Nutrition and physical activity for frail clients with cognitive impairment

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON49643

Source
ToetsingOnline

Brief title
Goed Gevoed in Beweging bij Opella

Condition

- Muscle disorders

Synonym
fitness, physcial performance

Research involving
Human

Sponsors and support

Primary sponsor: Opella
Source(s) of monetary or material Support: St. Alliantie Voeding in de Zorg

Intervention

Keyword: cognitive impairment, nutrition, older adults, physical activity

Outcome measures

Primary outcome

Change in physical performance as measured with the Short Physical Performance Battery (SPPB).

Secondary outcome

Nutritional status, delay or prevention of institutionalization, number of falls, and quality of life of frail older adults with cognitive impairment receiving home care.

Study description

Background summary

A deteriorating nutritional status and physical performance in frail older adults with cognitive impairment is associated with an increased risk of institutionalization. This is also observed in practice by Opella: a significant part of the frail older adults with cognitive impairment/dementia is malnourished or at high risk of malnutrition when admitted to a nursing home. Therefore, Opella * as partner of the *Alliantie Voeding in de Zorg* * wants to offer a subgroup of the pilot-clients in the DOW pilot study an additional intervention aimed at optimizing their nutritional status and physical performance.

Study objective

The aim of this Eat well, Move well intervention is to study the effect (in addition to DOW) on physical performance, nutritional status, delaying or preventing institutionalization, number of falls, and quality of life of frail older adults with cognitive impairment receiving home care.

Study design

A controlled, non-randomized intervention study, with two parallel, independent

groups in which each subject will be followed for the duration of one year.
- The intervention group consists of clients receiving care according to DOW and the additional Eat well, Move well intervention.
- One control group consists of clients receiving care according to DOW without the additional intervention.

Intervention

The Eat well, Move Well intervention consists of a nutritional and a physical activity component. Every subject in the intervention group receives a nutritional and physical activity plan and advice that is tailored to their personal situation and possibilities.

Study burden and risks

There are no risks of participating in the intervention, and the measurements will be conducted following a standardized protocol with safety measures in place. This is a group-related study: participation of clients with cognitive impairment is important and relevant, as people with cognitive impairment are at higher risk for malnutrition, physical decline, falling, and institutionalization. Therefore, the proposed study should be conducted within the group it concerns and who may eventually benefit from new evidence-based practice.

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

- multiple health domain problems including cognitive impairment
- willing to participate and signed informed consent

Exclusion criteria

- life expectancy <12 months
- on a waiting list for nursing home placement
- client has a legally incapacitated statement or the GP judges that, based on the 4 criteria of Appelbaum and Grisso a client does not have the decisional capacity to consent/refuse participation
- extreme physical or cognitive impairments making participation impossible, as judged by the GP and/or Opella care professional and/or client and/or informal caregiver.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	20-09-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL66497.081.18