Effects of real-time feedback during decline walking on kinematic and kinetic gait parameters (Up & Down): study protocol

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Abbreviations

cm	centimeter
dFLA	dynamic functional leg alignment
fKROM	frontal knee range of motion
GRAIL	Gait Real-time Analysis Laboratory
ICC	Intraclass Correlation Coefficient
kg	kilogram
LW	level walking
m	meter
OA	osteoarthritis
vGRF	vertical ground reaction force

Synopsis

Title of the project

Up & Down - Effects of real-time feedback during decline walking on kinematic and kinetic gait parameters

Name and address of the sponsor

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Short summary

Control of the dynamic functional leg alignment (dFLA) and biomechanical load are important joint related aspects regarding the development of osteoarthritis (OA). Research on level walking with feedback on load related parameters provided innovative treatment possibilities. Concerning walking on sloped surfaces, fundamental biomechanical knowledge exists. However, deeper insights into the control of the dFLA during decline walking, and the usefulness of real-time feedback are missing.
This study is set up as cross-sectional observation of gait under four conditions, which follows a randomized sequence in order to avoid carry over effects. Thirty (30) participants aged between 18 and 35 years will be included. They will complete a three-dimensional gait analysis on a 5-m ramp with 10° inclination. Afterwards they will be observed under four different conditions a) self-paced walking b) self-paced walking with internal focus of

attention, c) self-paced walking with real-time feedback, and d) condition c speed-matched walking, on a 10° declined split belt treadmill. The primary outcome parameter will be the frontal knee range of motion (fKROM). Secondary outcomes include the ground reaction force loading rate, spatial-temporal parameters, sagittal frontal and transversal kinematics, and kinetics for the lower extremities.

The findings should improve the understanding of effects of real-time feedback on the control of the dFLA and lower limb loading. Results will be published in a peer-review journal.

Rationale and background information

The prevalence of symptomatic osteoarthritis (OA) was estimated to be about 3-9% in European adults aged over 19 and increases towards to 9-15% in those over 60 years[1]. Biomechanical loading was identified as one of highly relevant parameters concerning the development of knee OA and the management of conservative OA therapy[2,3]. In this context, kinematic and kinetic parameters have been studied thoroughly during level walking. Previous studies reported on altered gait parameters in incline and increasing inclination walking[4,5]. However, declined walking is, due to higher vertical ground reaction forces (vGRF), even more challenging for the musculoskeletal system[6-8] and the control of the dynamic functional leg alignment (dFLA). Especially knee and hip joint compression forces increase with the grade of inclination[9]. The medio-lateral load distribution and loading velocity generally is associated with knee valgus / varus thrust[10], which was reported for level walking (LW) up to 6° in healthy persons[11,12]. Beside one x-ray based study data for declined walking is missing[10]. As loading and neuromuscular control have been shown to be important in the prevention and treatment of knee OA[13,14], feedback is an effective tool supporting patients[15,16]. Especially real-time feedback targeting at the sensorimotor control of the dFLA during walking has not been investigated yet.

Assessment of uphill or downhill locomotion has mainly been studied using instrumented ramps[6,17]. Only few studies have been done on instrumented treadmills with incliniation[5,18,19]. But in those the kinetic measurement technology is not sufficient comparable. Furthermore, knowledge on the agreement of ramp and treadmill derived kinetic and energy data is missing.

To our knowledge, the influence of motor control interventions as internal focus of attention and real-time feedback on prior mentioned biomechanical factors in declined walking have not been studied before.

Study goals and objectives

This cross-sectional observation of decline walking under four conditions, aims at enhancing the understanding of the effects of real-time feedback on lower limb gait kinematics and kinetics. Furthermore, the agreement of kinematic and kinetic parameters of 10° decline and incline walking between ramp and treadmill will be assessed.

