Chapter 6

Automatized, standardized and patient-tailored progressive walking-adaptability training: a proof-of-concept study

Abstract

Background: Treadmill training augmented with visual images projected on the belt’s surface may help improve walking adaptability. Moreover, patient-tailored automatization and standardization may increase the feasibility of walking-adaptability therapy. We developed C-Gait, a treadmill protocol consisting of a baseline walking-adaptability assessment involving seven putatively distinct walking-adaptability tasks and a decision-algorithm to automatically update training content and execution parameters to patients’ performance and perceived challenge.

Objectives: To examine the feasibility, acceptability and clinical potential of C-Gait training (main objective) and to evaluate the validity of the baseline assessment (secondary objective).

Design: Longitudinal proof-of-concept study with pre-training, post-training and retention tests (baseline assessment and walking-related clinical measures).

Methods: 24 healthy adults, 12 healthy elderly and 28 patients with gait and/or balance deficits (GD) performed the baseline assessment; the GD group received 10 C-Gait training sessions over a 5-week period. Baseline assessment scores and walking-related clinical measures served as outcome measures.

Results: C-Gait training exhibited significant progression in training content and execution, with considerable between-patient variation and minimal overruling by therapists. C-Gait training was well accepted and led to improvements in walking adaptability and general walking ability, which prevailed at retention. Baseline assessment scores differed over groups and difficulty levels, and had no to moderate correlations with walking-related clinical measures, and limited correlations among walking-adaptability tasks.

Limitations: C-Gait was evaluated in a small yet diverse cohort. More encompassing studies are required to further establish its apparent merits. The validity of treadmill-based walking-adaptability assessment against an overground standard remains to be established.

Conclusions: C-Gait offers automatized, standardized and patient-tailored walking-adaptability training, which is feasible and well accepted, with good potential for improving task-specific and generic measures of walking.
Introduction
Elderly persons may suffer from walking problems, which may increase their fall risk. To promote safe community ambulation and to prevent falls, the ability to adapt walking to environmental challenges and hazards may have to be trained [1-5]. Recently, novel training devices and interventions have been developed for this purpose, among which is C-Mill training. The C-Mill (Motek, Amsterdam, the Netherlands) is an instrumented treadmill that can project visual images (or objects) on its walking surface. When walking on the treadmill the patient can be instructed to hit (goal-directed stepping) or avoid (obstacle avoidance) projected visual objects. In this manner, both repetitive stepping and walking adaptability can be practiced using the C-Mill, which has led to the development of novel training paradigms [6-12]. Furthermore, the C-Mill is equipped with a large embedded force platform to quantify center-of-pressure (COP) movements, which may be used for real-time performance feedback to the patient, as well as for adapting walking speed and presentation of visual objects to the patient's performance [13-15]. C-Mill training allows therapists to flexibly attune the training to the specific abilities and needs of individuals. Specifically, therapists can modify training content (i.e., type and duration of particular walking-adaptability tasks) and execution parameters (i.e., belt speed, difficulty level, handrail use) to prevent demotivation during training, as could be induced by offering training content that is either too challenging or too easy, according to the motivational flow model [16]. However, at present, no objective guidelines exist regarding the design of treadmill-based gait training programs and how to adapt them to individual needs and treatment goals. These aspects are currently left to the therapist supervising the training, who has to be well versed in operating the C-Mill. This requirement may limit the practical potential of C-Mill training, combined with the fact that operating the C-Mill may draw the therapist's attention away from monitoring, instructing and assisting the patient.

To address these problems we developed an automatized and standardized patient-tailored C-Mill training protocol, called ‘C-Gait’. C-Gait consists of (1) a standardized assessment of the baseline performance on seven, supposedly distinct, walking-adaptability tasks (i.e., goal-directed stepping, tandem walking, obstacle avoidance, slalom walking, adaptation to suddenly shifting obstacles and targets, adaptation to speed changes and dual-task walking), addressing some of the previously defined
walking-adaptability domains [17], and (2) a training protocol based on a decision-
algorithm that determines training content and execution parameters for each training
session on the patient’s performance and perceived challenge during the preceding
session. Although this training protocol is automatically generated and tailored to
individual competencies, it can be overruled if deemed necessary by the therapist.

The main objective of the present proof-of-concept study was to examine the feasibility,
acceptability and clinical potential of C-Gait training in patients with gait and/or balance
deficits. Feasibility was evaluated in terms of progress and between-patient variation in
training content and execution parameters, patients’ performance and perceived
challenge, and the degree of overruling by therapists. We expected the automated
training protocol to be progressive in terms of belt speed, difficulty level and handrail
use, with considerable between-patient variation in training content and execution
parameters, but an overall high (but not perfect) performance and moderately perceived
challenge, and minimal overruling by therapists, indicating feasible individual therapy
that is neither too easy nor too challenging [16]. Acceptability of C-Gait training was
assessed after completing the C-Gait training protocol with a questionnaire. Finally, the
clinical potential of C-Gait training was evaluated by comparing baseline assessment
scores and walking-related clinical measures between pre-training, post-training and
retention tests.

