

# **ORIGINAL ARTICLE**

# Evaluation of the efficacy of animal-assisted therapy based on the reality orientation therapy protocol in Alzheimer's disease patients: a pilot study

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Received 18 September 2014; revision received 5 May 2015; accepted 18 May 2015.

**Key words:** AAT, Alzheimer' disease, non-pharmacological therapies, public health, ROT.

### **Abstract**

**Background:** The aim of this study was to evaluate the efficacy of animal-assisted therapy (AAT) in elderly patients affected by Alzheimer's disease based on the formal reality orientation therapy (ROT) protocol.

**Methods:** Our study was carried out at an Alzheimer's centre for 6 months. A homogeneous sample (age, Mini-Mental State Examination (MMSE), 15-item Geriatric Depression Scale (GDS)) of 50 patients was selected at random and successively. Patients were divided into three groups: (i) 20 patients received a course of AAT (AAT group) based on the ROT protocol; (ii) 20 patients were engaged exclusively in activities based on the ROT group; and (iii) 10 patients (control group) participated in no stimulations. MMSE and GDS were administered at time 0 (T<sub>0</sub>) and time 1 (T<sub>1</sub>) to all three groups. Differences within groups between T<sub>0</sub> and T<sub>1</sub> for GDS and MMSE scores were analyzed by Student's *t*-test. Differences between group means were analyzed using an ANOVA test with the Bonferroni-Dunn test for post-hoc comparisons.

**Results:** Both the AAT group and ROT group had improved GDS scores and showed a slight improvement in terms of mood. On the GDS, the AAT group improved from 11.5 ( $T_0$ ) to 9.5 ( $T_1$ ), and the ROT group improved from 11.6 ( $T_0$ ) to 10.5 ( $T_1$ ). At the same time, a slight improvement in cognitive function, as measured by the MMSE, was observed. In the AAT group, mean MMSE was 20.2 at  $T_0$  and 21.5 at  $T_1$ , and in the ROT group, it was 19.9 at  $T_0$  and 20.0 at  $T_1$ . In the control group, the average values of both the GDS and MMSE remained unchanged. The Bonferroni-Dunn results showed statistically significant differences between groups, particularly between the AAT group and the other two (P < 0.001).

**Conclusions:** Pet therapy interventions based on the formal ROT protocol were effective and, compared to the ROT, provided encouraging and statistically significant results.

## INTRODUCTION

In 2012, it was estimated that there were 36 million people worldwide—one million in Italy alone—with Alzheimer's and other dementias, and these figures are likely to increase dramatically in the coming years due to the exponential increase in the elderly population.<sup>1,2</sup> Dementia is a syndrome that is characterized

by progressive impairment of multiple cognitive functions (phasic, gnosis, and praxis), that involves memory, and that interferes with the performance of patients' activities of daily living. The aetiology of this disease is unknown. We know that it is a degenerative, irreversible, and primary disease; it is caused by the progressive atrophy of the cerebral cortex and

leads to the loss of cholinergic neurons.<sup>3</sup> Given the lack of efficacy of anticholinesterase drug therapy, an increasing number of studies are investigating the validity of different cognitive stimulation techniques to improve and slow down the progressive course of Alzheimer's disease.<sup>4</sup>

As part of the rehabilitative and psychosocial interventions aimed at patients with cognitive impairment—in addition to contextual therapy,5 validation therapy,6 and reminiscence therapy6-8—one of the most common therapies is reality orientation therapy (ROT). ROT is an intervention for patients with amnesic deficits, episodes of confusion, and spatialtemporal disorientation. Its principal objective is to reorient the patient through repeated multimodal stimulations with respect to his or her personal history, environment and time. This goal can be achieved through two complementary modes of operation: formal ROT and informal ROT (or ROT in class).9 The former consists of repeated stimulation of spatialtemporal reorientation during the course of the day, through interactions between the patient and health professionals or family members. Formal ROT involves a small group of patients (4-6 subjects), who are homogeneous in terms of cognitive impairment, who meet for about 45 min/day in a well-structured environment. Currently, ROT is one of the most widely used rehabilitation interventions for patients suffering from dementia, and it is one of the few interventions that have achieved positive results in patients with Alzheimer's dementia.10