The primary research question is, whether real-time feedback alters the frontal knee range of motion when compared to self-paced walking on the one hand, and matched speed walking on the other hand. The secondary aspect focuses on the effect of lower limb loading in decline walking. Thirdly, parameters of interest will be compared between declined/inclined ramp and declined/inclined treadmill walking. Consequently, underlying hypotheses were phrased as follows:

Primary null hypothesis: Means of the outcome "frontal knee range of motion" are equal across the four conditions a) self-paced walking, b) self-paced walking with internal focus of attention, c) self-paced walking with real-time feedback, and d) condition c speed-matched walking. Predefined contrasts hypothesize that:

1) The outcome of self-paced walking with internal focus of attention and self-paced walking with real-time feedback is equal to speed matched walking (bc=d)
2) The outcome of self-paced walking with internal focus of attention and self-paced walking with real-time feedback is equal to self-paced walking (bc=a)
3) The outcome of self-paced walking with real-time feedback is equal to self-paced walking with internal focus of attention (c=b)

Primary alternative hypothesis: Means of the outcome "frontal knee range of motion" are NOT equal across the four conditions a) self-paced walking, b) self-paced walking with internal focus of attention, c) self-paced walking with real-time feedback, and d) condition c speed-matched walking. Two-sided testing will be applied, as knowledge from existing literature is only moderate. Predefined contrasts hypothesize that:

1) The outcome of self-paced walking with internal focus of attention and self-paced walking with real-time feedback is NOT equal to speed matched walking (bc≠d)
2) The outcome of self-paced walking with internal focus of attention and self-paced walking with real-time feedback is NOT equal to self-paced walking (bc≠a)
3) The outcome of self-paced walking with real-time feedback is NOT equal to self-paced walking with internal focus of attention (c<b)

Secondary null hypothesis: Means of the outcome "ground reaction force loading rate" are equal across the four conditions a) self-paced walking, b) self-paced walking with internal focus of attention, c) self-paced walking with real-time feedback, and d) condition c speed-matched walking. Predefined contrasts are for this outcome concordant with those of the primary hypothesis.

Secondary alternative hypothesis: Means of the outcome "ground reaction force loading rate" are NOT equal across the four conditions a) self-paced walking, b) self-paced walking with internal focus of attention, c) self-paced walking with real-time feedback, and d) condition c speed-matched walking. Two-sided testing will be applied, as knowledge from existing literature is only moderate. Predefined contrasts are for this outcome concordant with those of the primary hypothesis.

Tertiary null hypothesis:

1) The agreement of continuous kinematic and kinetic outcomes of the lower limb (see list of outcome parameters) between decline ramp walking and speed-matched decline treadmill walking is lower than 0.75 (ICC).
2) The agreement of continuous kinematic and kinetic outcomes of the lower limb (see list of outcome parameters) between decline ramp walking and self-paced decline treadmill walking is lower than 0.75 (ICC).
3) The agreement of continuous kinematic and kinetic outcomes of the lower limb (see list of outcome parameters) between incline ramp walking and speed-matched incline treadmill walking is lower than 0.75 (ICC).
4) The agreement of continuous kinematic and kinetic outcomes of the lower limb (see list of outcome parameters) between incline ramp walking and self-paced incline treadmill walking is lower than 0.75 (ICC).

Tertiary alternative hypothesis:

1) The agreement of continuous kinematic and kinetic outcomes of the lower limb (see list of outcome parameters) between decline ramp walking and speed-matched decline treadmill walking is at least 0.75 (ICC).
2) The agreement of continuous kinematic and kinetic outcomes of the lower limb (see list of outcome parameters) between decline ramp walking and self-paced decline treadmill walking is at least 0.75 (ICC).
3) The agreement of continuous kinematic and kinetic outcomes of the lower limb (see list of outcome parameters) between incline ramp walking and speed-matched incline treadmill walking is at least 0.75 (ICC).
4) The agreement of continuous kinematic and kinetic outcomes of the lower limb (see list of outcome parameters) between incline ramp walking and self-paced incline treadmill walking is lower at least 0.75 (ICC).

