
Rapid diagonal forward stepping with alternate feet	Generation Short steps	Long steps	6 multi-directional push/pull						
Rapid stepping with alternate feet in random cued direction	Short steps	Long steps	6 multi-directional push/pull						

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Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
'Jogging' (or fast walking) in place, on a thin foam mat	Feet barely off floor	Knees to hip-height	6 multi-directional push/pull				
Rapid diagonal forward stepping with alternate feet, on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull				
Rapid stepping with alternate feet in random cued direction, on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull				
HR:	BP:		Ov	verall rating of perceiv	ved cha	llenge:	
Overall comments for	• the session:			X=			

'Mobile' tasks: Session 7

Initial - HR:	BP:	Repeat I - HR: BP:				Repeat 2 - HR:			
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcon (0=≤2 steps, 1=m X=loss of bala	nulti step,	RPC	# Rests during task	Rest after task (Y/N)	
Walking forward	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull						
Walking forward, turning head left and right	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull						
Walking forward, looking up and down	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull	•					
Walking and stepping over obstacles	 Low/short obstacles Define: 	 High/long obstacles Define: 	6 multi-directional push/pull	er,					
Forward braiding	Walk on the line	Step further across; long steps; traffic light	6 multi-directional push/pull	C	5				
Side stepping	Short steps	Long steps	6 multi-directional push/pull						
Turning on the spot (alternate between turning to the left and to the right)	Turn slowly	Turn quickly	6 multi-directional push/pull						

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Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Turning on the spot with eyes closed (alternate between turning to the left and to the right)	Turn slowly	Turn quickly	6 multi-directional push/pull				
Turning on the spot, in cued direction	Turn slowly	Turn quickly	6 multi-directional push/pull				
Four square stepping	Short steps	Long steps	6 multi-directional push/pull				
HR:	BP:		01	verall rating of percei	ved cha	Illenge:	
TOTALS/AVERAG	ES		. Cr	0= = X=			
Overall comments fo	r the session:			Ch Or			
				$-\gamma$			

'Mobile' tasks: Session 8

Initial - HR:	BP:	Repeat I -	Repeat I - HR: BP:		Repeat 2 - HR:			BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, 1=multi step, X=loss of balance)		RPC	# Rests during task	Rest after task (Y/N)
Walking forward	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull					
Walking backward	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull					
Walking forward with eyes closed	Short steps; walk slowly	Long steps; walk quickly	6 multi-directional push/pull	•				
Tandem walking forward	Not heel-toe; steps close to line	Traffic light	6 multi-directional push/pull	Ch.				
Side stepping	□ Short steps	Long steps	6 multi-directional push/pull	C	5			
Sideways braiding	Steps not fully crossed	Traffic light	6 multi-directional push/pull					
Side stepping over obstacles	 Low/short obstacles Define: 	 High/long obstacles Define: 	6 multi-directional push/pull					

Turning on the spot (alternate between turning to the left and to the right) Image: Turn slowly Image: Turn quickly 6 multi-directional push/pull Turning on the spot in cued direction Image: Turn slowly Image: Turn quickly 6 multi-directional push/pull Image: Turn slowly Image: Turn quickly 6 multi-directional push/pull 6 multi-directional push/pull	Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
cued direction Intrin quickly Four square stepping Short steps Image: Short steps Image: Long steps Image: Short steps Image: Short steps Image: Short steps Image: Shor	Turning on the spot (alternate between turning to the left and to the right)	Turn slowly	Turn quickly					
Four square stepping I Long steps push/pull HR: BP: Overall rating of perceived challenge: TOTALS/AVERAGES 0= I= X=		Turn slowly	Turn quickly					
TOTALS/AVERAGES 0= 1= X=	Four square stepping	Short steps	Long steps					
	HR:	BP:		Ov	erall rating of perceiv	ed cha	llenge:	
Overall comments for the session:	TOTALS/AVERAG	GES		(er	1=			
	Overall comments f	or the session:			"h			

'Mobile' Tasks: Session 9

Initial - HR: BP:		Repeat I -	Repeat I - HR: BP:		Repeat 2 - HR:			BP:	
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, 1=multi step, X=loss of balance)		RPC	# Rests during task	Rest after task (Y/N)	
Walking forward on a thin foam mat	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull						
Walking backward on a thin foam mat	Short steps; walk slowly	Long steps; traffic light	6 multi-directional push/pull						
Side stepping on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull	•					
Four square stepping on a thin foam mat	□ Short steps	Long steps	6 multi-directional push/pull	Ch.					
Tandem walking forward	Not heel- toe; steps close to line	Traffic light	6 multi-directional push/pull	C	7/				
Tandem walking backward	Not heel- toe; steps close to line	Traffic light	6 multi-directional push/pull						
Sideways braiding	Steps not fully crossed	Traffic light	6 multi-directional push/pull						

Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)	
Turning on the spot with eyes closed (alternate between turning to the left and to the right)	Turn slowly	Turn quickly	6 multi-directional push/pull					
Forward braiding	Walk on the line	 Step further across; long steps; traffic light 	6 multi-directional push/pull					
Walking forward with eyes closed	Short steps; walk slowly	Long steps; walk quickly	6 multi-directional push/pull					
HR:	BP: Overall rating of perceived challenge:							
TOTALS/AVERAGE	S		CL	0= = X=				
Overall comments for	the session:			W OF				
Version date: 20 October 2017 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml						Pag		

