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

Published: 18-02-2016
Last updated: 19-04-2024

To study the effectiveness of the PhysioDom HDIM intervention in maintaining or improving nutritional status and quality of life. Furthermore, the effects on behavioural determinants, appetite, dietary intake, weight, physical activity, and physical...

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

Summary

ID

NL-OMON44887

Source
ToetsingOnline

Brief title
PhysioDom HDIM: effect study

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 effect study are:

- Change in MNA score (nutritional status) after six months of intervention.

- Change in SF36 score (quality of life) after six months of intervention

Secondary outcome

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

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), and physical functioning (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, which will take place in the summer of 2015. The second step is a large-scale effect study, taking place from January 2016. This research protocol comprises only the effect study.

Study objective

To study the effectiveness of the PhysioDom HDIM intervention in maintaining or improving nutritional status and quality of life. Furthermore, the effects on behavioural determinants, appetite, dietary intake, weight, physical activity,

and physical functioning are studied. Finally, a process evaluation and cost-effectiveness evaluation are carried out.

Study design

The effect study will have a duration of ninemonths, employing a quasi-experimental design with 3 (control group) to 4 (intervention group) effect measurements.

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 participants). 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 organizations, which can include a care referral to another health care professional. The participants in the control group receive usual care.

Study burden and risks

Participants will be visited three (control group) to four (intervention group) times for measurement of the study outcomes. Visits will take place at the participant*s home and will take between half an hour and two hours, depending on the questions and procedures included at the different measurement moments. Furthermore, participants are asked to fill out a paper questionnaire three (control group) to four (intervention group) times, which will take 20-60 minutes for each questionnaire. Measurements are not invasive; the burden of the measurements can be considered as minimal. The intervention activities include a weekly check of the PhysioDom HDIM TV channel, weekly measurements of weight, measurements of appetite, nutritional status and diet quality (once every three months), 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 coaching) and the fact that this intervention is complementary to regular home care. Besides a financial and/or material reward, it is estimated that participants will benefit from the intervention: through frequent monitoring of nutritional parameters there is an early detection of deterioration, followed by timely and tailored follow-up by the care organization.

Contacts

Public
Wageningen Universiteit

Stippeneng 4
Wageningen 6708 WE
NL
Scientific
Wageningen Universiteit

Stippeneng 4
Wageningen 6708 WE
NL

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, and must receive one or more of the following types of care:
-Domestic care
-Personal care
-Nursing care
-Individual or group support (including persons receiving informal care or living in a sheltered accommodation or service flat).

Exclusion criteria

-Severe cognitive impairment (Mini Mental State Examination < 20)

-Receiving terminal care
-Expected length of receiving care < 12 months
-Clients who are bedridden or bound to a wheelchair
-Clients with intramural care
-Not being able to watch television

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2016
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	09-06-2016
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	

Date:	18-05-2017
Application type:	Amendment
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	NL53619.081.15