Methods/Design

Trial design

The study is set up as cross-sectional observation of gait under four conditions, which follows a randomized sequence in order to avoid carry over effects. Chronologically, the assessments will start with the tertiary observation, investigating agreements between declined/inclined ramp and treadmill walking. Thereafter, three out of four conditions (self-paced walking, self-paced walking with internal focus of attention, and self-paced walking with real-time feedback) are tested under block randomization of their six possible permutations (ABC, BCA, CAB, CBA, ACB, BAC). With three conditions (n=3), this represents the smallest number of permutations, equaling a Williams design, where each condition precedes each other condition equally often and each treatment occurs equally frequently at each position[20]. The fourth corresponding condition (speed-matched walking), can technically not take place before the corresponding real-time feedback condition, and is therefore exempted from the sequence randomization and always follows after self-paced walking with real-time feedback. Numbers of participants assessed for eligibility, allocated to assessments, and analyzed will be recorded by a modified CONSORT flow chart[21], without consideration of losses to follow-up, due the cross-sectional study design. Figure 1 illustrates a flowchart of the trial design.

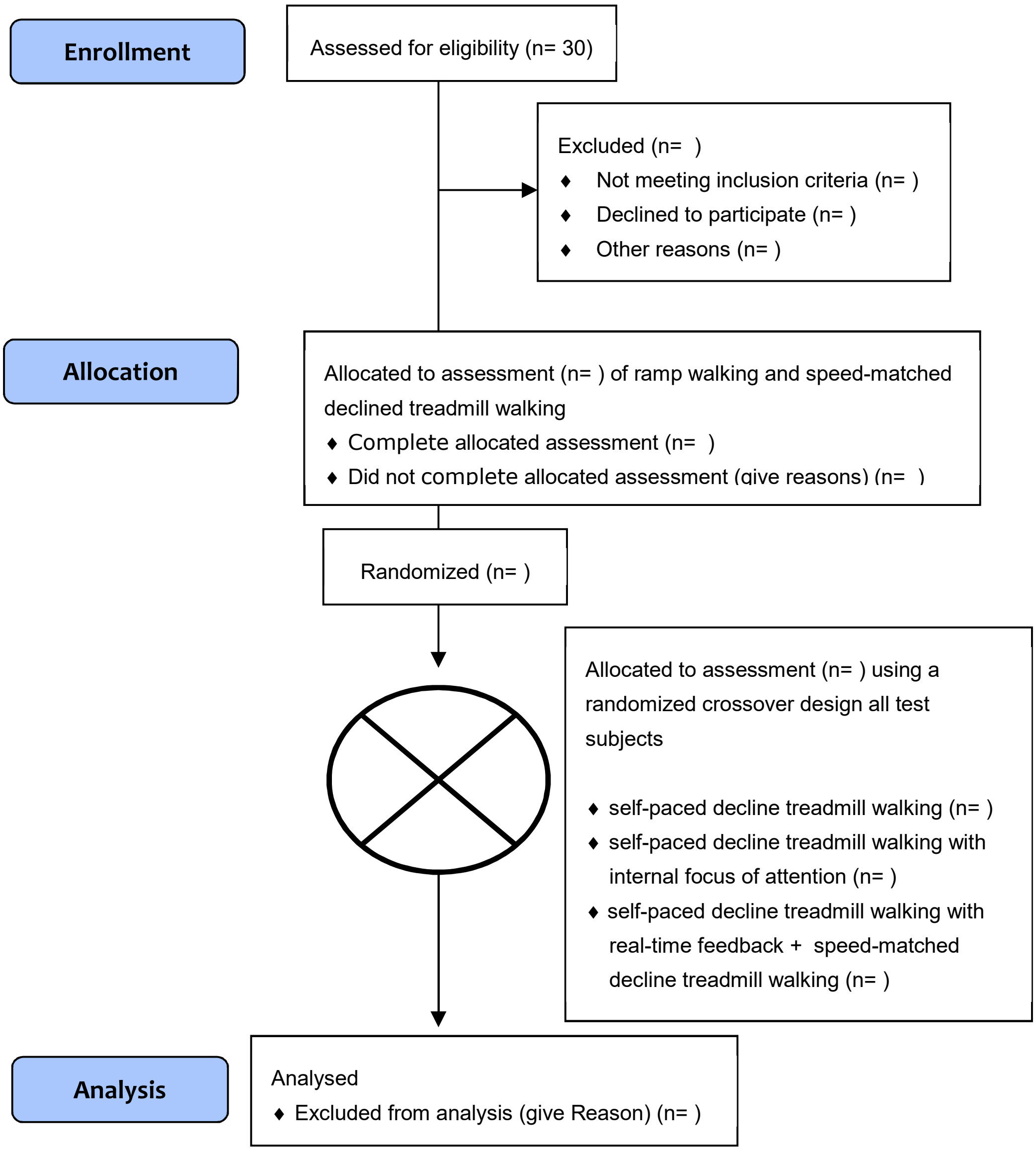

Figure: Flow diagram of the progress through the phases of the trial[21]

Sample size estimation and study population

As knowledge and studies concerning the effect of real-time feedback during decline walking is missing, sample size calculation based on proven effects is not applicable. Therefore sample size was arbitrary estimated with 25 based on the number of participants included in topic-specific studies, ranging from 14 to 40[15,22-24]. Taking into account a drop out of 20% we will recruit 30 participants.

Those healthy participants will be included, according to the following inclusion criteria: 1) age from 18-35 years, 2) body mass index from 18.5 to 29.99 kg/m², 3) no chronical joint diseases and/or OA surgery, and 4) no neuro-motor diseases. Participants will be excluded from the analysis in case of 1) non-physiological and non-symmetrical gait patterns, and 2) severe outliers (more than two standard deviations).

Recruitment, informed consent and randomization