'Mobile' tasks: Session 10

Initial - HR:	BP:	Repeat I -	HR: BP:		Repeat	2 - HR	:	BP:
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, I=n X=loss of bal	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Tandem walking forward	Not heel- toe; steps close to line	Traffic light	6 multi-directional push/pull					
Tandem walking backward	Not heel- toe; steps close to line	□ Traffic light	6 multi-directional push/pull					
Forward braiding	Walk on the line	Step further across; long steps; traffic light	6 multi-directional push/pull	•				
Backward braiding	Walk on the line	Step further across; long steps; traffic light	6 multi-directional push/pull	Ch.				
Tandem walking forward on a thin foam mat	Not heel- toe; steps close to line	□ Traffic light	6 multi-directional push/pull		7/			
Tandem walking backward on a thin foam mat	Not heel- toe; steps close to line	Traffic light	6 multi-directional push/pull					
Forward braiding on a thin foam mat	Walk on the line	Step further across; long steps; traffic light	6 multi-directional push/pull					

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0	Walk on the line	Step further across; long	6 multi-directional				(Y/N)
		steps; traffic light	push/pull				、
	Steps not fully crossed	Traffic light	6 multi-directional push/pull				
Turning on the spot with eyes closed in cued direction	Turn slowly	Turn quickly	6 multi-directional push/pull				
HR:	BP:		Ov	erall rating of perceiv	ed cha	llenge:	
TOTALS/AVERAGES			V	0= = X=			
Overall comments for the	e session:			0			

'Mobile & Unpredictable' Tasks: Session 11

Initial - HR:	nitial - HR: BP:		BP: Repeat I - HR: BP:			Repeat 2 - HR:			BP:	
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcon (0=≤2 steps, I=m X=loss of bal	nulti step,	RPC	# Rests during task	Rest after task (Y/N)		
Kicking soccer ball against wall	[none]	Stand further from wall; kick outside BOS; kick with each leg	6 perturbations: PT attempts to take ball, nudges participant							
Throwing hand ball against a wall	Large ball	Small ball; stand further from wall; throw with each arm	6 perturbations: PT attempts to take ball, nudges participant							
Kicking soccer ball against wall, standing on a thin foam mat	[none]	Stand further from wall; kick outside BOS; kick with each leg	6 perturbations: PT attempts to take ball, nudges participant	er.						
Throwing hand ball against a wall, standing on a thin foam mat	Large ball	Small ball; stand further from wall; throw with each arm	6 perturbations: PT attempts to take ball, nudges participant	C	ク					
Walking with sudden stops and changes in direction	Walk slowly	Walk quickly	6 multi-directional push/pull/trip							
Move to different corners of the room	Walk slowly	Walk quickly	6 multi-directional push/pull/trip							

Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Walking with sudden stops and changes in direction, obstacles around the room	Walk slowly	Walk quickly	6 multi-directional push/pull/trip				
Move to different corners of the room, obstacles around the room	Walk slowly	Walk quickly	6 multi-directional push/pull/trip				
Four square stepping to unpredictable cued direction	□ Short steps	Long steps	12 multi-directional push/pull/trip				
'Dodgeball'	Ball thrown at upper body	Ball thrown rapidly at feet	internal				
HR:	BP:		Ov	verall rating of perceiv	ved cha	llenge:	
TOTALS/AVERAGE	S			0= = X=			
Overall comments for	the session:			γ			i

'Mobile & unpredictable' tasks: Session 12

Initial - HR: BP:		Repeat I - HR: BP:			Repeat 2 - HR:			BP:	
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcon (0=≤2 steps, I=m X=loss of bala	nulti step,	RPC	# Rests during task	Rest after task (Y/N)	
Kicking soccer ball back and forth with physiotherapist	Within reach; kicked slowly	Step to reach; kicked quickly	internal					~ /	
Throwing ball back and forth with physiotherapist	Large ball; within reach	Small ball; step to reach	internal						
Kicking soccer ball with physiotherapist, standing on a thin foam mat	Within reach; kicked slowly	Step to reach; kicked quickly	internal						
Throwing ball with physiotherapist, standing on a thin foam mat	Large ball; within reach	Small ball; step to reach	internal	ch.					
Walking with sudden stops and changes in direction	Walk slowly	Walk quickly	12 multi-directional push/pull/trip		7/				
Move to different corners of the room	Walk slowly	Walk quickly	12 multi-directional push/pull/trip						
Walking with sudden stops and changes in direction, obstacles around the room	Walk slowly	Walk quickly	12 multi-directional push/pull/trip						

Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Move to different corners of the room, obstacles around the room	Walk slowly	Walk quickly	l 2 multi-directional push/pull/trip				
Four square stepping to unpredictable cued direction	□ Short steps	Long steps	l 2 multi-directional push/pull/trip				
'Dodgeball'	Ball thrown at upper body	Ball thrown rapidly at feet	internal				
HR:	BP:		o	verall rating of percei	ved cha	llenge:	
TOTALS/AVERAGE	S		61	0= = X=			
Overall comments for	• the session:			Ch .			

Booster sessions

Initial - HR:	BP: Repeat I - HR: BP:			Repeat 2 - HR:			BP:	
Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcor (0=≤2 steps, 1=r X=loss of ba	nulti step,	RPC	# Rests during task	Rest after task (Y/N)
Standing still with feet hip- width apart, eyes closed	Wide base of support	Feet together	6 multi-directional lean-and-release					
Rapid tap-ups forward with alternate feet	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull					
Rapid tap-ups to alternate sides	Low step Step Height:	Unstable surface (e.g. soccer ball)	6 multi-directional push/pull					
Rapid stepping with alternate feet in random cued direction	□ Short steps	Long steps	6 multi-directional push/pull	ch,				
Turning on the spot, in cued direction	Turn slowly	Turn quickly; eyes closed	6 multi-directional push/pull	C	5/			
Side stepping/braiding	Short steps	Long steps; thin foam mat	6 multi-directional push/pull/trip					
Forward tandem/braiding	Steps close to line	Long steps; thin foam mat	6 multi-directional push/pull/trip					