A secondary objective was to evaluate the face validity of the baseline assessment by
comparing C-Gait outcome measures (belt speed and composite score representing
participant’s performance over standardized difficulty levels) across groups varying in
walking ability (healthy adults, healthy elderly and patients with gait and/or balance
deficits) as well as overall task performance between two difficulty levels. If the baseline
assessment indeed taps into walking adaptability, then its outcome measures are
expected to differ among participant groups as a function of expected walking
adaptability and between difficulty levels. Item validity was evaluated by correlating
performance across the seven walking-adaptability tasks encompassing the baseline
assessment; these should be limited if the tasks in question represent separate aspects
of walking adaptability. Finally, we correlated the aforementioned composite score with
walking-related clinical measures of patients with gait and/or balance deficits.
Considering the strong focus on walking adaptability rather than general walking ability, we expected no or only moderate correlations between the baseline composite score and walking-related clinical measures.

**Methods**

*Participants*

Twenty-four healthy adults (HA), 12 healthy elderly without gait and/or balance deficits (HE) and 28 patients with gait and/or balance deficits (GD) were included, all of whom had no previous experience with the C-Mill. The GD group was recruited from two physical therapy practices (Amstelland in Amstelveen and Boot & Broersen in Lisse, the Netherlands) and one rehabilitation center (Revant Lindenhof in Goes, the Netherlands). Inclusion criteria for the GD group were age ≥65 years and Short Physical Performance Battery (SPPB) score ≤9 or first-ever stroke ≥3 months ago, a Functional Ambulation Categories (FAC) score ≥3, and high risk of falling based on fear of falling and/or falling history as indicated by the physical therapist. Exclusion criteria were interfering treatments that could influence the effects of C-Gait training. All participants had to be able to understand and execute simple instructions, and were not allowed to have any contra-indication to physical training or severe uncorrected visual deficits. Persons eligible for participation were informed about the study, both verbally and in writing, and provided informed consent. The study protocol was approved by the Medical Ethical Reviewing Committee of VU University Medical Centre (Amsterdam, the Netherlands; protocol number 2015/057).

*Study design*

All three groups (HA, HE, GD) performed the C-Gait baseline assessment to evaluate its face validity in terms of between-group differences while for only the GD group also walking-related clinical measures were assessed to determine their relation with the C-Gait assessment. After these pre-training tests (T1), the GD group received five weeks of C-Gait training. Post-training tests (T2, within 1 week after the last training) and retention tests (T3, 6 weeks after the last training) included re-assessment of the C-Gait baseline assessment and walking-related clinical measures. All measurements and training sessions were part of regular physical therapy treatment regimen. All involved therapists were trained in using the C-Gait protocol.
C-Gait baseline assessment

A 20-minute C-Gait baseline assessment of walking adaptability was performed using the seven different tasks mentioned in the Introduction (Figure 1) [17]. All but the cognitive dual-task, which consisted of an auditory Stroop task, were assessed at a lower and higher level of difficulty (Appendix 1) to determine participants’ first C-Gait training in terms of content and execution parameters. C-Gait baseline assessment was performed at comfortable walking speed, which was determined for each participant by slowly increasing the belt speed in steps of 0.1 km/h until the participant reported it as comfortable. Subsequently, belt speed was increased by 0.5 km/h followed by a stepwise decrease (0.1 km/h) until the participant reported it as comfortable again. These two indications of comfortable walking speed were then averaged and taken to represent the participant’s comfortable belt speed.

Figure 1. The C-Mill and the seven C-Gait walking-adaptability tasks.
C-Gait training follows a decision-algorithm-based training protocol based on expert advice and literature (Appendix 1). Training content and execution parameters of the first training session were automatically generated based on performance during the baseline assessment. Each subsequent training session was automatically generated to performance and perceived challenge of the preceding training. Training content is an adjustable parameter automatically modified from session to session based on the patient’s performance; the poorer the task performance, the longer will be the relative training duration of that particular task in the next training session. Adjustable training execution parameters in the current proof-of-concept study were the difficulty level of walking-adaptability tasks and belt speed, which were automatically increased in odd and even training sessions, respectively, depending on the patient’s performance in the preceding training session. Stepwise increments in difficulty level and belt speed were kept relatively small (i.e., 1 level and 10%, respectively), ensuring that the training remained safe and tolerable. The third adjustable execution parameter was handrail use (0-1-2 hands; never, rarely, sometimes, often, always, as documented for each walking-adaptability task for each training session); patients were automatically advised to diminish handrail use when belt speed or difficulty level was increased. When the highest level for a task was reached, patients were additionally challenged to diminish handrail use, to perform the task at an even higher walking speed (+10%) and/or to perform the auditory Stroop-task concurrently. After completing a particular task during the training, patients were asked to rate how challenging the task was: 'hard' (1 point), 'neutral' (2 points) or 'easy' (3 points). When the answer deviated from the actual performance for three consecutive training sessions, the protocol was adjusted accordingly. Appendix 1 details the cut-off performance of each task used to adjust training content and execution parameters, along with other decision-algorithm elements.

