Frailty screening using gait analysis and physical activity

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57195

Source
ToetsingOnline

Brief title
FSGAIT

Condition

- Other condition

Synonym
vulnerability - fragility

Health condition

Frailty screening op basis van fysieke activiteit

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Accelerometry, Frailty, Gait Analysis, Physical activity, Screening

Outcome measures

Primary outcome

The primary endpoint is the classification accuracy, sensitivity, and specificity of frailty obtained by different machine learning methods. Different models will be generated based on gait variables collected by wearables sensors during daily life.

Secondary outcome

The secondary endpoint is the comparison of classification models of gait variables collected by wearables sensors with the standard clinical assessments.

Study description

Background summary

Frailty, an age-related clinical syndrome, is closely related to adverse outcomes such as disability and incapacitation. Early intervention can delay or reverse deterioration progress. Therefore, early screening and assessment could be greatly beneficial. Many measurement instruments are available to evaluate frailty by examining different aspects of it. However, most of these instruments only evaluate frailty during clinical visits or in a controlled laboratory environment where physical tests are performed. Examining frailty in the context of daily life functioning may better reflect real capacity and function. Walking ability has been reported to be closely linked to frailty. However, there are few studies that address gait in daily life and examine the association with frailty. Examining walking during daily life could provide a

screening for the presence of frailty and be used for early diagnosis of frailty. This could support subsequent personalized guided interventions

Study objective

This study aims to examine the classification accuracy of screening older people with and without frailty based on physical activity and gait analysis in their daily life environment. A classification model will be created based on physical activity patterns, gait outcomes, clinical assessment methods, and a combination of both. The classification performance will be validated using Area Under the Curve, and the accuracy, sensitivity, and specificity will be calculated of the models.

Study design

Observational study.

Study burden and risks

All assessments are non-invasive and will be performed according to established guidelines. Assessment instruments are part of care-as-usual. All assessments will be done during the first home visit . For (pre)frail older participants from the outpatient those not yet been assessed during clinical consultation will be completed. The sensor is lightweight and will be attached to the thigh with special skin-sensitive tape. There is no need for charging or removing the device. Participants can perform all their usual activities. Therefore, we consider the risks of the current study negligible, and the burden for the participants minimal. This approach could enable early screening of frailty and support personalized, guided interventions. It aligns with current trends in care that emphasize the importance of providing assessments and support in one's own environment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- Be able to walk independently without or with a walking aid other than a walker, for at least 3 minutes continuously inside and/or outside.
- Capacity to consent
- Evaluated as being frail or pre-frail or frail by the clinical assessment
[for frail/prefrail group]

Exclusion criteria

- A history of central neurological problems (e.g., cerebral vascular accident, acquired brain damage, or Parkinson*s Disease).
- The participant is terminally ill (i.e., life expectancy < 3 months according to the attending physician).
physician).

Inability to communicate (e.g., severe hearing, vision and language judged by clinicians).
- Severe cognitive impairment defined by MMSE (0-17) or indicated by clinical diagnosis.
non-frail particpiants:
One or more of the Fried criteria: weakness; self-reported exhaustion; slow walking speed; and low physical activity.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2024
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	26-02-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL84887.042.23