Frequently, a combination of cognitive and mood disorders is observed in patients with Alzheimer's disease, which is why, in addition to cognitive therapies, therapies based on affective/motivational, emotional, and psychological stimulation are useful. These therapies facilitate the application of animal-assisted therapy (AAT) in patients with dementia. The presence of a therapy animal acts as an affective and emotional stimulus on patients and improves mood. When patients develop a strong bond with an animal, this facilitates the administration of non-pharmacological therapeutic techniques in resistant patients with dementia.

The present study aimed to assess the use of AAT adapted to the formal ROT protocol. 10,18 For this reason, subjects with mild-to-moderate Alzheimer's disease were selected in order to evaluate the therapy's applicability and efficacy.

## **METHODS**

This study was carried out at the Alzheimer's Daycare Centre, ASL Naples1—Frullone Hospital, from January 2013 to June 2013. The head geriatrician wanted to try AAT because patients were not responding to routine non-drug therapies.

#### The team

The team was formed by a zootherapist, who was responsible for animal health, preventing zoonoses, verifying the suitability of the setting, and creating activities that involved a dog and reproduced ROT stimulations (Menna, 2012, unpublished data). The zootherapist's task was to define, in agreement with the psychotherapist, the appropriate setting for the animal and structured (ROT) play; the psychotherapist established the most suitable approach for patients and structured the setting with input from a veterinarian. The dog, a 7-year-old female Labrador retriever, met hospital policy for participating in AAT programmes (i.e. documentation of current vaccinations, controllability and temperament). The dog was trained through an educational programme for the pet therapy at the La Voce del Cane's dog educational centre (Naples, Italy); the programme followed the guidelines of the Italian National Educational Sports Center (love of dogs). All procedures necessary to guarantee a high standard of animal welfare were undertaken. When the dog became agitated (e.g. yowling, slapping) and did not respond to attempts to redirect her behaviour, the veterinarian promptly intervened to minimize the effects of the stressing situation by changing the activity, keeping a distance between the dog and the stressing stimulus, or caressing the dog.

This study was approved by the Ethical Committee of the University of Studies of Naples Federico II, and it conforms to the provisions of the Declaration of Helsinki (1996). Informed consent was obtained from all participants. Sensitive data have been handled with confidentiality and securely stored.

# Operative method

# Preliminary stage

The head geriatrician at the Alzheimer's Daycare Centre randomly selected an initial group of 50 patients (37 women, 13 men) with mild-to-moderate Alzheimer's disease and absence of behavioural

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Table 1 Comparative plan of a formal ROT intervention and an AAT intervention based on the formal ROT protocol

	Formal ROT	AAT intervention		
Step 1	Structuring the setting	Structuring the setting		
	2. Presenting the therapist/patient	2. Presenting the zootherapist/dog/patient		
	3. Stimulating cognitive function	<ol><li>Stimulating cognitive function through repeated requests for information about the dog (e.g. name, breed, age, and sex)</li></ol>		
Step 2	1. Temporal orientation (day, month,	1. Temporal orientation (day, month, year, and season)		
	year, and season)	2. Spatial orientation (place, structure, floor, room, city, country, and region)		
	2. Spatial orientation (place, structure, floor, room, city, country, and region)	<ol><li>Stimulation of memory by telling a story about their own pets; play structured activities with the dog (e.g. hide the ball)</li></ol>		
	3. Stimulation of memory			
Step 3	<ol> <li>Stimulation of memory (attention)</li> <li>Understanding of language (story)</li> </ol>	<ol> <li>Structured game/interaction with the dog (attention: fetch, hide the ball, caring for the dog)</li> </ol>		
		<ol><li>Understanding of language (story: giving the dog commands and waiting for the execution of the command)</li></ol>		
Step 4	1. Closing speech (ritualized)	Closing speech (ritualized: washing hands)		

AAT, animal-assisted therapy group; ROT, reality orientation therapy group.

disorders. The subjects were then divided into the following three groups: (i) the AAT group; (ii) the ROT group; and (iii) the control group. The subjects were homogeneous for age (mean  $\pm$  SD:  $75\pm6$  years; range: 62-85 years), sex, and diagnosis of mild-to-moderate Alzheimer's disease (mean Mini Mental State Examination (MMSE): 20.1, 95% confidence interval (CI): 20.0–20.1; mean 15-item Geriatric Depression Scale (GDS): 11.5, 95% CI 11.5–11.6).