C-Gait training was provided twice a week and every training session lasted about thirty minutes of which circa twenty minutes were spent on actual treadmill walking. All assessment and training sessions were supervised by a trained physical therapist. At the start of each training session, the automatically generated training protocol was provided as an advice to the therapist, who could overrule the training protocol by
manually adjusting the proposed training content and training execution parameters per task when deemed appropriate or necessary; the degree of overruling by physical therapists was recorded.

**Outcome measures**

Outcome measures of the C-Gait baseline assessment comprised its belt speed and the composite score, performance per walking-adaptability task and overall performance averaged over the seven walking-adaptability tasks, as detailed here. Task performance of slalom walking, tandem walking, speed adaptations, goal-directed stepping, obstacle avoidance and walking with suddenly shifting obstacles and targets was defined as the percentage correctly performed steps relative to the projected visual objects (based on COP at mid-stance, Appendix 1). Cognitive dual-task performance during walking was quantified as the percentage correct answers. The composite score of the baseline assessment was an average score based on average performance over the six walking-adaptability tasks at the higher level of difficulty and the performance of the cognitive dual-task, thereby combining different aspects of walking adaptability. The composite score of the baseline assessment ranged from 0 (poor performance) to 8 (excellent performance), as detailed in Appendix 1.

Walking-related clinical measures included the 10 Meter Walking Test [10MWT], Timed Up-and-Go [TUG], Activities specific Balance Confidence scale [ABC] and SPPB. The 10MWT and TUG were performed three times at comfortable walking speed; subsequently, the average time to perform the whole 10 meter and TUG, respectively, was calculated [18,19]. The ABC was assessed to determine balance confidence and had a possible range from 0-100% [20,21]. The SPPB involved standing balance, timed 4m walk, and five sit-to-stands, with the sum of the three components comprising the SPPB score (0-12 points) [22].

**Statistical evaluation of the validity of the baseline assessment**

The face validity of the baseline assessment was evaluated by 1) comparing the belt speed and composite score between groups (HA, HE and GD) using one-way ANOVAs and 2) comparing overall performance (excluding the cognitive dual-task task) between difficulty levels using a Group (HA, HE, GD) by Level (lower and higher difficulty level)
repeated-measures ANOVA. Post-hoc analyses of main effects and interactions were assessed using independent t-tests (Group effects) and paired-samples t-tests (Level effects). Degrees of freedom were adjusted if the assumption of sphericity (following Mauchly’s test, using the Greenhouse-Geisser correction) or the assumption of equal variances (following Levene’s test) was violated. The item validity was evaluated by correlating the performances on the walking-adaptability tasks at the higher difficulty level with each other, using non-parametric Spearman’s correlation coefficients and Cronbach’s α. C-Gait outcome measures were correlated with the walking-related clinical measures of the GD group using non-parametric Spearman’s correlation coefficients to determine their relation.

Examination of the feasibility, acceptability and clinical potential of C-Gait training

The feasibility of C-Gait training was assessed in terms of progress and between-patient variation in training content and execution parameters as well as in patients’ performance and perceived challenge and the degree of therapists’ overruling of the advised C-Gait training protocol. The progress in belt speed, difficulty level, perceived challenge (all averaged over the tasks) and overall performance were visualized over the 10 training sessions for all patients with two representative cases highlighted. These progressions were analyzed using repeated-measures ANOVAs with the within-subject factor Training (10 levels) or with non-parametric Friedman’s ANOVAs followed by paired-samples t-tests or Wilcoxon signed-rank tests as post-hoc tests. Between-patient variation in terms of content (relative duration) was illustrated by two representative cases, while for handrail use (number of hands used, averaged over the tasks) the percentage of patients using the handrails during the first and last training session was given and the difference between those training sessions was analyzed using a Wilcoxon signed-rank test. The degree of overruling by therapists on the advised C-Gait training protocol was presented using the percentage disagreement between advised and performed training content and execution parameters.

The acceptability of C-Gait training was assessed in terms of patients’ experience after C-Gait training using a custom-made evaluation questionnaire with 1-10 rating scales and multiple-choice questions (Appendix 2). The number of patients per score and the
number of patients experiencing improvement(s) and/or discomfort(s) after training were reported.

