PhysioDom Home Dietary Intake Monitoring: telemonitoring of nutritional parameters and other outcomes in community dwelling elderly people receiving home care: a pilot study

Published: 25-06-2015
Last updated: 21-04-2024

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

Summary

ID

NL-OMON40816

Source
ToetsingOnline

Brief title
PhysioDom HDIM: pilot studie

Condition

- Other condition

Synonym
health, Undernutrition

Health condition

ondervoeding en gezondheid van (kwetsbare) ouderen in het algemeen.

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Home care, Older adults, Telemonitoring, Undernutrition

Outcome measures

Primary outcome

The main study parameters of the whole research project are:

- Change in SF36 score (quality of life)

- Change in MNA score (nutritional status)

Secondary outcome

The secondary objectives of this research project are listed below and are corresponding with the subsequent levels of outcomes as shown in the logic model in Figure 1.

On the participant level:

- To perform a process evaluation including the feasibility, acceptability and implementation fidelity of the PhysioDom HDIM intervention (including feasibility of telemonitoring of blood pressure) (outputs).

- To study the effects of the PhysioDom HDIM intervention on behavioural determinants of dietary intake and physical activity (initial objectives).

- To study the effects of the PhysioDom HDIM intervention on dietary intake and physical activity (intermediate objectives).

- To study the effects of the PhysioDom HDIM intervention on nutritional parameters (weight, appetite), physical functioning, and self-management (long term objectives).

- To study the cost effectiveness of the PhysioDom HDIM intervention (overall aim).

On the health care professional/organizational level:

- To perform a process evaluation among involved health care professionals and technicians including the usability, feasibility, acceptability and implementation fidelity of the Physiodom HDIM intervention (outputs, initial objectives, intermediate objectives).

Study description

Background summary

Governments and care organizations are increasingly turning towards the use of Ehealth to improve health or support health care. Studies have shown that Ehealth can contribute to improving health in patients with chronic diseases like CVD and diabetes. It is also known that (frail) elderly in general can benefit from Ehealth applications. With regard to healthy ageing, a good nutritional status is essential. However, the percentage of undernutrition among community dwelling elderly ranges from eleven to 35 percent, with the highest prevalence observed among elderly home care clients. Ehealth might contribute to maintaining or improving nutritional status in elderly people. However, there is no scientific base for this yet. In this research project, we will employ a telemonitoring system called *PhysioDom Home Dietary Intake Monitoring (HDIM)* to monitor nutritional and other parameters in community dwelling elderly receiving home care. The first step in this research project comprises pilot testing of this telemonitoring system.

Study objective

The objectives of this pilot study are to test the feasibility, acceptability

and implementation fidelity of the telemonitoring intervention; to test the study procedures for effect evaluation; and to determine the likelihood of achieving desired impact on the primary and secondary outcomes.

Study design

The pilot intervention study will have a duration of three months, employing a one group pre-test post-test design.

Intervention

The PhysioDom HDIM intervention consists of a telemonitoring system which will be employed by participants at home to perform self-measurements of weight, appetite, nutritional status, dietary intake (primary objective of telemonitoring), physical activity (secondary objective), and blood pressure (tertiary objective, optional for a selection of patients). Outcomes of self-measurements will be displayed on the participant*s TV and will be send to the district nurse. She will receive alerts when results go beyond a predefined threshold. The telemonitoring system will be embedded in usual care: when a district nurse receives an alert, she will provide follow-up according to the care procedures and protocols which apply to the care organization, which can include a care referral to another health care professional.

Study burden and risks

Participants will be visited twice to be interviewed about the effects of the intervention. Visits will take place at the participant*s home and will take around one hour. Measurements are not invasive; the burden of the measurements can be considered as minimal. The participant*s intervention activities includes a daily check of the participant*s personal TV channel (exception: Saturday and Sunday), weekly measurements of weight, monthly measurements of appetite, nutritional status and diet quality, wearing a pedometer for one week per month and monthly measurement of blood pressure (not for every participant). The risks associated with participation can be considered negligible, because of the nature of the intervention (monitoring) and the fact that this intervention is complementary to regular home care. Besides a financial reward, it is estimated that participants will benefit from the intervention. Through frequent monitoring of nutritional and other parameters there is an early detection of deterioration, followed by timely and tailored follow-up by the care organization.

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

In order to be eligible for participation in this study, individuals should be aged 65 or over, must live in the municipality of Nunspeet and must have a care referral for at least one of the following types of care:
-Domestic care
-Personal care
-Nursing care
-Individual or group support

Exclusion criteria

-Severe cognitive impairment (Mini Mental State Examination (MMSE) < 20)
-Receiving terminal care
-Expected length of receiving home care < 3 months
-Not having a television at home
-Clients with a visual impairment (in such a way, that they are not able to watch the

television screen)
-Clients with a physical impairment (in such a way, that they are not able to use the telemonitoring system)
-Clients with intramural care

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-08-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	25-06-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL50423.081.14

Study results

Date completed: 01-12-2015

Actual enrolment: 21

Summary results
Trial is onging in other countries