Voluntary task	Adaptation to reduce difficulty	Adaptation to increase difficulty	Perturbation	Outcome (0=≤2 steps, I=multi step, X=loss of balance)	RPC	# Rests during task	Rest after task (Y/N)
Backward tandem/braiding	Steps close to line	Long steps; thin foam mat	6 multi-directional push/pull/trip				
Walking with sudden stops and changes in direction, obstacles around the room	Walk slowly	U Walk quickly	6 multi-directional push/pull/trip				
Kicking soccer ball against wall	[none]	Kick outside BOS; on thin foam mat	6 perturbations: PT attempts to take ball, nudges participant				
HR:	BP:			verall rating of percei	ved cha	llenge:	
			- 4	I= X=			
Overall comments for	r the session:			- 06			
Overall comments for	r the session:			<u> </u>			
Overall comments for	r the session:			- 0 ₇			
Overall comments for	r the session:			<u> </u>			
Overall comments for	r the session:			<u> </u>			
Overall comments for	r the session:						

5. TASK DESCRIPTIONS

Types of external perturbations

I) Lean and release

a. Forward-directed lean-and-release perturbation. The participant stands facing the physiotherapist, leaning forward with some of his body weight supported by the physiotherapist. He should be leaning far enough forward that his shoulders and hips are ahead of his toes; however, smaller lean angles can be used with more impaired individuals. The physiotherapist's hands are on the participants' shoulders. At an unexpected time, the physiotherapist releases her hands and the participant starts to fall forward, requiring a step to regain stability. The goal is for the participant to take as few steps as possible to recover.



Figure 6.1. Forward-directed lean-and-release perturbation. The participant leans forward and the physiotherapist supports his weight (left). The physiotherapist releases her support and the participant steps to recover his balance (right).

b. Backward-directed lean-and-release perturbation. The participant stands in front of and facing away from the physiotherapist, leaning backward with some of his body weight supported by the physiotherapist. He should be leaning far enough backward that his shoulders and hips are behind his heels; however, smaller lean angles can be used with more impaired individuals. The physiotherapist's hands are on the participants' shoulders. At an unexpected time, the physiotherapist releases her hands and the participant starts to fall backward, requiring a step to regain stability. The goal is for the participant to take as few steps as possible to recover upright standing balance.



Figure 6.2. Backward-directed lean-and-release perturbation. The participant leans backward and the physiotherapist supports his weight (left). The physiotherapist releases her support and the participant steps to recover his balance (right).

c. Lateral-directed lean-and-release perturbation. The participant stands with his feet close together, leaning to the right (or left) with some of his body weight supported by the physiotherapist's hands. He should be leaning far enough to the right (or left) that the midline of the pelvis is aligned over the right (or left) foot; however, smaller lean angles can be used with more impaired individuals. The physiotherapist's hands are on the participant's right (or left) shoulder and

right (or left) hip. At an unexpected time, the physiotherapist releases her hands and the participant starts to fall to the right (or left), requiring a step to regain stability. The goal is for the participant to take as few steps as possible to recover balance.



Figure 6.3. Backward-directed lean-and-release perturbation. The participant leans to the left and the physiotherapist supports his weight (left). The physiotherapist releases her support and the participant steps to recover his balance (right).

2) Multi-directional push/pull/trip

a. Multidirectional push. The physiotherapist places her hands on the participant's hips or shoulders and pushes him forward, requiring a reactive step to regain stability. Alternatively, one of the physiotherapist's hands could be on the hip and the other on the shoulder; a push forward at the level of one scapula would facilitate a diagonal reactive step. In all scenarios, the physiotherapist should be ready to assist with the recovery, if necessary, by having a light hold of the safety harness. The physiotherapist should only provide assistance if the participant is unable to regain stability independently; this is true with every reaction. Note that backward-directed pushes are not performed.



Figure 6.4. Forward-directed push perturbation. The physiotherapists' hands may be placed at the hips (top images) or with one hand on the hips and one on the shoulders.



Figure 6.5. Lateral-directed push perturbation. The physiotherapist places her hands on the participant's right (or left) hip or shoulder and pushes him to the left (or right), requiring a reactive step to regain stability.

b. Multi-directional pull perturbation. The physiotherapist may pull the participant's shoulders or pull on the harness to cause the participant to start to fall forward, requiring a reactive step to regain stability.



Figure 6.6. Forward-directed pull perturbation. The physiotherapist places her hands on the participant's shoulders (top) or pulls on the harness (bottom).



Figure 6.7. Backward-directed pull perturbation. The physiotherapist uses the shoulders, hips, or harness to pull the participant backward, requiring a reactive step to regain stability.



Figure 6.8. Lateral-directed pull perturbation. The physiotherapist uses the shoulders, hips or harness, to pull the participant to the right (or left), requiring a reactive step to regain stability.

c. Trip perturbation while walking. As the participant walks (forward, backward, sideways), the physiotherapist places her foot in the path of the swing limb causing a trip. A reactive step is required to regain stability. A second person is recommended in this scenario as it is difficult for the physiotherapist doing the tripping to be in a place to provide support should it be needed.



Figure 6.9. Trip perturbation. The physiotherapist catches the participants' limb with her foot while walking.

Descriptions of voluntary tasks

Standing still with feet hip-width apart – participant stands unassisted with the eyes open and the feet positioned as wide as the hips. The lean-and-release perturbations are performed in random directions (forward, backward and lateral).