The clinical potential of C-Gait training was evaluated by subjecting C-Gait outcome measures and walking-related clinical measures to repeated-measures ANOVAs with Time as within-subject factor (3 levels: pre-training, post-training, retention) and paired-samples t-tests as post-hoc tests. For all analyses the criterion $p<.05$ was adopted for significant effects.

**Results**

In total, $n=22$ HA, $n=12$ HE and $n=28$ GD participants completed the baseline assessment; two participants of the HA group were excluded because of incomplete data. 26 GD participants completed the five-week C-Gait protocol (taking at least 6 ($n=1$), 7 ($n=1$), 9 ($n=2$) or 10 ($n=22$) out of 10 training sessions) and post-training tests; two GD participants (7%) dropped out after T1 due to interfering personal obligations and perceived stress with participation. 23 from these participants completed the retention tests; 3 participants (12%) were unable to complete the retention tests due to illness or interfering personal obligations. Participants’ characteristics are provided in Table 1.

<table>
<thead>
<tr>
<th>Table 1. Participant characteristics</th>
<th>HA (n=22)</th>
<th>HE (n=12)</th>
<th>GD (n=28)</th>
</tr>
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<tbody>
<tr>
<td>Gender, n male (%)</td>
<td>9 (41)</td>
<td>8 (67)</td>
<td>14 (50)</td>
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<td>Age, years</td>
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<td>70.25 ±5.23</td>
<td>69.96 ±11.40</td>
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<td>Height, m</td>
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<td>1.76 ±0.08</td>
<td>1.71 ±0.08</td>
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<td>Body mass, kg</td>
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<td>84.83 ±14.26</td>
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<td>NA</td>
<td>6/22</td>
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<td>Time since diagnosis, months †</td>
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<td>NA</td>
<td>12 (0-492)</td>
</tr>
<tr>
<td>FAC †</td>
<td>NA</td>
<td>NA</td>
<td>5 (4-5)</td>
</tr>
<tr>
<td>Walking aid indoors, n (%)</td>
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<td>NA</td>
<td>4 (14)</td>
</tr>
<tr>
<td>Walking aid outdoors, n (%)</td>
<td>NA</td>
<td>NA</td>
<td>10 (26)</td>
</tr>
<tr>
<td>Fear of falling †</td>
<td>NA</td>
<td>NA</td>
<td>5 (1-9)</td>
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</table>

GD: patients with gait and/or balance deficits, HE: healthy elderly, HA: healthy adults, FAC: Functional Ambulation Categories. † Reported as median (minimum-maximum).
Validity of C-Gait baseline assessment

Between-group differences in C-Gait outcome measures (face validity)

As expected, C-Gait’s belt speed and composite score varied significantly over groups \( (F(2,59)=6.10, p<.01, \eta^2=0.17 \) and \( F(2,59)=16.80, p<.01, \eta^2=0.36 \), respectively), with significantly lower belt speeds and composite scores for GD \((0.68 \pm 0.16\text{m/s and } 6.64 \pm 0.68, \text{respectively})\) than the HA group \((0.85 \pm 0.14\text{m/s, } t(48)=3.96, p<.01, d=1.13 \) and \( 7.46 \pm 0.18, t(31.75)=6.07 p<.01, d=1.65, \text{respectively})\). Moreover, the composite score was significantly higher for the HE \((6.98 \pm 0.33)\) than for the GD group \((t(37.30)=2.11, p<.05, d=1.83)\) but significantly lower than for the HA group \((t(32)=5.51, p<.01, d=1.83)\). No significant difference in belt speed was found between those groups \((GD \text{ vs. HE: } 0.76 \pm 0.24\text{m/s, } t(15.20)=0.99, p=.34, d=0.46 \) and HA vs. HE: \( t(15.29)=1.26, p=.23, d=0.46)\).

Between-level and between-group differences in overall performance (face validity)

Overall performance varied significantly between the two difficulty levels \((F(1,59)=49.46, p<.01, \eta^2=0.46)\), with lower performance for the higher difficulty level \((lower: 87.92 \pm 8.04\%, \text{higher } 84.37 \pm 7.68\%)\). In line with the between-group differences for the composite scores, performance also varied significantly over groups \((F(2,59)=13.50, p<.01, \eta^2=0.31)\), with significantly lower performances for GD \((86.15 \pm 7.34\%)\) and HE \((89.72 \pm 4.26\%)\) groups than for the HA group \((94.16 \pm 1.86%; t(31.31)=5.55, p<.01, d=1.50 \) and \( t(32)=4.25, p<.01, d=1.35, \text{respectively})\). Overall performance did not differ between GD and HE groups \((t(38)=1.57, p=.13, d=0.59)\). There was no significant interaction between group and difficulty level \((F(2,59)=0.87, p=.42, \eta^2=0.03)\).

