

Animal assisted interventions in dementia: effects on quality of life and neuropsychiatric symptoms.

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The objective of this study is to determine the effects of protocolled interventions with a visiting dog or FurReal Friend (robotic toy animal) on quality of life and neuropsychiatric symptoms in patients with dementia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON40879

Source

ToetsingOnline

Brief title

AAI in dementia

Condition

- Dementia and amnestic conditions

Synonym

Alzheimer's Disease, dementia

Research involving

Human

Sponsors and support

Primary sponsor: Open Universiteit

Source(s) of monetary or material Support: De Zorgboog

Intervention

Keyword: animal assisted therapy, dementia, psychiatric symptoms, quality of life

Outcome measures

Primary outcome

The primary study parameters are: mood (as measured by the Cornell), quality of life (QUALIDEM), the presence of agitation and aggression (CMAI) and the presence of neuropsychiatric symptoms in general (NPI).

Secondary outcome

The secondary study parameters are: cognitive status (MMSE, GDS & GIP), functional status (IDDD), blood pressure and heart rate, weight, changes in medication and intercurrent diseases.

Study description

Background summary

Dementia is a very challenging disease, with severe impact on both the person and his or her family. The cognitive and functional decline is usually accompanied by neuropsychiatric symptoms like agitation, aggression, apathy and anxiety. Carers are often struggling to connect with people with dementia in a meaningful way. The quality of life of people with dementia is often diminished and very difficult to influence. Nowadays professionals are more inclined to use complementary interventions (like music therapy) in dementia care. Animal assisted interventions are a complementary intervention in which animals are used to influence internal and external factors of specific target groups, like children with autism or people suffering from PTSD syndrome. Research shows that animals have a positive effect on basic human needs like (physical) contact, social interaction and support, feeling needed and useful, attachment, stress reduction, self-esteem and internal motivation. It is also known that stroking dogs has a positive influence on blood pressure and hormonal status. There is no reason to assume that these psychological and physiological effects will be different for people with dementia. On the contrary, compared to humans, animals have several advantages that might be additionally beneficial to people with dementia. Especially the non-verbal communication, the

unconditional attachment, the stimulation of multiple senses (in dementia care also known as 'snoezelen') and the attractiveness as a stimulus are important animal qualities in the interaction with people with dementia. Anecdotal information from nursing homes indeed shows effects along these lines, yet unfortunately systematical, methodologically sound research is lacking. This study aims to provide in this hiatus and to contribute to establishing animal assisted interventions as an meaningful complementary intervention in dementia care.

Study objective

The objective of this study is to determine the effects of protocolled interventions with a visiting dog or FurReal Friend (robotic toy animal) on quality of life and neuropsychiatric symptoms in patients with dementia.

Study design

The study design is a mixed-methods randomised controlled trial. Due to the nature of the study blinding is not possible.

Intervention

Participating clients are randomly divided in three groups:

- a controlgroup with a protocolled regular social intevention (drinking coffee), once a week.
- a group with a protocolled intervention with dogs, once a week.
- a group with a protocolled intervention with a robotic toy animal (FurReal Friend Lulu), once a week.

The protocolled aspect of the interventions consists of a specific, recurrent protocol of introduction and supervision. This means that all clients are situated in a circle and the intervention (dog/Lulu) is introduced to each client individually. Each client is asked what he/she wants to do with the dog or Lulu (e.g. pet, stroke, watch, play) and this is repeated in a circular pattern. In the control group clients also sit in a circle while drinking coffee (or something similar) and are also addressed individual in turn. The intervention will run for 8 weeks, followed by a 4 week follow-up period without intervention. The total duration of the study is 12 weeks.

Study burden and risks

All participating clients in the intervention groups will be enrolled in a weekly activity with a duration of 45 minutes, during 8 weeks. Subsequently, when possible depending on dementia stage and symptoms, they will be subjected to blood pressure measurements 2 times a week, weight measurement once a week and a once-only interview.

All other measurements are done by proxy via the designated formal carers.

Clients in the dog group risk being bitten or scratched or the transfer of zoonotic diseases. These risks are minimized by using specifically trained and selected dogs only, that are all fully vaccinated, treated for parasites and have regular veterinary checkups. Furthermore, all dog handlers are specifically trained in working with people with dementia and in recognizing stress signals in their dogs. A diversional therapist will be present at all times to monitor the welfare of the clients.

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

dementia diagnosis

ZZP 5 or ZZP 7 residential care referral

living in 24/7 psychogeriatric setting

willing to participate (verbal/non-verbal)
consent by formal caregiver

Exclusion criteria

signs of verbal or non-verbal resistance to participate
traumatic event concerning animals/dogs in life history
severe aggression that could endanger other clients, staff or the dogs
allergy for dogs

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2015
Enrollment:	113
Type:	Actual

Ethics review

Approved WMO	
Date:	10-11-2014
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Not approved	
Date:	30-11-2015

Application type: Amendment
Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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	NL50623.096.14