Adaptation to reduce difficulty – have participant adopt a wider base of support (BOS) Adaptation to increase difficulty – have participant stand with the feet together Progressions of this task:

Eyes closed – if participant is unable, the lights in the room should be dimmed (alternatively, dark sunglasses may be worn)

Standing on a thin foam mat

- Standing on a thick foam mat
- Turning head to the right and left to spot a target
- Looking up and down to spot a target
 - Counting backwards by 3's from a random number given by physiotherapist Eyes closed and counting backwards – as written above, but combined

Rapid weight-shifting left and right – participant shifts his body weight from one foot to the other as quickly as possible, and the feet remain in contact with the floor. The task is repeated until all perturbations are accomplished.

Adaptation to reduce difficulty – have participant adopt a wider BOS

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Adaptation to increase difficulty - have participant stand with the feet together

Rapid weight-shifting forward and backward –participant stands with feet either 'side-by-side' or in a 'stride position' and shifts his body weight forward and backward; if feet are 'side-by-side' then body weight rocks from toes to heels and back; if feet are in stride then body weight transfers from one foot to the other as quickly as possible; part of each foot always remains in contact with the floor. The task is repeated until all perturbations are accomplished.

Adaptation to reduce difficulty –have participant adopt a wider BOS, with the feet either sideby-side or in stride

Adaptation to increase difficulty – have participant stand with the feet together (if side-by-side) or with the feet in tandem (if in stride position)

Throwing and catching a ball – if the participant has use of both arms he should catch and throw a ball back and forth with the physiotherapist; if the participant has functional use of only one arm he should hit a ball back that has been thrown by the physiotherapist.

Adaptation to reduce difficulty – have participant adopt a wider BOS

Adaptation to increase difficulty – have participant stand with the feet together

Rapid arm raises forward and to the sides – participant raises one arm, then both arms, to 90 degrees of shoulder flexion as quickly as possible and stops as quickly as possible; participant raises two arms, then one arm at a time, to 90 degrees of shoulder abduction as quickly as possible and stops as quickly as possible.

Adaptation to reduce difficulty – have participant adopt a wider BOS

Adaptation to increase difficulty – have participant stand with the feet together

Rapid stepping forward with alternate feet – participant steps forward as quickly as possible with the right foot then returns it to the starting position, then steps forward as quickly as possible with the left foot, and then returns it to the starting position; there should be a transfer of body weight to the stepping foot once it touches down in the forward position. The task is repeated until all perturbations are accomplished.



Figure 6.10. Rapid stepping forward with alternate feet

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps Progressions of this task: Standing on a thin foam mat

Rapid stepping backward with alternate feet – participant steps backward as quickly as possible with the right foot, then returns it to the starting position, then steps backward as quickly as possible with the left foot, and then returns it to the starting position; there should be a transfer of body weight to the stepping foot once it touches down in the backward position. The task is repeated until all perturbations are accomplished.



Figure 6.11. Rapid stepping backward with alternate feet

Adaptation to reduce difficulty – have participant take short steps

Adaptation to increase difficulty – have participant take long steps

Progressions of this task:

Standing on a thin foam mat

Rapid stepping to the right (right foot) – participant steps with the right foot to the right as quickly as possible, then back to the starting position; there should be transfer of body weight to the right foot once it touches down in the lateral position. The task is repeated until all perturbations are accomplished.

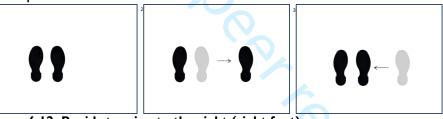


Figure 6.12. Rapid stepping to the right (right foot)

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps

Rapid stepping to the left (left foot) – participant steps with the left foot to the left as quickly as possible, then back to the starting position; there should be transfer of body weight to the left foot once it touches down in the lateral position. The task is repeated until all perturbations are accomplished.

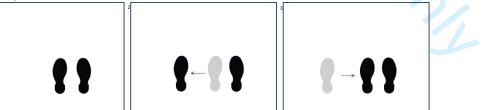


Figure 6.13. Rapid stepping to the left (left foot)

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps

Rapid stepping to alternate sides– participant steps with the right foot to the right as quickly as possible (including body weight transfer), then back to the starting position; then he steps with the left foot to the left as quickly as possible (including body weight transfer), then back to the starting position. The task is repeated until all perturbations are accomplished.

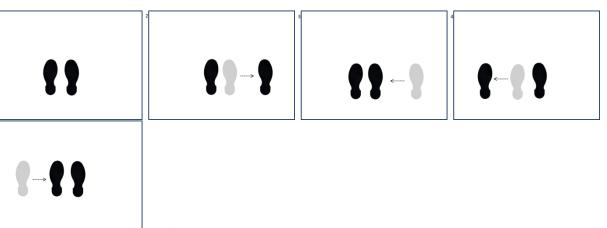


Figure 6.14. Rapid stepping to alternate sides

Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps Progressions of this task:

Standing on a thin foam mat

Rapid tap-ups forward with alternate feet – participant stands with a step in front of his feet; he lifts up the right foot and lightly touches the step, then places it back on the floor; then he lifts up the left foot and lightly touches the step, then places it back on the floor. The goal is to maintain the body weight over the stance limb, i.e. no transfer of body weight forward. The task is repeated until all perturbations are accomplished.

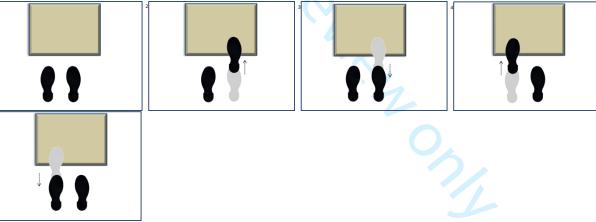


Figure 6.15. Rapid tap-ups forward with alternate feet

Adaptation to reduce difficulty – have participant tap-up to a low step Adaptation to increase difficulty – have participant tap-up to an unstable surface, e.g. a soccer ball

Progressions of this task:

Standing on a thin foam mat

Walking in place – participant alternates stepping with the right and the left foot. The participant should not move from the spot, though a small amount of 'drift' is typical. The task is repeated until all perturbations are accomplished.

