WalkWell Gait reTrainer: Remote patient monitoring and gait retraining for knee OA

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Our objective is to design and evaluate proof-of-concept of the WalkWell Gait reTrainer, an affordable, user-friendly continuous gait feedback system, complete with remote patient monitoring capabilities to support clinical care. We hypothesize that...

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57285

Source
ToetsingOnline

Brief title
WalkWell Gait reTrainer

Condition

- Joint disorders

Synonym
degenerative joint disease, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Erasmus MC LSH TKI

Intervention

Keyword: Foot progression angle, Gait retraining, Remote monitoring

Outcome measures

Primary outcome

Qualitative data from participants and physiotherapists on how they use the WalkWell Gait reTrainer (i.e. user experience). We will also explore the participant*s ability to consistently alter their FPA in response to the feedback given by the WallWell Gait reTrainer, and their ability to maintain their target FPA over a short period of one week (i.e. feasibility).

Secondary outcome

Quantify correlations among the data collected and evaluate the associations between biomechanical parameters and other variables including participant demographics.

Study description

Background summary

Osteoarthritis (OA) is a leading cause of disability and source of societal cost. OA is a complex, chronic disease predominantly caused by increased mechanical load on joint cartilage. Gait retraining has been shown to modify mechanical load in knee OA patients, with real-time feedback to assist patients with optimizing gait patterns. Altering the foot progression angle (FPA), i.e., toe in or toe out, is relatively easy and reduces knee loading. Gait feedback typically requires practice sessions in a lab using expensive equipment. However, continuous feedback in one*s natural environment could yield more effective and sustainable gait adaptations. With remote monitoring, clinicians can monitor patient performance between treatment sessions.

Study objective

Our objective is to design and evaluate proof-of-concept of the WalkWell Gait

reTrainer, an affordable, user-friendly continuous gait feedback system, complete with remote patient monitoring capabilities to support clinical care. We hypothesize that this system is usable in a community and home setting, and permits clinicians to remotely monitor progress, to yield efficient and effective gait adaptations. The data collected in this study will be pivotal in planning future large-scale intervention trials to assess the system's efficacy.

Study design

We will evaluate the feasibility and user experience of the WalkWell Gait reTrainer to provide feedback on the FPA in healthy volunteers; and a 1-week follow-up to investigate the feasibility and user experience of remote monitoring.

Study burden and risks

Participants will attend a visit to the lab involving biomechanical assessment, performing walking with different FPAs. Participants will rate the comfort of each walking pattern. Total time for data collection will be approximately 2-3 hours in the lab. Afterwards, during a 1-week follow-up period, we will evaluate their experience with using the device at home during daily walks, using questionnaires and interviews.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy controls:
over 45 years old
able to walk for at least 15 to 30 minutes for 3 to 7 days per week without any walking aids

Physiotherapists:
work for at least two years as a physiotherapist in primary care
provide treatment for patients with knee complaints two or more times per week
have affinity with technical developments in physiotherapy care

Exclusion criteria

Healthy controls:
Activity-related knee pain and morning knee stiffness or stiffness of 30 minutes or more.
Traumatic knee injury or surgery in the past year.
Any neurological, rheumatological, or metabolic disorders affecting mobility.
Other diagnosed causes of knee symptoms (e.g. tendonopathy).
Musculoskeletal conditions affecting the ankles, hips, pelvis or lumbar spine.
Body mass index > 35 kg/m2.
Cognitive impairments.
Unable to communicate in either Dutch or English

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2025
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	03-02-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87301.078.24