Correlations among walking-adaptability tasks (item validity).

Performances of only 4 out of the 21 possible pairs of walking-adaptability tasks were significantly correlated: 1) goal-directed stepping and walking with suddenly shifting obstacles and targets \((r_s=0.56, p<.01)\), 2) tandem walking and obstacle avoidance \((r_s=0.46, p<.05)\), 3) speed adaptations and walking with a cognitive dual-task \((r_s=0.43, p<.05)\), and 4) tandem walking and walking with suddenly shifting obstacles and targets \((r_s=0.52, p<.01)\). This limited number of significant low-to-moderate correlations suggest that most of these tasks indeed capture distinctive aspects of walking.
adaptability; this suggestion is corroborated by an overall Cronbach’s α of 0.71, with removal of any task yielding lower α-values.

Correlation between C-Gait baseline assessment and walking-related clinical measures.
Belt speed correlated significantly with 10MWT ($r_s=-0.72, p<.001$), TUG ($r_s=-0.57, p<.01$) and SPPB ($r_s=0.50, p<.01$) but not with the ABC ($r_s=0.26, p=.20$). The composite score, in contrast, only correlated significantly with TUG ($r_s=-0.48, p<.05$) and not with other walking-related clinical measures (10MWT: $r_s=-0.29, p=.14$; SPPB: $r_s=0.10, p=.63$; ABC: $r_s=0.03, p=.88$), suggesting that it addresses a distinctive construct that is not or only moderately targeted by standard clinical measures.

Feasibility of C-Gait training
Training progress. Figure 2 shows the progress in belt speed, difficulty level, patient’s performance and perceived challenge over the 10 training sessions for all GD participants. Belt speed increased significantly over sessions ($F(1.53,32.12)=21.35, p<.01, \eta^2=0.50$), with significant post-hoc differences between all odd sessions and the consecutive even sessions ($t(21)>2.08, p<.05, r>0.41$), consistent with the algorithm’s speed adjustments in even sessions. The difficulty level also increased significantly over sessions ($X^2(22)=36.51, p<.01$), with post-hoc tests revealing significant or trend differences between consecutive sessions 1 and 2 ($Z(22)=1.95, p=.051, r=0.42$), 3 and 4 ($Z(22)=2.17, p<.05, r=0.46$), 4 and 5 ($Z(22)=1.81, p=.071, r=0.39$) and sessions 8 and 9 ($Z(22)=1.77, p=.076, r=0.38$). Patients’ performance and perceived challenge did not vary systematically over sessions ($F(4.52,94.81)=1.21, p=.29, \eta^2=0.05$ and $X^2(22)=13.94, p=.13$, respectively). Throughout all training sessions overall performance remained high (mean performance was 87.23%) and patients perceived training sessions as neutrally challenging (mean challenge was 2.05, neither too easy, nor too difficult). Handrail use decreased from 61% (session 1) to 14% (session 10) of the patients using both hands for support, while the percentage of patients using no handrail increased from 11% (session 1) to 36% (session 10) ($Z(22)=3.26, p<.01, r=0.70$).

As is evident from Figure 2, between-patient variation in belt speed and difficulty level was large (ranging respectively from 0.37 to 1.52 m/s and from 2.0 to 4.9). We highlighted progression profiles in training execution parameters for two representative
cases. Patient A started C-Gait training with a relatively high belt speed, relatively lower difficulty level but without handrail use. Over the sessions, both speed and difficulty levels increased. In contrast, patient B had a relatively low belt speed, high difficulty level and used handrail with two hands. Over sessions, speed increased, difficulty level remained high and handrail use was reduced. Finally, training content progressed differently for patients A and B, as visualized by the different changes in relative training duration of the seven walking-adaptability tasks, which again underscores that the tasks address distinct walking-adaptability aspects. Together, these observations testify to the feasibility of the patient-tailored element of C-Gait training.
Figure 2. Feasibility results: progress and between-patient variation in training content and execution parameters, performance and perceived challenge over the 10 training sessions for the GD group with the mean and two representative cases (Patient A and B) highlighted.
Therapists’ overruling.

Overruling by therapists with the advised training in clinical practice was minimal: the automatically proposed difficulty level was adjusted in 4.10% of all occasions, belt speed in 5.48% and content in 5.48%.

Acceptability of C-Gait training

Patients scored C-Gait as useful, motivating, challenging, fun, user-friendly, suitable and would recommend it to peers (Figure 3). Patients described an increase in physical fitness (n=19), safety of walking (n=17), walking speed (n=14), and confidence during walking indoors, outdoors on smooth surfaces, outdoors on irregular surfaces and/or in crowded environments (n=20). Patients reported only mild discomfort during and after training sessions, without exhibiting any serious adverse events related to the training. Discomfort during (once: n=2, frequently: n=5) and after (once: n=2, frequently: n=6) training sessions mainly comprised of muscle soreness, fatigue and shortness of breath.