Adaptation to reduce difficulty - have participant step with minimal height from floor

Adaptation to increase difficulty – have participant step with maximum height from floor, i.e. knees raised to hip-height Progressions of this task: Walking on the spot on a thin foam mat Eyes closed – if participant is unable, the lights in the room should be dimmed Increased speed to 'jogging', or fast walking, on the spot

Jogging, or fast walking, on the spot on a thin foam mat

Rapid stepping forward and backward with the right foot – participant shifts his body weight to the left foot and then steps forward with the right foot, shifting some body weight forward but not enough to completely unweight the left; then the participant shifts his body weight back to the left foot in order to take a full step as far backward as possible with the right foot, and accepts some body weight on the right. The task is repeated until all perturbations are accomplished.



Figure 6.16. Rapid stepping forward and backward with the right foot

Adaptations to reduce difficulty – have participant take short steps; have participant rest momentarily between transitioning from front to back or from back to front Adaptation to increase difficulty – have participant take long steps Progressions of this task:

Standing on a thin foam mat

Rapid stepping forward and backward with the left foot – participant shifts his body weight to the right foot and then steps forward with the left foot, shifting some body weight forward but not enough to completely unweight the right; then the participant shifts his body weight back to the right foot in order to take a full step as far backward as possible with the left foot, and accepts some body weight on the left. The task is repeated until all perturbations are accomplished.



Figure 6.17. Rapid stepping forward and backward with the left foot

Adaptations to reduce difficulty – have participant take short steps; have participant rest momentarily between transitioning from front to back or from back to front Adaptation to increase difficulty – have participant take long steps Progressions of this task:

Standing on a thin foam mat

Rapid step-ups with alternate feet - participant stands with a step in front of his feet; he steps up onto the step with the right foot, shifts his body weight forward and steps up with the left foot, placing it on the step in a comfortably-wide position; then he steps down with the right foot, shifts his

body weight back onto the right foot and steps down with the left. The process is repeated with the right foot leading until 3 perturbations are completed; then the left leads until the final 3 perturbations are completed.

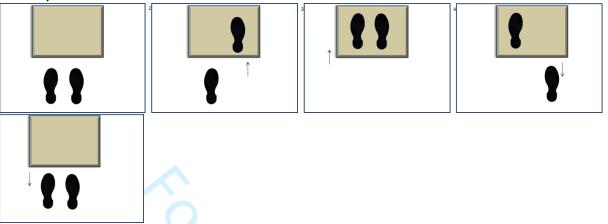


Figure 6.18. Rapid step-ups with alternate feet

Adaptation to reduce difficulty – have participant step-up to a low step

Adaptation to increase difficulty – have participant step-up to an unstable surface, for e.g., a step placed on a thin foam mat, or thick foam pad

Progressions of this task:

Standing on a thin foam mat – i.e. the person is standing on the mat, but the step may be on a hard surface, depending on the adaptation for difficulty

Rapid tap-ups to alternate sides – participant stands with a step lateral to each foot; he lifts up the right foot and lightly touches the step on the right, then places it back on the floor; then lifts up the left foot and lightly touches the step on the left, then places it back on the floor. The goal is to maintain the body weight over the stance limb, i.e., no transfer of body weight to the side tapping-up. The task is repeated until all perturbations are accomplished.

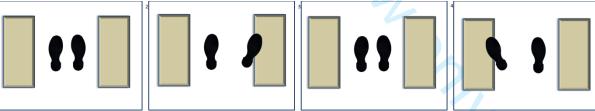


Figure 6.19. Rapid tap-ups to alternate sides

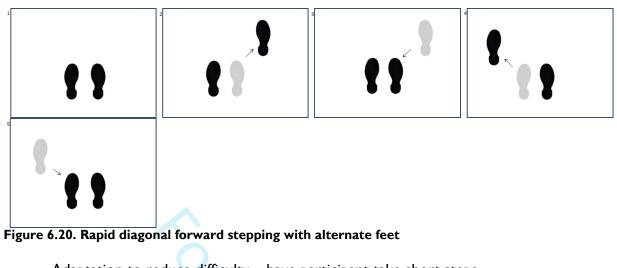
Adaptation to reduce difficulty – have participant tap-up to a low step Adaptation to increase difficulty – have participant tap-up to an unstable surface, e.g. a soccer ball

Progressions of this task:

Standing on a thin foam mat – i.e. the person is standing on the mat, but the step/obstacle may be on a hard surface, depending on the adaptation for difficulty

Rapid diagonal forward stepping with alternate feet – participant steps diagonally forward (a 45° angle) as quickly as possible with the right foot, then returns it to the starting position, then steps diagonally forward as quickly as possible with the left foot, then returns it to the starting position; there should be a transfer of body weight to the stepping foot once it touches down in the diagonal position. The task is repeated until all perturbations are accomplished.

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Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps Progressions of this task:

Standing on a thin foam mat

Rapid stepping with alternate feet in random physiotherapist-cued directions – participant

stands in the centre of 6 targets placed on the floor (e.g., different colored Agility Dots); physiotherapist calls out a color and the participant steps to the colored dot with one foot (transferring some body weight) and then returns that foot to the centre; the process repeats with the next randomly called color. The task is repeated until all perturbations are accomplished.

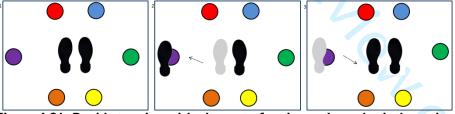


Figure 6.21. Rapid stepping with alternate feet in random physiotherapist-cued directions

Adaptation to reduce difficulty – targets require short steps Adaptation to increase difficulty – targets require long steps Progressions of this task: Standing on a thin foam mat

Walking forward – participant takes steps to travel in a forward direction. Walking continues until all perturbations are accomplished.