Students and staff of the FH Campus Wien – University of Applied Sciences will be addressed with the study information via in-house corridor monitors and an email newsletter. If interested, they may contact the primary investigator. A research team member will check eligibility and provide study details. An assessment date will be agreed in case of willingness and eligibility of the potential participant. Written informed consent will be obtained from the participants prior to the assessments. The participants will randomly be assigned to one of the three sequences, by means of a prepared sequence list as derived from a random sequence generator online tool. Due to the nature of the studied conditions, it will neither be possible to conceal the allocation, nor to blind participants or researchers. A participant will pass through all assessments within one day. Shopping vouchers of 30 € will be offered as incentive for participation.

Safety considerations and participant insurance

No adverse event are to be expect. The participants will be instructed by the principal investigator on treadmill walking and the safety system. The safety system will consist of a safety harness that will be attached to a suspension system, two handrails, light gates at the front and back of the belt and an emergency button at the operating desk. The participants will have five minutes of familiarization with the treadmill operated with matched walking speed from the level walking trials. All participants will be insured by a clinical trial insurance.

Examination Procedures

At first, height will be measured with a stadiometer to the nearest 0.5 cm (SECA 213), and weight with a medical scale (Marsden M-420). Furthermore, joint range of motion and functional hamstring flexibility will be assessed. Thereafter, all participants will be equipped with 43 retroreflective markers on bony landmarks and 16 markers on four rigid clusters on thighs and shanks. Five level walking trials will captured to evaluate if gait pattern is physiological or not. Participants will have to walk on a five-meter ramp with 10° inclination which is equipped with 24 infrared cameras (Vicon, Oxford, United Kingdom) and two force plates (Kistler, Winterthur, Switzerland). After seven left and seven right foot strikes on the force plates for up and down walking each, the participants will be guided to the Gait Real-time Analysis Interactive Lab (GRAIL, Motekforce Link, Amsterdam, Netherlands), which is located next door. The GRAIL is a dual-belt treadmill equipped with two force plates, a 180° virtual reality screen and a motion capturing system with ten infrared cameras. After the familiarization phase on the treadmill with an inclination of 10° and with matched speed of incline walking, three times a period of 20 seconds will be recorded within 3 minutes. The investigator will explain the self-paced mode of the treadmill to the participant afterwards. The self-paced mode will adapt the belt speed automatically based on the position of the participant on the treadmill. Following a familiarization phase, data will be recorded as before.