<table>
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<th>4</th>
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Figure 3. Acceptability results: patients’ experience (n=26) after C-Gait training assessed with a custom-made questionnaire, presented as the number of patients (n) per score for 7 items.
Clinical potential of C-Gait training

C-Gait’s belt speed and composite score, 10MWT, TUG and SPPB improved over time (all $F(1.53,33.75)>5.22$, $p<.01$, $\eta^2>0.19$), with significant post-training improvement (all T2 vs. T1 $t(22)>2.26$, $p<.05$, $r>0.43$ and all T3 vs. T1 $t(22)>2.22$, $p<.05$, $r>0.43$) and retention after 6 weeks (all T3 vs. T2 $t(22)<1.40$, $p>.18$, $r<0.29$). For the ABC we missed data for 1 participant; however, we saw similar results for this clinical measure, namely a significant improvement over time ($F(2,42)=6.98$, $p<.01$, $\eta^2=0.25$), with significant post-training improvement (T2 vs. T1 $t(21)=3.52$, $p<.01$, $r=0.61$ and T3 vs. T1 $t(21)=2.96$, $p<.05$, $r=0.54$) and retention after 6 weeks (T3 vs. T2 $t(21)=0.47$, $p=.65$, $r=0.10$) (Figure 4).
Figure 4. Clinical potential results: effect of C-Gait training on C-Gait baseline assessment scores (belt speed and composite score) and walking-related clinical measures (10 Meter Walking Test [10MWT], Timed ‘Up and Go’ test [TUG], Activities specific Balance Confidence scale [ABC] and Short Physical Performance Battery [SPPB]). Error bars represent the standard error and asterisks represent significant differences ($p<.05$) compared to the pre-training tests.
Discussion

We developed C-Gait, a protocol for baseline assessment of walking adaptability and a decision-algorithm that adaptively and progressively updates training content and execution parameters to patient’s performance and experienced challenge. In this proof-of-concept study, we examined the feasibility, acceptability, and clinical potential of the C-Gait training protocol (main objective) and evaluated the validity of its baseline assessment (secondary objective). Face validity of the baseline assessment was evidenced by significant between-group (C-Gait outcome measures and overall performance) and between-level (overall task performance) differences in expected directions. Item validity was evidenced by limited correlations among the seven walking-adaptability tasks, suggesting that they represented largely distinctive walking-adaptability aspects. Finally, no-to-moderate correlations between the composite score and walking-related clinical measures were found, suggesting added value. Considering that the baseline assessment focuses strongly on walking adaptability rather than walking ability in general, the added value most plausibly pertains to walking adaptability, although in the absence of a gold standard for (overground) walking adaptability [17] this is difficult to prove.

With regard to our main objective, C-Gait training proved feasible, and exhibited significant progression and considerable between-patient variation in terms of training content and execution parameters, high overall task performance and minimal overruling of the proposed training by therapists in clinical practice. Acceptance of therapists and confidence in a given therapy are prerequisites for automatized and standardized forms of therapy. Automatization enhanced the feasibility of C-Gait training by enabling therapists to supervise patients instead of operating technology; operational duties may be further reduced by recording handrail-use with a force sensor [23]. Standardization was successful in providing progressive (i.e., significant changes in belt speed, difficulty level and handrail use over training sessions) and patient-tailored (i.e., large between-patient variation in training content and execution parameters) training, testifying to C-Gait’s feasibility for patients who vary widely in terms of self-selected walking speed, handrail use and walking adaptability. C-Gait training was well accepted by patients with gait and/or balance deficits. They rated the progressive training as moderately challenging while maintaining high but suboptimal levels of task
performance, suggesting that the training was indeed challenging but not too easy or difficult, which is important for motivational flow [16].

Last but not least, C-Gait training has good clinical potential, as evidenced by significant task-specific (C-Gait outcome measures) and generic (walking-related clinical measures) improvements from pre-training to post-training, which all prevailed 6 weeks later (retention); observed gains in 10MWT and SPPB were greater than their known small (0.05 m/s) and substantial (1.0 points) meaningful changes [24], respectively. Future studies are warranted to further establish the apparent merits of automatized, standardized and patient-tailored progressive walking-adaptability training vis-à-vis conventional gait training or conventional C-Mill training [8,10]. Such studies, with more participants, therapists and care centers, seem now quite feasible owing to C-Gait’s automatized and standardized nature of assessment and training, which may help answering questions like which patient would benefit most from treadmill-based walking-adaptability training. This seems timely considering that conventional C-Mill walking-adaptability training showed clinical potential for groups with similar levels of walking ability as our GD group [6,9,25]. However, based on the current evidence, C-Mill training does not seem more effective than other interventions in groups with greater walking-ability (and cognitive) limitations [10], although two conventional C-Mill therapy trials are still running [11,12]. The developed patient-tailored C-Gait walking-adaptability assessment and training protocol may facilitate identification of responders and non-responders to walking-adaptability training by collecting and combining standardized baseline and training data suitable for database research. Validation of the treadmill-based baseline assessment of walking-adaptability aspects may be required against an overground standard, which seems now possible with the recently developed Interactive Walkway [30].