The AAT group included 20 patients (16 women, 4 men) selected according to the following criteria: (i) absence of fear or aversion towards the dog; (ii) willingness to interact with the dog; and (iii) patient's personal history with animals (i.e. patient had a dog in the past). This group received a course of AAT interventions based on the ROT protocol. The ROT group included 20 patients (14 women, 6 men) were engaged exclusively in ROT activities covered. The remaining 10 patients (7 women, 3 men) formed the control group, which participated in no stimulations.

# Test

To compare the general clinical impact between the three groups, the geriatrician administered the MMSE and GDS to all patients involved in this study at the beginning of the programme (T<sub>0</sub>) and at end of the 6-month programme (T<sub>1</sub>). The MMSE was used to assess cognitive impairment, <sup>19,20</sup> and the GDS was used to assess depressive symptoms and the patient's reactions to hospitalization and illness status. <sup>21,22</sup>

#### Formal ROT

The formal ROT intervention was performed on a weekly basis according to the formal ROT proto-

col.<sup>9,10,18</sup> Sessions were 45 min, and they were held over a 6-month period.

# AAT adapted to formal ROT

Each AAT intervention occurred once a week for 45 min over a 6-month period. The initial 15 min involved reintroducing the dog to each patient and helping the patient develop spatial-temporal orientation, the next 20 min was structured activity with the dog, and the last 10 min involved the same ending activities each time. At the end of AAT intervention, in the closing speech, there is the washing hands (Table 1, AAT intervention).

The activities with the dog were based on the formal ROT protocol. The therapeutic approach was based on the stimulation of cognitive functions such as attention, language skills, and spatial-temporal orientation. The interactions with the animal were structured according to ROT, with some adaptations (Table 1).

# Data analysis

Data were entered into an Excel file. At each time ( $T_0$  and  $T_1$ ), the mean  $\pm$  SD was calculated for MMSE and GDS. Differences within groups between  $T_0$  and  $T_1$  for GDS and MMSE scores were analyzed by Student's t-test. Differences in the mean between groups were analyzed using an ANOVA test with the Bonferroni-Dunn test for post-hoc comparisons. All the statistical analyses were performed with STATA version 10.0 (StataCorp, College Station TX, USA).

## **RESULTS**

All the groups involved in our study were homogeneous for age, sex, and cognitive impairment (mean

MMSE: 20.1, 95%CI: 20.0–20.1; mean GDS: 11.5, 95%CI 11.5–11.6) (Table 2). The results of the GDS for the AAT group showed that the mean score decreased from 11.5 at  $T_0$  to 9.5 at  $T_1$ ; in the ROT group, GDS decreased from 11.6 at  $T_0$  to 10.5 at  $T_1$ . In the control group, the mean the GDS score decreased from 11.5 to 11.0. Data analysis showed a statistically significant improvement in the ROT group and, especially, the AAT group (P < 0.000) (Fig. 1).

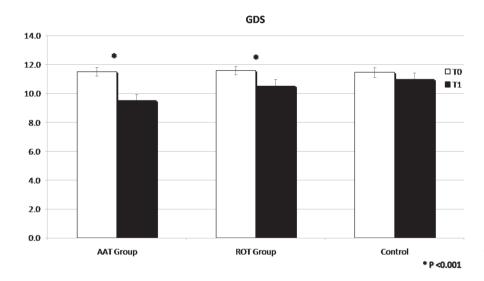
The results of the MMSE for the AAT group showed that the mean score increased from 20.2 at  $T_0$  to 21.5

at  $T_1$ ; in the ROT group, MMSE increased from 19.9 at  $T_0$  to 20.2 at  $T_1$ . Both groups had a statistically significant improvement (P < 0.000) (Table 3). In the control group, the mean MMSE remained virtually unchanged ( $T_0$ : 20.1;  $T_1$ : 20.0) (Fig. 2). Post-hoc comparisons ( $T_1$ ) conducted by ANOVA are reported in Figures 3 and 4, which show the statistical differences between the AAT, ROT, and control groups. In particular, there were statistically significant differences between AAT group and the other two groups (P < 0.001).

