Eat well, Move well (Goed Gevoed in Beweging)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23522

Source
Nationaal Trial Register

Brief title
GGiB

Health condition

mental and physical impairment

Sponsors and support

Primary sponsor: Opella, Stichting Alliantie Voeding in de Zorg
Source(s) of monetary or material Support: Opella, Stichting Alliantie Voeding in de Zorg, Wageningen University & Research

Intervention

Outcome measures

Primary outcome

Physical Performance as measured with the Short Physical Performance Battery (SPPB)

Secondary outcome

- Other physical performance parameters:
o Physical Activity in minutes per day: measured with a pedometer during 5 consecutive days.
o Hand grip strength in kg: measured with hand dynamometer:
o Timed up and Go test (TUG)
o Number of falls in the past 12 months according to the registration of falls from Opella which is part of usual care in the Opella care registration system.

- Nutritional status and intake:
o Weight and height: taken from client's file.
o Dietary intake of energy, protein and fluid: assessed with 3 day food diary
o Risk of malnutrition: measured with SNAQ65+ (29), taken from client's file.
o Diet Quality: assessed with the 'Eetscore' questionnaire (30).

- Wait list for nursing home: yes/no as recorded in client's file.
- Quality of Life: measured with the SF-12 questionnaire (31)

Study description

Background summary

Rationale: 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 is malnourished or at high risk of malnutrition when admitted to a nursing home. In addition, Opella is currently implementing a new care system called "het Domein Overstijgend Werken" (DOW) in collaboration with the Dutch Government. As part of this larger implementation project Opella – as partner of the 'Alliantie Voeding in de Zorg' – wants to investigate if providing care according to the new care system (DOW) combined with an additional intervention aimed at optimizing nutritional status and physical performance (Eat well, Move well intervention) has positive effects on the health related outcomes of clients.

Objective: The aims are to investigate the effect of the Eat well, Move well intervention combined with DOW and DOW alone (without Eat well, Move well intervention) on physical performance, nutritional status, delaying or preventing institutionalization, number of falls, and quality of life of frail older adults with cognitive impairment.

Study design: A controlled, cluster-randomized intervention study, with three parallel, independent groups; one intervention and two control groups. Subjects will be followed for one year. Randomization will be done at the level of the Opella care teams (cluster). The intervention group consists of clients who receive care according to DOW combined with the Eat well, Move well intervention. One control group consists of clients who receive care according to DOW without the Eat well, Move well intervention. The second control group consists of clients who receive care as is usual in other parts of the Netherlands (DOW not yet implemented) and without the Eat well, Move well intervention.

Study population: Community-dwelling frail (problems in multiple health domains) clients with cognitive impairment receiving home care from Opella and living in Ede or Wageningen.

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.

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

Study objective

Care according to the new care system (DOW) combined with an additional intervention aimed at optimizing nutritional status and physical performance (Eat well, Move well intervention) has positive effects on health related outcomes of clients.

Study design

Baseline, 6 and 12 months

Contacts

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Eligibility criteria

Inclusion criteria

The inclusion criteria for the Eat well, move well intervention study are similar to the inclusion criteria set by Opella for the DOW pilot-study, these criteria are:
- Multiple health domain problems as diagnosed by the general practitioner (GP) with one of the following tools used in common general practice;

- ‘Transmuraal zorgassessment Geriatrie (TRAZAG)’ / Care assessment Geriatrics: answered ‘Yes’ to 3 or more domains of the start list
- Easycare: outcome frail (red) based on Trap 1 or Trap 2
- Groningen Frailty Index-score (GFI): 4 or higher
- Cognitive impairment based on the outcome of the Mini Mental State Examination (MMSE) (9) or the outcome of the Clock Drawing Test ‘Kloktekentest’ assessed less than a year ago by the GP or a medical specialist. Criteria for the MMSE-score are <24 and >17 points and for the Clock Drawing Test <3 points
- Willing to participate and signed informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Life expectancy <12 months (as judged by GP)
- On a waiting list for nursing home placement
- Client has not the capacity to participate because:
o The client has a legally incapacitated statement
OR
o The client has not the decisional capacity to consent or refuse to participating in the study based on the criteria: 1. Ability to communicate a choice about participating in the study; 2. Ability to understand the study information; 3. Ability to appreciate the study information and consequences of participation in relation to his/her own situation; 4. Ability to reason rationally about participating in the study.
- Unable to participate in study elements (intervention elements and/or measurements) 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)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-05-2019
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	30-07-2019
Application type:	First submission

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
NTR-new	NL7916
Other	METC-WU : 18/19

Study results