**Conclusion**

C-Gait provides a feasible and well-accepted protocol for automatized, standardized, patient-tailored and progressive training, with good potential for improving both task-specific and generic measures of walking, paving the way for assessing and training large and diverse groups of patients with walking-adaptability limitations.
References


Appendix 1: details on C-Gait baseline assessment and decision-algorithm

The C-Gait protocol was based on shared experiences of, and structured focus group discussions with, clinical professionals (mostly physical therapists and rehab physicians) [26]. Additionally, protocol decisions followed recommendations for improving training protocols from previous trials with untailored standard C-Mill training protocols [6,8,11,27]. Finally, evidence-based ingredients for effective rehabilitation (see [28] and references therein) and motor learning (see [29] and references therein) were incorporated into the design of the protocol. As presented below, the protocol starts with the C-Gait baseline assessment to determine a patient’s starting level, followed by session-to-session adjustments in training content (every training session), belt speed (even training sessions) and difficulty level (odd training sessions) based on patients’ performance and perceived challenge.
C-Gait baseline assessment

<table>
<thead>
<tr>
<th>Familiarization on the treadmill</th>
<th>±2.5 min</th>
<th>Determine comfortable walking speed</th>
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<tbody>
<tr>
<td>Walking-adaptability tasks</td>
<td>±6.5 min</td>
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<tr>
<td>Lower difficulty level (level 2)</td>
<td></td>
<td>1 min: goal-directed stepping</td>
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<td></td>
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<td>±1.5 min: obstacle avoidance*</td>
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<td></td>
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<td>1 min: slalom walking</td>
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<td>1 min: speed adaptations</td>
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<td></td>
<td></td>
<td>1 min: tandem walking</td>
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<tr>
<td></td>
<td></td>
<td>1 min: walking with suddenly shifting obstacles and targets</td>
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<tr>
<td>Assessment of cognitive dual-task</td>
<td>1.5 min</td>
<td>Walking while performing an auditory Stroop-task</td>
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<tr>
<td>Walking-adaptability tasks</td>
<td>±6.5 min</td>
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<tr>
<td>Higher difficulty level (level 4)</td>
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<td>1 min: goal-directed stepping</td>
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<td>±1.5 min: obstacle avoidance*</td>
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<td>1 min: slalom walking</td>
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<td></td>
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<td>1 min: speed adaptations</td>
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<td></td>
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<td>1 min: tandem walking</td>
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<td></td>
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<td>1 min: walking with suddenly shifting obstacles and targets</td>
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<tr>
<td>Total</td>
<td>±20 min</td>
<td>Incl. the walking break in between tasks (15 s)</td>
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*A minimum of 15 obstacles had to be performed to determine completion. To keep the task similar for each participant, in terms of the number of presented obstacles, the number of steps between obstacle presentations was standardized. Therefore, the time of this task varied slightly between participants.

C-Gait performance and composite score

Task performance was defined as the percentage correctly performed steps relative to the projected visual objects. For slalom walking, tandem walking and speed adaptations, steps were correctly performed if COP at mid-stance was within the projected area. For goal-directed stepping and obstacle avoidance, steps were correctly performed if COP at mid-stance ± half of the foot size was inside or outside the projected area, respectively. For walking with suddenly shifting obstacles and targets, the weighted average of correctly performed steps and correctly avoided obstacles was calculated. Cognitive dual-task performance was quantified as the percentage correct answers.

The C-Gait composite score was based on the difficulty level and performance and ranged from zero to ten to make it easy to interpret for therapists (with 0 being the worst possible score and 10 being the best attainable score). Only for the baseline assessment, the maximal attainable score was 8, due to the standardized (non-maximal) levels of difficulty (see below).
Chapter 6

- C-Gait score for each task: Level * 2 * Performance (%) / 100
- C-Gait score for the cognitive performance: Performance (%) / 10 * (8/10)
- C-Gait composite score: Mean C-Gait scores on high level + C-Gait score for the cognitive performance

**Difficulty levels**

Each task consisted of 5 difficulty levels (except for the cognitive dual-task). The increments in difficulty levels for each task were based on

