ISRCTN93568533 https://doi.org/10.1186/ISRCTN93568533

A study into the effects of activities with animals on the well-being of Dutch nursing home patients with dementia

Submission date
23/08/2017

Recruitment status
No longer recruiting

Registration date
18/09/2017

Overall study status
Completed

Last Edited
13/04/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to explore the effect of dog or robot assisted activities on nursing home clients with dementia. The researchers are specifically interested in what happens during the activities. Do participating clients display less problematic behavior? Do they interact more with either the dog/robot or each other?

Who can participate?
Patients with dementia living in De Zorgboog, a large Dutch nursing home

What does the study involve?
Participants are randomly allocated to attend videotaped weekly group activity sessions with either a dog (and handler), a robot (FurReal Friend, with handler), or a handler only, over a period of 8 weeks. Quality of life, mood and behaviour are assessed during this time period and a 4 week follow-up using questionnaires.

What are the possible benefits and risks of participating?
Participating in this study will provide nursing home clients with an additional weekly activity for 8 weeks providing social contact and the possibility to interact with either a dog or an animal-robot. Interacting with dogs could potentially increase risk of injury, disease or inconvenience due to allergies. These risks have been minimised by using only certified animal-assisted intervention dogs that have been vaccinated and checked by a veterinarian. Furthermore, people with known dog allergies are excluded from participating. The study is also covered by a specific research insurance policy during the course of the intervention period.

Where is the study run from?
De Zorgboog Nursing Homes (Netherlands)

When is the study starting and how long is it expected to run for?
September 2014 to March 2019

Who is funding the study?
De Zorgboog Nursing Homes (Netherlands)

Who is the main contact?
Ms Lonneke Schuurmans

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL50623.096.14

Study information

Scientific Title
Animal-assisted interventions in Dutch dementia care: effects on quality of life and neuropsychiatric symptoms

Study objectives
Quality of life and neuropsychiatric symptoms of nursing home clients with dementia are positively influenced by group sessions offering either dog-assisted activities or robot-assisted activities, when compared with a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee Atrium-Orbis-Zuyd (Heerlen, The Netherlands), 10/11/2014, ref: NL50623096.14

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Dementia

Interventions
Nursing home clients are randomised via computer generated random numbers to three groups with protocolled activities:
Group 1: dog assisted activity group sessions with handler
Group 2: robot assisted activity group sessions with handler (FurReal Friend robot)
Group 3: (control): group sessions with a visiting student

Nursing home clients attend videotaped once a week group sessions with a total duration of 8 weeks and a 4 week follow-up. Quality of life, mood and behavior of participating clients are measured using questionnaires.

Intervention Type
Other

Primary outcome measure
1. Social interaction during sessions
2. Neuropsychiatric symptoms during sessions

Each client will participate in one intervention session a week. All sessions will be videotaped for the entire duration of the study (8 weeks). Videos will be analysed after the intervention period using video-coding to calculate the amount of social interactions and neuropsychiatric symptoms displayed during the sessions.

Secondary outcome measures
Questionnaires will be used to measure several secondary outcomes at all or a subset of the following timepoints: baseline (t0), after 4 weeks (t1, halfway), after 8 weeks (t2, at the end of the intervention period), after 12 weeks (t3, 4 weeks post intervention follow-up):
1. Quality of life, measured using Qualidem at t0, t1, t2, t3
2. Depression, measured using Cornell Scale for Depression in Dementia (CSDD) at t0, t1, t2, t3

3. Neuropsychiatric symptoms, measured using Neuropsychiatric Inventory Questionnaire (NPI-Q) at t0, t1, t2, t3
4. Agitation, measured using Cohen-Mansfield Agitation Inventory (CMAI) at t0, t1, t2, t3
5. Medication usage, measured using medical records at t0, t2
6. Intercurrent diseases, measured using medical records at t0, t2
7. Dementia stage, measured using Clinical Dementia Rating (CDR) at t0, t2
8. Functional state, measured using Interview for Deteriorating in Daily living activities in Dementia (IDDD) at t0, t2
9. Dementia, assessed using Gedragsobservatie Intramurale Psychogeriatrie (GIP, general dementia assessment tool, Dutch) at t0, t2

Overall study start date
01/09/2014

Completion date
01/03/2019

Eligibility

Key inclusion criteria
1. 24/7 nursing home client
2. Diagnosis of dementia
3. Consent by legal guardian

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Clients resisting participation, either verbal or non-verbal
2. Clients with a trauma related to animals in life history
3. Clients with a dog allergy
4. Clients with severe aggression that might endanger other clients or the participating dogs

Date of first enrolment
01/11/2014

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
De Zorgboog
Bakel
Netherlands
5760 AA

Sponsor information

Organisation
Open Universiteit Nederland

Sponsor details
Valkenburgerweg 177
Heerlen
Netherlands
6419 AT

Sponsor type
University/education

Website
http://www.ou.nl

ROR
https://ror.org/018dfmf50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
De Zorgboog Nursing Homes

Results and Publications

Publication and dissemination plan

Results will be published as part of a PhD project in several peer reviewed journals. Publication should ensue no later than 01/03/2019. The trialists intend to publish the video-coding sheet and study protocol as an online supplement to the publications in a peer-reviewed journal, if the journal in question offers that type of online supplement.

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan
Due to the sensitive nature of the video-material the trialists are obliged under restrictions set by the medical ethics committee to destroy the video-material after completion of the PhD project. The medical
records and questionnaires of participants will be kept in the medical archive of the nursing home
for 15 years.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/09/2019	13/04/2021	Yes	No