Moving through Levels of Care. Maintaining functioning during older adults' transition to the nursing home, a pilot study.

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

Summary

ID

NL-OMON51580

Source
ToetsingOnline

Brief title
Moving through Levels of Care. The pilot study

Condition

- Other condition
- Lifestyle issues

Synonym
physical activity in people with dementia

Health condition

Veroudering, dementie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Structurele financiering voor Academische Werkplaatsen Ouderenzorg van ZONMW

Intervention

Keyword: Dementia, Feasibility, Informal care giver, Suitability

Outcome measures

Primary outcome

1. Proportions of eligible, included, moved and dropped out participants

(quantitative endpoint); organizational barriers to recruitment (qualitative

endpoint);

2. a. The number of subsequent days needed to reliably assess physical activity;

b. Percentage and reason of data loss;

c. Interview with proxy / relative to assess feasibility for

themselves and participant;

3. Standard error of measurement (SEM), smallest detectable change (SDC) and

mimimal important change (MIC) of (life-space) mobility, physical activity

levels, and quality of life outcomes;

4. Means, average change and corresponding confidence intervals of the outcomes

are calculated to determine the study sample size of the

intended study.

Secondary outcome

The following outcome measures will be calculated from the Dutch translation of

the Life-Space Assessment

1. Content validity (the participants in this study will not be asked for this

purpose);

2. Construct validity (convergent and divergent) based on correlations with

other measured constructs collected during the pilot study;

3. SEM, SDC, MIC (see also point 3 for primary outcome measures).

Study description

Background summary

From cross-sectional studies it is known that the degree of physical activity among nursing home residents suffering dementia is lower than among their community-dwelling counterparts. It is still unknown when the changes in physical activity occur: before the transition to the nursing home (as a trigger) or after (as a consequence). It is also unclear to what extent the living environment, the deterioration in health status or other personal circumstances, and aspects of the transition procedure itself contribute to the changes in physical activity before, during and after the transition into nursing homes.
We aim to initiate a study to investigate the change in physical activity, mobility and living environment during the transition from home to a nursing home of older people who are about to move to a nursing home. Due to several uncertain factors concerning recruitment and data collection, a pilot study will first be conducted.

Study objective

The primary objectives of the pilot study are:
1. To determine a successful strategy for recruiting and following-up participants during their transition phase from home to a nursing home;
2. To determine the suitability of the study procedure;
3. To select feasible and suitable measurement instruments for the intended larger study;
4. To collect data for sample size calculation for the intended larger study.

Secondary objective is:
1. To collect data to validate the Dutch translation of the Life-Space

Assessment.

Study design

Observational pilot study.

Study burden and risks

There is no alternative setting available that is comparable to the transition to a nursing home, which will be the residents' last station, making this study group-related.
There are no direct benefits to participating in this study, but we intended to minimize the burden on participants by selecting only outcomes with proven low burden and high acceptance in people with dementia, all of relatively short duration (15 minutes for the physical assessment in total per visit; followed by wearing an accelerometer for the next 5 days); by involving family members / informal care givers (to fill in questionnaires, respectively (20 minutes at a time)); and by having all measurements/assessments taken at home. Risks in participating in this study are considered negligible due to the observational design. Indirect benefits can be the informal home visits in which time is taken for the participant and his or her family member/carer and participants can feel meaningful and heard.

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

- Diagnosed with any type of dementia and an indication for long-term care
- Community dwelling at the time of recruitment and inclusion;
- On the waiting list for nursing home placement or otherwise an expected transfer to a nursing home within six months (Long-term care);
- Presence of a relative or informal carer who is willing to participate in the study.

Exclusion criteria

- The subject has moved to a nursing (or residential care) home before the first assessment;
- The subject moves to a nursing home with an temporary indication / other indication than long-term care.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	08-06-2022
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	02-05-2022
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	NL80341.042.22