Cue2Walk, cost-effectiveness of automated freezing detection and provision of external cues in comparison to usual care in people with Parkinson*s disease

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The aim of this study is to determine whether the at-home use of Cue2Walk medical device in people with PD who experience FoG, is (cost-)effective as compared to usual care.

Ethical review	Approved WMO
Status	Pending
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON57004

Source
ToetsingOnline

Brief title
Cue2Walk_costeffectiveness

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: (Cost-)effectiveness, Cueing, Freezing of gait, Parkinson□s disease

Outcome measures

Primary outcome

Primary outcomes to measure the effects of the intervention will be the disease-specific self-reported Quality of Life (Parkinson*s Disease Questionnaire, PDQ-39) and Time in Freezing of Gait (i.e. frequency and duration of FoG episodes; measured by the Cue2Walk device).

The economic evaluation will be performed for general health-related quality of life (EuroQol 5 Dimensions 5 Level Survey; EQ-5D-5L) and Quality Adjusted Life Year (QALY). It will include a cost-effectiveness analysis and a Budget Impact Analysis. The cost-effectiveness as compared to usual care will be assessed from both a healthcare and a societal perspective.

Secondary outcome

Secondary outcomes will be Falls Efficacy (balance confidence, Falls Efficacy Scale), numbers of falls (measured by weekly diary and telephone/app contact), Freezing of Gait severity (measured by the New Freezing of Gait Questionnaire and the Patient Reported Outcomes for Freezing of Gait), independence in ADL (Nottingham Extended ADL index), daily mobility (Cue2Walk step count score), mood (Hospital Anxiety and Depression Scale), Gait-Specific Attentional Profile, Acceptance of Illness (Chronic Illness Acceptance Questionnaire),

Caregiver Burden (Zarit's Burden Interview Short Form). We will also use patient reported experience measures to quantify Patient Experiences regarding the care they receive during the intervention phase and we will record user experiences.

Study description

Background summary

Freezing of gait (FoG) is one of the most common and disabling motor symptoms of Parkinson*s disease (PD). It is characterized by the sudden, transient, and involuntary inability to produce ongoing forward locomotion. It is a highly debilitating symptom of PD, a risk factor for cognitive decline, leads to impaired mobility, daily functioning, gait instability, to fall-related injuries and associated medical costs and severely affects quality of life (QoL). Approximately 50-75% of the total worldwide population of people with PD incur FoG. In the Netherlands this amounts to about 37000 people.

Currently, rehabilitation therapy is the treatment of choice for people with FoG as it responds only moderately to medication or other forms of treatment, such as deep brain stimulation. A number of studies have shown that FoG is significantly associated with poorer QoL in PD, which supports the need for innovative rehabilitation strategies. External cueing is a proven strategy to overcome FoG episodes and an essential part in the management of FoG, in combination with other forms of compensation strategies. Typically, a standard metronome is used that patients need to activate themselves after FoG occurs. However, this is often too late to adequately address sudden FoG, the metronome requires continuous handling by the user and thus has limited effectiveness. In addition, lack of initiative and apathy are common symptoms in PD, compounding the problem of self-administration of cueing methods.

A literature review of literature up to August 2020 found that training aimed at reducing FoG episodes or ameliorating the underlying correlates of FoG was moderately effective compared to usual care, while generic exercises were not. Relevantly, no retention effects were seen after cessation of training. This review thereby supports the implementation of targeted training and medical devices as a treatment for FoG with the need for long-term engagement. The Cue2Walk approach explicitly addresses the above mentioned problems and needs.

The Cue2Walk, a Medical Device Class I CE-certified leg-worn device, addresses the debilitating effects of FoG episodes at home with *smart cueing* by

combining automatic detection of a freezing episode with manual or automatic rhythmic cues (auditory or vibro-tactile) to improve QoL. It may significantly reduce the need for frequent visits to the physical therapist. The organization of care changes from supervised training trajectory to a coaching trajectory in which the therapist monitors the rehabilitation process at longer intervals. The patient independently uses the device to enhance mobility and therefore the Cue2Walk promotes self-management in the own home environment, ultimately leading to a more satisfying life with enhanced QoL.