This procedure will be repeated on the treadmill with a declination of 10°. Thereafter, the three following tasks will be performed in the order as specified in the sequence list.

Self-paced decline walking

The participants will be instructed to walk on the declined treadmill with self-selected speed. They will complete a five-minute familiarization period and a three-minute measurement period. Within the measurement phases, three times a period of 20 seconds of self-paced walking will be recorded.

Self-paced decline walking with internal focus of attention

The participants will be instructed to walk on the declined treadmill with self-selected speed. During walking, they will have to concentrate on an internal focus of attention, as keeping their spine as long towards the ceiling as possible. The participants will complete a five-minute familiarization period and a three-minute measurement period. In the measurement phase, three times a period of 20 seconds of self-paced walking

Self-paced decline walking with real-time feedback, followed by speed-matched decline walking

The participants will be instructed to walk on the declined treadmill with self-selected speed. During walking, they will have to concentrate on specific real-time feedback presented on the projection screen. This feedback visualization will represent the simplified frontal knee alignment movement using the participants knee position in relation to the ankle. The participants will complete a five-minute familiarization period and a three-minute measurement period. In the measurement phases, three times a period of 20 seconds of self-paced walking will be recorded. After this task, a control trial will take place with matched speed and without any feedback instruction.

Ethical and data protection aspects

This study will be submitted to the ethics committee of the Medical University of Vienna. With respect to participating students, there is a teacher-student relationship between researcher and participants. Besides general ethical principles, i.e. voluntary participation, data protection and confidentiality, provision of contact details of the research team, it will be emphasized in the course of obtaining informed consent, that refusing or withdrawing consent will not have any consequences on the remaining academic education. Participants will be assigned a continuous study code (UD01 – UD30) to protect identifiable data. The assignment key will be locked in the study manager office, separate from identifiable study data.

Outcome parameters

Height, bodyweight and inter-anterior superior iliac spine distance will be measured at the beginning of all sessions. Furthermore, flexibility of hamstrings and triceps surae will be assessed clinically. The primary outcome of this study is the frontal knee range of motion during the stance phase. Stance phase will be defined between heel-strike and toe-off of the observed leg. A second focus is on the ground reaction force loading ratio. Thirdly, the kinematics for the sagittal, frontal and transversal plane for hip, knee and ankle and the external moments for the sagittal and frontal plane for hip, knee and ankle will be assessed as well as step time, step length, step width, cadence and walking speed (table 1).

Area	Outcome Measure
Kinematic	3 planes of hip angle range of motion (°)
	Minimum sagittal hip angle (°)
	Maximum sagittal hip angle (°)
	3 planes of knee angle range of motion (°)
	Minimum sagittal knee angle (°)
	Maximum sagittal knee angle (°)
	Sagittal ankle angle range of motion(°)
	Minimum sagittal ankle angle(°)
	Maximum sagittal ankle angle(°)
	3 planes of pelvis angle range of motion (°)
	3 planes of trunk angle range of motion (°)
	Minimum sagittal trunk angle (°)
	Minimum sagittal trunk angle (°)
Kinetics	First peak load (N)
	Moment of first peak load (%)
	Average loading rate (N s-1)
	Maximum loading rate (N sec-1)
	Knee joint forces (N/kg)
	3 planes of minimum of hip external moments (Nm/kg)
	3 planes of maximum of hip external moments (Nm/kg)
	3 planes of minimum of knee external moments (Nm/kg)
	3 planes of maximum of knee external moments (Nm/kg)
	Minimum of sagittal ankle external moment (Nm/kg)
	Maximum of sagittal ankle external moment (Nm/kg)

Area	Outcome Measure
	Frontal knee abduction moment impulse (Nm/kg s)
	Frontal knee adduction moment impulse (Nm/kg s)
Spatio-temporal parameters	Walking velocity (m sec^{-1})
	Cadence (steps min^{-1})
	Step length (m)
	Step width (m)
	Stance phase duration (% gait cycle)
	Swing phase duration (% gait cycle)

Table 1: List of tertiary outcome parameters

Kinematic data will be time normalized from heel strike to heel strike, kinetic data from heel strike to toe-off. Individual participant data will expressed as average per condition. Time normalization, data processing and parameter calculations will be done with self-developed scripts in MATLAB 2018a (The Mathworks, Natrick, MA, USA).