Adaptations to reduce difficulty – have participant take short steps, or walk slowly Adaptation to increase difficulty – have participant take long steps; traffic light^{*} Progressions of this task:

Turning head to the right and left – to spot a target Looking up and down – to spot a target Stepping over obstacles –e.g. pool noodles

^{*} Traffic Light = participant walks at a fast pace like he would if crossing a street; physiotherapist counts down like the traffic light would in the crosswalk

Eyes closed – if participant is unable, the lights in the room should be dimmed Walking on a thin foam mat

Forward braiding – participant takes a step forward with the right foot that crosses the midline path and lands lateral to, and slightly ahead of, the left foot; then he brings the left foot out and around the right foot, taking a step across the midline path that lands lateral to, and slightly ahead of, the right foot; then the process repeats until all perturbations are accomplished.



Figure 6.22. Forward braiding

Adaptation to reduce difficulty – walk on the line Adaptations to increase difficulty - increase distance of step across line; take bigger steps; increase the walking speed Progressions of this task: Walking on a thin foam mat

Side stepping – participant stands on left side of room; he takes a step to the right with the right foot, followed by a step to the right (medially) with the left foot; the stepping continues until the edge of the room/available space is reached; then, starting from the right side of the room, he will walk in the opposite direction – left foot steps to left, followed by right foot stepping to left. Stepping continues until all perturbations are accomplished.

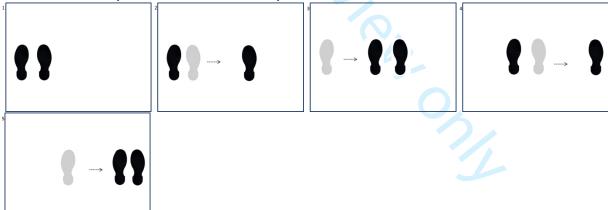


Figure 6.23. Side stepping

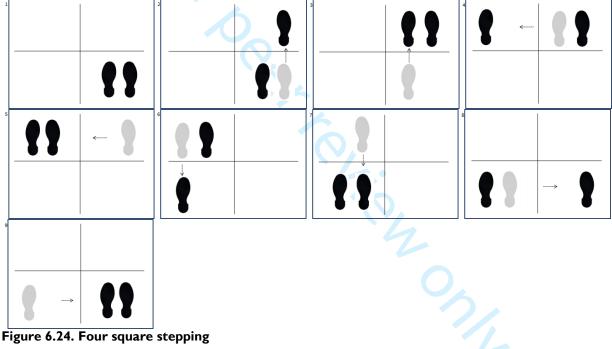
Adaptation to reduce difficulty – have participant take short steps Adaptation to increase difficulty – have participant take long steps Progressions of this task: Stepping over obstacles –e.g. pool noodles

Walking on a thin foam mat

Turning on the spot, alternating to the right and left – participant takes steps to turn continuously in a clockwise direction. After a few turns (or 3 perturbations) the participant changes direction and turns counter-clockwise (until the final 3 perturbations are completed).

- Adaptation to reduce difficulty have participant turn slowly
- Adaptations to increase difficulty have participant turn quickly
- Progressions of this task:
 - Eyes closed if participant is unable, the lights in the room should be dimmed Cued direction – physiotherapist calls out 'right' or 'left' and the participant turns in the direction called; it may be the same direction or a change in direction Cued and Eyes closed – as written above but combined

Four square stepping – using tape, a cross is marked out on the floor creating 4 squares; participant stands in the bottom right-hand square facing forward; he is asked to step forward over the line with one foot then the other into the top right-hand square; then to step sideways, over the tape with the left foot and then the right into the top left-hand square; then to step backwards with one foot and then the other into the bottom left-hand square; and then finally, to step sideways with the right foot, then the left into the bottom right-hand square. He does that pattern a few times (or 3 perturbations) and then switches directions, moving in a clockwise pattern (until the final 3 perturbations are completed).



Adaptation to reduce difficulty – have participant take short steps over the lines Adaptation to increase difficulty – have participant take long steps over the lines Progressions of this task:

- Stepping on a thin foam mat
- Cued direction physiotherapist calls out 'change' or 'switch' and the participant begins moving in the opposite direction

Walking backward – participant takes steps to travel in a backward direction. Walking continues until all perturbations are accomplished.

Adaptation to reduce difficulty – have participant take short steps, or walk slowly Adaptation to increase difficulty – have participant take long steps; traffic light Progressions of this task:

Walking on a thin foam mat

Tandem walking forward - participant takes a step forward with the right foot and places the right heel ahead of the left toes; then he brings the left foot out and around the right foot, and places the left heel ahead of the right toes; then the process repeats until all perturbations are completed.



Figure 6.25. Tandem walking

Adaptations to reduce difficulty – participant takes longer steps (i.e. heel and toes don't touch) or participant places feet close to the line but not on the line

Adaptation to increase difficulty – traffic light

Progressions of this task:

Walking on a thin foam mat

Sideways braiding – participant stands at the right edge of the room; he is asked to walk to the left; he takes a step with the right foot that crosses over the left foot and lands lateral to, and slightly ahead of, the left foot, with part of his foot on the midline; then he brings the left foot out from behind the right and steps to the left, landing on the midline; then he takes a step with the right foot that crosses behind the left foot and lands lateral to, and slightly behind, the left foot, with part of his foot over the right foot and steps to the left; and then the process repeats until he walks as far as he possibly can within the available space. Then he is asked to do the opposite and walk to the right. This pattern continues until all perturbations are accomplished.