Results from a pilot study among 16 users of the Cue2Walk are promising, with reduced severity of FoG, increased self-reported general health status and no experienced detrimental effects. Therefore we hypothesize that the use of the Cue2Walk medical device in rehabilitation therapy for PD patients with FoG will result in an improved QoL as compared to usual care, as well as reduced health care costs and a reduction in Time in Freezing of Gait. Expected secondary outcomes are amongst others: reduced fall events, improved Falls Efficacy, improved Activities of Daily Living, better mobility, better mood and reduced caregiver burden as compared to usual care.

Study objective

The aim of this study is to determine whether the at-home use of Cue2Walk medical device in people with PD who experience FoG, is (cost-)effective as compared to usual care.

Study design

We will conduct an observer-blinded, multicenter randomized clinical trial with 2 parallel groups. The intervention group (Group 1) will receive a 24-week intervention and the control group (Group 2) will be placed on a waiting list for 24 weeks. After these 24 weeks, an 8-week naturalistic follow-up will be implemented for participants in Group 1, while participants in Group 2 will receive the same intervention as Group 1, but for 8 weeks.

Intervention

The intervention is 24 weeks in duration. In the first week, the participants in Group 1 will be instructed on general therapy goals as well as on use and handling of the device, and how to adequately respond to the cueing signals that the device generates. The Cue2Walk is worn during the waking hours and only provides a cueing signal when needed, i.e., when freezing of gait has been detected. The participant immediately starts using the device. Therefore, the participants use the wearable device in their own living environment during the entire 24-week period. Participants can contact Cue2Walk using mail or chat via a secure portal on the project website for additional instruction or clarification. Technical support can be given remotely via the secure Cue2Walk

Int. support portal. Usage of this e-health component will be encouraged and monitored. All other medical care will continue as usual.

Participants allocated to Group 2 will be placed on a waiting list for 24 weeks, during which they will receive usual care.

After these 24 weeks, an 8-week naturalistic follow-up will be implemented for participants in Group 1, while participants in Group 2 will receive the same intervention as Group 1, but for 8 weeks.

Study burden and risks

Participants may benefit from this study as the Cue2Walk device is aimed at reducing the severity of FoG, which is associated with increased QoL. Pilot data among 16 users of the device showed that none of the users had experienced any detrimental effects. Participants will continue receiving usual medical care, so no risks are expected.
Screening will take place at Amsterdam UMC, location VUmc, at Radboudumc or at the home of the participant. The Cue2Walk is worn during the waking hours and only provides a cueing signal when needed, i.e., when freezing of gait has been detected. The 24-week intervention will be performed in the own living environment.
Participants will be asked to fill out various questionnaires at home at various time points throughout the study.

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

1. Diagnosis of Parkinson's disease according to UK Brain bank criteria
2. Daily Freezing of Gait
3. Hoehn-Yahr stage 2-4
4. Stable medication regime and/or DBS settings
5. Ability to walk 5 min while unassisted by another person

Exclusion criteria

1. Participation in another clinical study
2. Use of a personal cueing device at home
3. Previous use of the Cue2Walk medical device
4. Presence of co-morbidities that would hamper participation
5. Cognitive impairment preventing understanding of therapeutic instructions (MoCa Score <16)

Contraindications for the use of the device:
1. An allergy to one of the materials that the device or strap is made of
2. A significantly abnormal gait pattern
3. Absence of sensitivity to both cueing signals (auditory and vibro-tactile)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	84
Type:	Anticipated

Medical products/devices used

Generic name:	Cue2Walk
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-09-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT06416345

Register	ID
CCMO	NL86310.018.24