Physiotherapist Overseen Whole-body Exercises for Residents with Dementia: a non-randomized pilot study

Published: 05-03-2025
Last updated: 02-05-2025

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57434

Source
ToetsingOnline

Brief title
(POWER-D)

Condition

- Other condition

Synonym
Adherence, experiences

Health condition

Therapietrouw, mogelijke nadelige effecten, ervaringen, spierkracht, evenwicht, loopsnelheid, mobiliteit, zelfstandigheid in dagelijkse zorgtaken, psychiatrische gedragsproblemen bij dementie

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Geen

Intervention

Keyword: Dementia, Exercise, Long-term care, Rehabilitation

Outcome measures

Primary outcome

Primary study parameters that will be evaluated at the end of the intervention (13 weeks): Adherence to the intervention regarding successfully followed exercise sessions in relation to total available sessions; adverse events related to the intervention; the experiences of participants and exercise conductors.

Secondary outcome

Secondary study parameters: the effects on physical performance (strength, static balance, walking speed, mobility) assessed with the Short Physical Performance Battery and the Timed Up and Go, ADL independence with the Functional Independence Measure, and neuropsychiatric symptoms of dementia assesses with the Neuropsychiatric Inventory-Nursing Hom

Study description

Background summary

Physiotherapy is frequently employed in the treatment of nursing home residents with dementia. However, studies adhering to exercise guidelines, incorporating sufficient strength, balance and endurance exercises, have not yet been

conducted in this population.

Study objective

To assess the adherence to the intervention regarding successfully followed exercise sessions, adverse events related to the intervention and experiences of intervention supervisors and participants. Secondly, we will evaluate intervention effects on physical performance (leg strength, static balance, walking speed), independence in daily activities (ADL), and neuropsychiatric symptoms of dementia.

Study design

single-arm experimental pilot study.

Intervention

two times per week 45 minutes group exercise with strength and balance exercises, two times per week 20 minutes aerobic stationary cycling on self-selected resistance

Study burden and risks

Participants will undergo four physical tests (Short Physical Performance Battery consisting of a sit-to-stand test, balance test, and walking speed test; and the timed up an go test) that are part of a normal physical assessment by a physiotherapist. Tests will be conducted twice (start and end of the study). The other parameters can be assessed without burdening the participant. There are no expected risks by participating in 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

- By a physician documented diagnosis of dementia in the patient file. In the Nether-lands, the diagnosis of dementia is usually made before admission to the nursing home. The primary physician or a geriatric specialist can make the diagnosis, and there is no legislation according to what criteria the diagnosis can be made.
- Able to walk 50 meters without the help of a person (walking aids are allowed).
- Informed consent by the family/informal caregiver in charge.
- No expected resistance to the intervention, as perceived by the physician in charge.

Exclusion criteria

- Behavioural problems that interfere with participation in a group intervention, according to the physician in charge and/or the psychologist in charge.
- Other factors listed by the physician in charge that could make it unfavourable for the resident to take part in the study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-03-2025
Enrollment:	36
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-03-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL87232.058.24