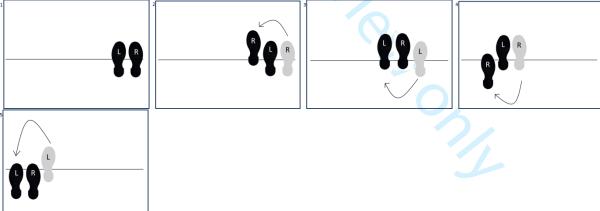


Figure 6.26. Sideways braiding

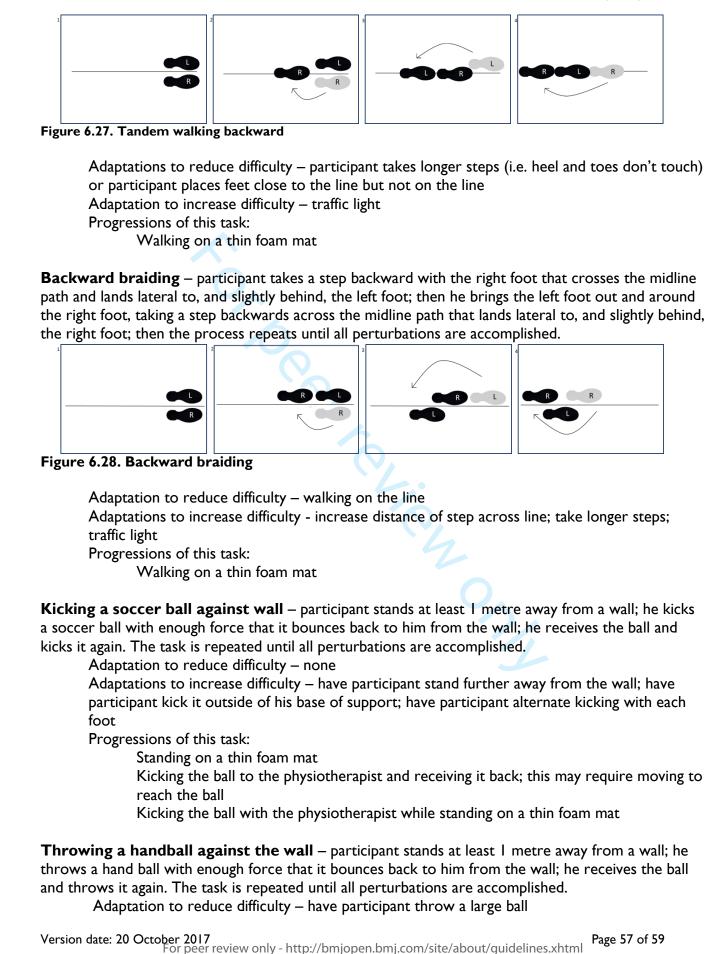
Adaptations to reduce difficulty – participant's foot does not fully cross over or behind the stance foot; or, participant's foot crosses but does not come into contact with midline Adaptation to increase difficulty – traffic light Progressions of this task:

Walking on a thin foam mat

Tandem walking backward - participant takes a step backward with the right foot and places the right toes behind the left heel; then he brings the left foot out and around the right foot, and places the left toes behind the right heel; then the process repeats until all perturbations are completed.

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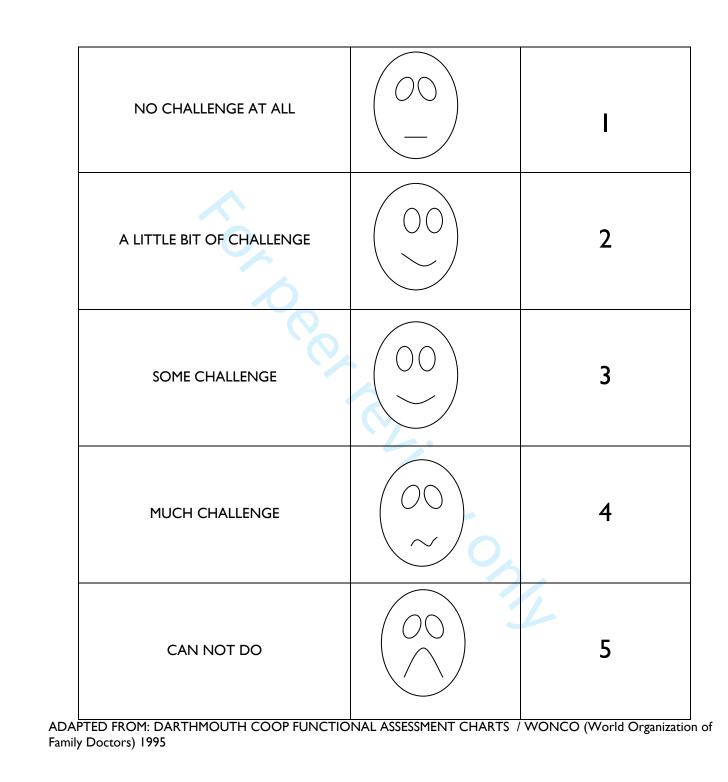


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Toronto Perturbation-Based Balance Training: Program Manual