Table 2 Sociodemographic and clinical features of study population

	AAT	ROT	Control	P-value <sup>†</sup>
Female (n)	16 (80%)	14 (70%)	7 (70%)	_
Age, mean ± SD (years)	$75.25 \pm 6.06$	$74.95 \pm 5.47$	$75.1 \pm 5.83$	0.987
GDS T <sub>0</sub> (mean ± SD)	$11.5 \pm 0.30$	$11.6 \pm 0.28$	$11.5 \pm 0.33$	0.498
GDS T <sub>1</sub> (mean ± SD)	$9.5 \pm 0.46^{9}$	$10.5 \pm 0.43$ §	$11.0 \pm 0.46^{\ddagger}$	0.000
MMSE $T_0$ (mean $\pm$ SD)	$20.2 \pm 0.26$	$19.9 \pm 0.23$	$20.1 \pm 0.38$	0.120
MMSE $T_1$ (mean $\pm$ SD)	$21.5 \pm 0.33^{\ddagger}$	$20.2 \pm 0.31$ §	$20.0 \pm 0.20$ §	0.000

†P-value for differences between groups. <sup>‡,§,†</sup>Statistical differences between the groups by ANOVA. AAT, animal-assisted therapy group; GDS, Geriatric Depression Scale; MMSE, Mini-Mental State Examination; ROT, reality orientation therapy group; T<sub>0</sub>, time 0; T<sub>1</sub>, time 1.

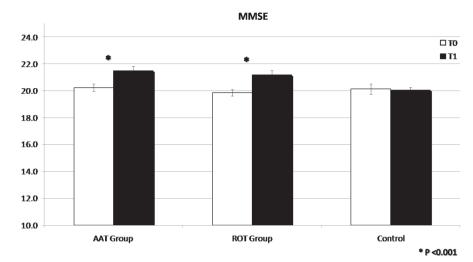


**Figure 1** Data analysis by Student's t-test within each group at time 0 ( $T_0$ ) and time 1 ( $T_1$ ). \*P < 0.000. AAT, animal-assisted therapy; GDS, Geriatric Depression Scale; ROT, reality orientation therapy.

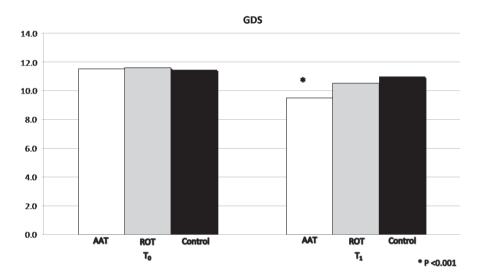
Table 3 Statistical differences by Student's t-test within each group

	GDS (mean $\pm$ SD)			MMSE (mean $\pm$ SD)		
Groups	T <sub>0</sub>		P-value <sup>†</sup>	T <sub>0</sub>		P-value <sup>†</sup>
AAT	11.5 ± 0.30	9.5 ± 0.46	0.000	20.2 ± 0.26	21.5 ± 0.33	0.000
ROT	$11.6 \pm 0.28$	$10.5 \pm 0.43$	0.000	$19.9 \pm 0.23$	$20.2 \pm 0.31$	0.000
Control	$11.5 \pm 0.33$	$11.0 \pm 0.46$	0.064	$20.1 \pm 0.38$	$20.0\pm0.20$	0.521

<sup>†</sup>P-value for differences within each group. AAT, animal-assisted therapy group; GDS, Geriatric Depression Scale; MMSE, Mini-Mental State Examination; ROT, reality orientation therapy group; T<sub>0</sub>, time 0; T<sub>1</sub>, time 1.