- Goal-directed stepping → increase in random variation in step length and step width
- Obstacle avoidance → increase in size and decrease in available response time (ART)
- Slalom walking → increase in sharpness of the curves
- Speed adaptations → increase in acceleration of the walking area
- Tandem walking → decrease in width of the walking area
- Walking with suddenly shifting obstacles and targets → increase in size and decrease in ART
**Patient-tailored walking-adaptability training**

**C-Gait training (decision algorithm)**

Set starting content (relative duration) and difficulty level for each task
- lower level $>90/80\%$ & higher level $>90/80\%$ → weighting factor 1 + start at level 5
- lower level $>90/80\%$ & higher level $=70/60<90/80\%$ → weighting factor 2 + start at level 4
- lower level $>90/80\%$ & higher level $<70/60\%$ → weighting factor 3 + start at level 3
- lower level $=70/60<90/80\%$ → weighting factor 4 + start at level 2
- lower level $<70/60\%$ → weighting factor 5 + start at level 1

**Extra:**
- Red = cut-off performance scores for goal-directed stepping, slalom walking, speed adaptations and tandem walking. Blue = cut-off performance scores for obstacle avoidance, walking with suddenly shifting obstacles and targets (and walking with a cognitive dual-task).

If the patient’s perceived challenge is 3 times in a row in contradiction with the performance, advice on the difficulty level or walking speed changes:
- Perceived as easy however poor performance → increase level or walking speed +10% 
- Perceived as difficult however high performance → decrease level or walking speed -10%

High performance ($>90/80\%$) on the highest level (5) → weighting factor 0 (or not checked to train), however therapist can still choose to train this task with an optional extra challenge (less handrail use, a higher walking speed or a cognitive dual-task (same as auditory stroop-task)).
Appendix 2 (custom-made evaluation questionnaire)

1. Did you perceive the C-Gait training as useful? Select the box (mark) that fits best.

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2. Did you perceive the C-Gait training as motivating? Select the box (mark) that fits best.

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3. Did you perceive the C-Gait training as challenging? Select the box (mark) that fits best.

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4. Did you perceive the C-Gait training as fun? Select the box (mark) that fits best.

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5. Did you perceive the C-Gait training as user friendly? Select the box (mark) that fits best.

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6. Did you perceive the C-Gait training as suitable? Select the box (mark) that fits best.

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7. Would you recommend C-Gait training to peers? Select the box (mark) that fits best.

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8. Which part of the training did you perceive as easy? (multiple answers are possible)
   - Obstacle avoidance
   - Goal-directed stepping
   - Slalom walking
   - Walking with shifting obstacles and targets
   - Speed adaptations
   - Tandem walking
9. Which part of the training did you perceive as difficult? (multiple answers are possible)
   - Obstacle avoidance
   - Goal-directed stepping
   - Slalom walking
   - Walking with shifting obstacles and targets
   - Speed adaptations
   - Tandem walking
   - Walking with a cognitive dual-task

10. Do you think you have trained those parts sufficiently?
   - Yes
   - No
   Why ________________________________

11. Did you perceive discomfort(s) DURING one or more training sessions (e.g. severe fatigue, muscle soreness, dizziness, shortness of breath)?
   - Yes, multiple times
   - Yes, once
   - No

   If so, what were these discomforts? (multiple answers are possible):
   - Severe fatigue
   - Muscle soreness
   - Dizziness
   - Nausea
   - Shortness of breath
   - Painful joints, namely ________________________________
   - Other, namely ________________________________

12. Did you perceive discomfort(s) AFTER one or more training sessions (e.g. severe fatigue, muscle soreness, dizziness, shortness of breath)?
   - Yes, multiple times
   - Yes, once
   - No

   If so, what were these discomforts? (multiple answers are possible):
   - Severe fatigue
Chapter 6

- Muscle soreness
- Dizziness
- Nausea
- Shortness of breath
- Painful joints, namely__________________________________
- Other, namely_________________________________________

13. What did you think of the duration of a training sessions?
   - Good
   - Too long
   - Too short
   - Other, namely________________________________________

14. What did you think of the duration of the whole training period?
   - Good
   - Too long
   - Too short
   - Other, namely________________________________________

15. What did you think of intensity of the C-Gait training?
   - Good
   - Too light
   - Too hard
   - Other, namely________________________________________

16. Do you think your physical fitness has increased?
   - Yes
   - No

17. Do you think you have increased your safety during walking in your own environment?
   - Yes, continue to question b
   - No
   b. Can you describe how?

18. Do you think you have increased your walking speed?
   - Yes
   - No

19. Do you think you have increased your trust during walking?
   - Yes, continue to question b
Patient-tailored walking-adaptability training

b. If so, where? (multiple answers are possible)
   - No
   - Indoors
   - Outdoors, smooth terrain
   - Outdoors, uneven terrain
   - Outdoors, busy environment
   - Other, namely__________________________________________