Statistical analysis

All metric parameters will be analyzed with SPSS 26 (IBM Corporation, Armonk, NY, USA). Data will be tested for normality using the Shapiro-Wilk Test, and graphical inspections of Q-Q-plots. Differences between ramp-walking and matched speed / self-paced walking on the inclined / declined treadmill will be analyzed using paired two-tailed t-test and tested for agreement using ICC [3.1, absolute agreement, single measures] with SEM of the ICC. To evaluate differences between the four conditions (decline walking, internal focus of attention, real-time feedback, and matched speed walking), a one-factorial analysis of variance with repeated measures will be used. Contrasts will be employed to test aforementioned pre-specified hypotheses. In view of the legitimation given with the hypothesis, two-sided testing will be applied. One-dimensional statistical parameter mapping (1dSPM)[25] will be used to examine the steady parameters of the gait analysis. All other statistical tests than those related to the primary and secondary hypotheses are considered exploratory and statistical testing will be limited to tests as pre-specified by the hypotheses. Consequently. Bonferroni-Holm method will be used in terms of correcting for multiple testing. Alpha will be set to 0.05; exact p-values will be reported though.

Dissemination of results and publication policy

A manuscript will be submitted to a journal with peer review process (e.g. Gait & Posture) aiming for an open access publication. Coded raw data will be made available upon request and for non-commercial purposes after publication of the results.

Timeline of the project

Nov 2020	Submission to the local ethical committee (Medical University of Vienna)
Dec 2020	Ethical approval obtained
Jan 2021	Recruitment
Jan – Apr 2021	Field work
Mar – May 2021	Data analysis
May – June 2021	Finalization of manuscripts

Limitations and problems anticipated

The condition speed-matched walking cannot be included into the randomization procedure. Due to the nature of the studied conditions, it will neither be possible to conceal the allocation, nor to blind participants or researchers. Another limitation is that different force plates are used for ramp-walking and treadmill walking, as well as the continuous quality of declined treadmill force plate data cannot be guaranteed. Thereby a small systematic error can maybe affect the kinetic outcome. Findings of this study will apply only to healthy young adults.

Conflict of interest and funding information

The study team has no financial or academic conflict of interest to declare. No external funding will be requested.

