A study on the Effects of Socially Assistive Robots (SAR) in Intramural Elderly Health Care * A Quasi Experimental Trial.

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To assess the effectiveness of Socially Assistive Robot (SAR) interventions involving one specific SAR, the Paro system.

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

Summary

ID

NL-OMON37472

Source
ToetsingOnline

Brief title
Effectiveness of Paro in Psychogeriatric Care.

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Zuyd University of Applied Sciences
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dementia, intervention, intramural, robot

Outcome measures

Primary outcome

The primary objective of this study is to assess the effectiveness of Paro on individually (per subject) and short-term (during and after treatment) defined goals.

The goals can be categorized into two main groups:

1. For therapeutic purposes, involving psychological functioning, psychosocial well-being, social behavior and reactivation.

2. To facilitate daily care activities.

During each of the 4 periods (A, B, A, B) the behavior of the participants is measured 5 times by a Goal Attainment Scale i.e. the IPPA-score (Individually Prioritized Problems Assessment).

Secondary outcome

1. Psychological and psychosocial functioning during treatment (facilitating daily care activities).

The psychological and psychosocial functioning of the participant is measured based on a mood scale. The frequency of the measurements is equal to the measurements of the primary objective.

2. Experienced practical issues by care providers: semi structured questionnaires.

During the interventions (i.e. periods A en B) a questionnaire will be

conducted with the involved care providers, per participant, by the observer or

the investigator(s), at the end of each period. Resulting in 4 questionnaires

per participant

Study description

Background summary

The ongoing development of robotics on the one hand and, on the other hand, the foreseen relative
growth in number of elderly individuals suffering from dementia, raises the question of which contribution
robotics could have to rationalize and maintain, or even improve the quality of care.

Robotic applications supporting social behavior are a recent development. The domain of socially assistive robotics and in particular the study
of their effects in elderly care has not been studied comprehensively, resulting in a lack of insight into the evidence for the added value of these systems in supporting care provision in practice.
Paro was selected for this purpose because it is the only system with the European CE mark, guaranteeing basic technical
robustness, reliability and intrinsic safety.
Moreover, the large number of publications from the Paro developing team on application and effects support the potential of
Paro.

Two interventions involving Paro are developed in conjunction with four Dutch care providing organizations.
Research is required to scientifically investigate the effects of interventions featuring socially assistive robotics within real
elderly care settings.

Study objective

To assess the effectiveness of Socially Assistive Robot (SAR) interventions involving one specific SAR, the Paro system.

Study design

This intervention study will be conducted in the form of a quasi-experimental time series trial with within-subject comparison.
Due to the nature of the intervention, blinding is not feasible.
Due to the individual goals and effects of the interventions, randomization and a control group are also not suitable.

The study has an A-B-A-B design.
Each period has a duration of 1 month.

During period A treatment is as usual.
In period B the Paro-interventions are applied, 5 times per participant.
Given the subjective nature of observations, each participant is paired with one care provider during an A-B session in order to obtain comparable results.

Intervention

Participants will receive Paro involved interventions in their daily living/activities, over two periods of one month, as described in the intervention-protocol.
Involved care givers receive an instruction and training course prior to the start of the study.
Paro will be presented to the participant for the duration of the intervention (15 min).
With this interaction, individual goals are pursued, these goals are set during inclusion by the MDO team.

Study burden and risks

n.a.

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

1. Dementia
2. Undesirable psychological / psychosocial unrest or mood
3. Experienced difficulties in provision of daily care

Exclusion criteria

1. No written consent
2. Medical (somatic or psychiatric) objections against participation formulated by the Multidisciplinary team (MDO).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	01-08-2012
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2012
Application type:	First submission
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	NL40271.096.12