**Figure 2** Data analysis by Student's *t*-test within each group at time 0 ( $T_0$ ) and time 1 ( $T_1$ ). \*P < 0.000. AAT, animal-assisted therapy; MMSE, Mini-Mental State Examination; ROT, reality orientation therapy.



**Figure 3** Data analysis by the Bonferroni-Dunn test of mean differences between groups at time 0 ( $T_0$ ) and time 1 ( $T_1$ ). \*P < 0.001. AAT, animal-assisted therapy; GDS, Geriatric Depression Scale; ROT, reality orientation therapy.

# DISCUSSION

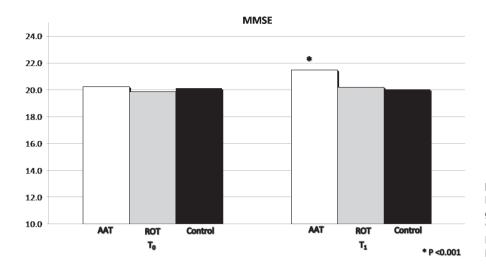
GDS scores, which can identify the presence of clinically relevant depressive symptoms,  $^{22}$  range from 0 (not depressed) to 30 (maximum severity of depression); we used a cut-off of 11. In the present study, the average GDS scores of AAT and ROT groups showed a slight improvement from  $T_0$  to  $T_1$  in terms of mood. The mean GDS score for the AAT group decreased from 11.5 to 9.5, a statistically significant improvement.

Additionally, a slight improvement in cognitive function, as measured by the MMSE, was observed in the AAT group. MMSE total test scores range from 0 (very serious) and 30 (asymptomatic); scores between 10 and 20 indicate moderate impairment and scores between 21 and 26 indicate mild impairment. The AAT and ROT groups, but especially the AAT group,

showed a statistically significant improvement in MMSE scores. The control group showed no significant changes on the MMSE and the GDS.

The results of MMSE and GDS analysis showed that both the ROT group and the AAT group experienced improvements in cognitive function and mood. However, the AAT group had a slightly greater improvement, which may be linked to patients' increased presence and participation during the AAT activities. Our results indicate that AAT interventions that are structured using ROT protocols may potentially be able to improve mood and depressive symptoms of elderly subjects.

ROT is a non-pharmacological therapy that is accredited and widely used; it stimulates patients mainly on a cognitive level. In this study, we adapted



**Figure 4** Data analysis by the Bonferroni-Dunn test of mean differences between groups at time 0 ( $T_0$ ) and time 1 ( $T_1$ ). \*P < 0.000. AAT, animal-assisted therapy; MMSE, Mini-Mental State Examination; ROT, reality orientation therapy.

the ROT protocol to activities involving structured play with a dog and worked to stimulate patients cognitively and emotionally. The results show that this approach was successful and worked better than ROT alone.

The present study had some limitations. First, this study acts as a preliminary observation because the study design was not randomized or double blinded and the sample size was small. Second, we used a limited neuropsychological battery. Third, we carried out a short-term evaluation (6 months), so we cannot determine whether GDS and MMSE improvement was persistent over time. In addition, because the therapeutic effect of AAT may depend on the relationship with both the animal and the zootherapist, we cannot distinguish between the differential impact of the dog and the zootherapist on patients of AAT group.

Our hypothesis is that the presence of an animal should motivate patients to perform tasks and improve their performance in statistically significant manner. The literature consulted suggests that a dog understands non-verbal language and can function as a patient's emotional sounding board, acting as a stimulus as a result. As demonstrated by the improved test results in the present study, this can indeed occur.<sup>23,24</sup>

In conclusion, AAT interventions have proven to be applicable and effective in stimulating cognition and improving mood, intervening also in deadlock phases in formal ROT. AAT interventions likely allows the non-medicalization of the symptom through structured play with the dog. We hypothesize that in

patients with mild-to-moderate Alzheimer's disease, AAT based on the ROT protocol can improve cognition and mood through repeated multimodal stimulation (verbal, visual, and tactile). However, this work is a first observation and further studies are required.

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