References

1. Hunter DJ, Bierma-Zeinstra S. Osteoarthritis. *Lancet.* 2019;393(10182):1745-1759.
2. Fransen M, McConnell S. Exercise for osteoarthritis of the knee. *Cochrane Database Syst Rev.* 2008(4):CD004376.
3. Vina ER, Kwoh CK. Epidemiology of osteoarthritis: literature update. *Curr Opin Rheumatol.* 2018;30(2):160-167.
4. Silder A, Besier T, Delp SL. Predicting the metabolic cost of incline walking from muscle activity and walking mechanics. *J Biomech.* 2012;45(10):1842-1849.
5. Pacifico D, Visscher R, List R, Item-Glatthorn JF, Casartelli NC, Maffiuletti NA. Discriminant validity and reproducibility of spatiotemporal and kinetic parameters during treadmill walking in patients with knee osteoarthritis. *Gait Posture.* 2020;80:77-79.
6. Lay AN, Hass CJ, Gregor RJ. The effects of sloped surfaces on locomotion: a kinematic and kinetic analysis. *J Biomech.* 2006;39(9):1621-1628.
7. Schwameder H, Lindenhofer E, Muller E. Effect of walking speed on lower extremity joint loading in graded ramp walking. *Sports Biomech.* 2005;4(2):227-243.
8. Kuster M, Sakurai S, Wood GA. Kinematic and kinetic comparison of downhill and level walking. *Clin Biomech (Bristol, Avon).* 1995;10(2):79-84.
9. Alexander N, Schwameder H. Lower limb joint forces during walking on the level and slopes at different inclinations. *Gait Posture.* 2016;45:137-142.
10. Farrokhi S, Voycheck CA, Gustafson JA, Fitzgerald GK, Tashman S. Knee joint contact mechanics during downhill gait and its relationship with varus/valgus motion and muscle strength in patients with knee osteoarthritis. *Knee.* 2016;23(1):49-56.
11. Paterson KL, Sosdian L, Hinman RS, et al. The influence of sex and obesity on gait biomechanics in people with severe knee osteoarthritis scheduled for arthroplasty. *Clin Biomech (Bristol, Avon).* 2017;49:72-77.
12. Sosdian L, Hinman RS, Wrigley TV, et al. Quantifying varus and valgus thrust in individuals with severe knee osteoarthritis. *Clin Biomech (Bristol, Avon).* 2016;39:44-51.
13. Ageberg E, Roos EM. Neuromuscular Exercise as Treatment of Degenerative Knee Disease. *Exercise and Sport Sciences Reviews.* 2015;43(1).
14. Richards R, van der Esch M, van den Noort JC, Harlaar J. The learning process of gait retraining using real-time feedback in patients with medial knee osteoarthritis. *Gait Posture.* 2018;62:1-6.
15. Luc-Harkey BA, Franz JR, Blackburn JT, Padua DA, Hackney AC, Pietrosimone B. Real-time biofeedback can increase and decrease vertical ground reaction force, knee flexion excursion, and knee extension moment during walking in individuals with anterior cruciate ligament reconstruction. *J Biomech.* 2018;76:94-102.
16. Tate JJ, Milner CE. Real-time kinematic, temporospatial, and kinetic biofeedback during gait retraining in patients: a systematic review. *Phys Ther.* 2010;90(8):1123-1134.
17. Strutzenberger G, Alexander N, Bamboschek D, Claas E, Langhof H, Schwameder H. Uphill walking: Biomechanical demand on the lower extremities of obese adolescents. *Gait Posture.* 2017;54:20-26.
18. Telhan G, Franz JR, Dicharry J, Wilder RP, Riley PO, Kerrigan DC. Lower limb joint kinetics during moderately sloped running. *J Athl Train.* 2010;45(1):16-21.
19. Dewolf AH, Ivanenko YP, Lacquaniti F, Willems PA. Pendular energy transduction within the step during human walking on slopes at different speeds. *PLoS One.* 2017;12(10):e0186963.
20. Williams E. Experimental Designs Balanced for the Estimation of Residual Effects of Treatments. *Australian Journal of Chemistry.* 1949;2(2):149-168.
21. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ (Clinical research ed).* 2010;340:c332-c332.
22. Richards RE, van den Noort JC, van der Esch M, Booij MJ, Harlaar J. Effect of real-time biofeedback on peak knee adduction moment in patients with medial knee osteoarthritis: Is direct feedback effective? *Clinical Biomechanics.* 2018.

23. Hunt MA, Takacs J, Hart K, Massong E, Fuchko K, Biegler J. Comparison of mirror, raw video, and real-time visual biofeedback for training toe-out gait in individuals with knee osteoarthritis. *Arch Phys Med Rehabil.* 2014;95(10):1912-1917.
24. Agopyan H, Griffet J, Poirier T, Bredin J. Modification of knee flexion during walking with use of a real-time personalized avatar. *Heliyon.* 2019;5(11):e02797.
25. Pataky TC, Robinson MA, Vanrenterghem J. Region-of-interest analyses of one-dimensional biomechanical trajectories: bridging 0D and 1D theory, augmenting statistical power. *PeerJ.* 2016;4:e2652.