	Adaptations to increase difficulty have participant throw a small hall have participant stand
	Adaptations to increase difficulty – have participant throw a small ball; have participant stand
	further away from the wall; have participant throw the ball with each arm
	Progressions of this task:
	•
	Standing on a thin foam mat
	Throwing the ball to the physiotherapist and receiving it back; this may require moving
	to catch it
	Throwing the ball with the physiotherapist while standing on a thin foam mat
Walk	ing with sudden stops and changes in direction – participant walks forward and at any
	he physiotherapist says 'stop', and the participant has to stop walking quickly, or says 'right'
(`left´),	and the participant has to turn to the right (left) and continue walking. The task continues until
ıll per	turbations are accomplished.
•	Adaptation to reduce difficulty – have participant walk slowly
	Adaptation to increase difficulty – have participant walk quickly
	Progressions of this task:
	Stepping over obstacles, e.g. pool noodles or steps – the participant has to walk in the
	frame and manage the obstacles while also stopping or changing direction on command
Move	to different corners of the room – participant stands in the centre of the room facing
	d; he is asked to move to one corner of the room (marked with different colored Agility Dots
or nur	nbers); he walks forward to the corners in front of him, then backward to return to the start
	on, or he walks backward to the corners behind him, then forward to return to the start
positic	on. The task continues until all perturbations are accomplished.
	Adaptation to reduce difficulty – have participant walk slowly
	Adaptation to increase difficulty – have participant walk quickly
	Progressions of this task:
	•
	Stepping over obstacles, e.g. pool noodles or steps – the participant has to walk in the
	frame and manage the obstacles while making his way to the correct pole
-	eball – the participant must avoid being hit by the ball that is being thrown at him by the
physio	therapist. This requires transfer of weight and reactive stepping.
. , -	Adaptation to reduce difficulty – physiotherapist throws ball at upper body
	Adaptation to increase difficulty – physiotherapist throws ball rapidly at participant's feet
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6. RATING OF PERCEIVED CHALLENGE SCALE





CONSORT 2010 checklist of information to include when reporting a randomised trial*

Title and abstract Introduction Background and objectives Methods Trial design	1a 1b 2a 2b 3a	Identification as a randomised trial in the title Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) Scientific background and explanation of rationale Specific objectives or hypotheses	
Background and objectives Methods	1b 2a 2b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) Scientific background and explanation of rationale	
Background and objectives Methods	2a 2b	Scientific background and explanation of rationale	
Background and objectives Methods	2b		
objectives Methods	2b		
Methods		Specific objectives or hypotheses	
	3a		
	3a		
i nai ucsiyn	Ja	Description of trial design (such as parallel, factorial) including allocation ratio	
5	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
r anticipanto	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were	
	U	actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they	
		were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	
•	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	
concealment		describing any steps taken to conceal the sequence until interventions were assigned	
mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	
Dlinding	110	interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	
CONSORT 2010 checklist			Pa
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		assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results		
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and
diagram is strongly		were analysed for the primary outcome
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was
		by original assigned groups
Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its
estimation		precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalisability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders
*We strongly recommend	d reading	g this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also
recommend reading CON	ISORT e	extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.
recommend reading cor		ming: for those and for up to date references relevant to this checklist, see <u>www.consort-statement.org</u> .

CONSORT 2010 checklist

T DieR

Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

ltem	Item	Where le	ocated **
number		Primary paper (page or appendix number)	Other [†] (details)
1.	BRIEF NAME Provide the name or a phrase that describes the intervention. WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention. WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).		
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.		

TIDieR checklist

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	WHEN and HOW MUCH
8.	Describe the number of times the intervention was delivered and over what period of time including
	the number of sessions, their schedule, and their duration, intensity or dose.
	TAILORING
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why,
	when, and how.
	MODIFICATIONS
10. [‡]	If the intervention was modified during the course of the study, describe the changes (what, why,
	when, and how).
	HOW WELL
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any
	strategies were used to maintain or improve fidelity, describe them.
12. [‡]	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the
	intervention was delivered as planned. rs - use N/A if an item is not applicable for the intervention being described. Reviewers – use '?' if information about the element is not reported/not
** Autho suffici † If the ir or othe	intervention was delivered as planned. rs - use N/A if an item is not applicable for the intervention being described. Reviewers – use '?' if information about the element is not reported/not ently reported. formation is not provided in the primary paper, give details of where this information is available. This may include locations such as a published pro- published papers (provide citation details) or a website (provide the URL).
** Autho suffici † If the ir or othe	intervention was delivered as planned. rs - use N/A if an item is not applicable for the intervention being described. Reviewers – use '?' if information about the element is not reported/not ently reported. formation is not provided in the primary paper, give details of where this information is available. This may include locations such as a published pro-
** Autho suffici † If the ir or othe ‡ If comp	intervention was delivered as planned. rs - use N/A if an item is not applicable for the intervention being described. Reviewers – use '?' if information about the element is not reported/not ently reported. formation is not provided in the primary paper, give details of where this information is available. This may include locations such as a published pro- published papers (provide citation details) or a website (provide the URL).
** Autho suffici † If the ir or othe ‡ If comp * We stro * We stro * The foce studies TIDieR c When a	intervention was delivered as planned. rs - use N/A if an item is not applicable for the intervention being described. Reviewers – use '?' if information about the element is not reported/not ently reported. formation is not provided in the primary paper, give details of where this information is available. This may include locations such as a published provide papers (provide citation details) or a website (provide the URL). leting the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.
 ** Autho suffici If the ir or othe If comp * We strop * We strop * The focus studies TIDieR of When a Statemo 	intervention was delivered as planned. rs - use N/A if an item is not applicable for the intervention being described. Reviewers – use '?' if information about the element is not reported/not ently reported. formation is not provided in the primary paper, give details of where this information is available. This may include locations such as a published pro- published papers (provide citation details) or a website (provide the URL). Ideting the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete. Ingly recommend using this checklist in conjunction with the TIDieR guide (see <i>BMJ</i> 2014;348:g1687) which contains an explanation and elaboration for each item are covered by other reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological feature are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a randomised trial is being reported thecklist should be used in conjunction with the CONSORT statement (see <u>www.consort-statement.org</u>) as an extension of Item 5 of the CONSORT 2010 Statemee clinical trial protocol is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT 202