

Positive Outcomes of Animal Assisted Therapy on Behavioural and Psychological Vulnerabilities for Institutionalized Elderly with Cognitive Deficits: A Randomized Controlled Study



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Abstract

Background: This study examines the therapeutic impact from the interactions between institutionalized patients with cognitive deficits presenting behavioural and psychological vulnerabilities at the San Felice Nursing Home in Segrate, Italy and dogs that carried out Animal Assisted Therapy from September 2003 to March 2024.

Methods: The sample consisted of 36 institutionalized subjects aged 65 to 95 years randomly divided between a control and a treatment group whose members participated in 14 weekly individual sessions of 30 minutes each. At enrollment and at the end of the therapeutic process, the following evaluation scales were administered to both groups: Mini-mental State Examination (MMSE); UCLA Neuropsychiatric Inventory (NPI, 12 items, 144 score); General Anxiety Disorder-7 (GAD-7); Cambridge Behavioral Inventory-Revised (CBI-R); and Hospital Anxiety and Depression Scales (HADS-A, HADS-D).

Results: In comparing the gain (post-treatment minus pre-treatment) for patients in the treatment group with those in the control group, we detected a large or very large effect for HADS-A (1.2 points, $d = 1.06$), HADS-D (2.2 points, $d = 1.49$), and GAD-7 (3.9 points, $r = .83$) based on Cohen's d or correlation coefficient r standard effect sizes. We detected a modest effect for MMSE ($d = .37$), while the effect sizes for the other three tests were very small.

Based on a Bonferroni correction for 6 tests, we obtained statistically significant results at a significance level of $\alpha = 0.05/6 = .0083$ for HADS-D ($p = 0.0003$) and GAD-7 ($p = 0.00003$). The tests for the other 5 instruments were not significant even at $\alpha = 0.05$.

Conclusions: The study showed significant improvement in anxiety and depression states in the institutionalized elderly patients who received Animal Assisted Therapy. No significant results were found in the behavioural and cognitive variables whilst changes in the UCLA-NPI indicators between treatment and control groups were detected and should receive further investigation.

Keywords: Animal Assisted Therapy; Anxiety; Cognitive Deficits; Depression; Institutionalized Elderly; Nursing Home

Abbreviations: MMSE: Mini Mental State Examination; AAT: Animal Assisted Therapy; GAD: General Anxiety Disorder; CBI-R: Cambridge Behavioral Inventory Revised; HADS: Hospital Anxiety and Depression Scale; UCLA: Neuropsychiatric Inventory

Introduction

The average lifespan of the population has been constantly increasing and with it important aging processes which usually lead to a slowing down of reflexes, a decrease in attention, reasoning capacity, and memory, and to alterations in behaviour which reduce the elderly person's ability to carry out normal activities of daily living [1]. Aging and lack of self-sufficiency mean

that many elderly people are residents in protected healthcare facilities. This difficult choice can often lead to mood deflection and to forms of anxiety and depression that aggravate pre-existing clinical pictures [2]. Behavioral and mood disorders in the elderly are, therefore, one of the major causes of institutionalization and negatively contribute to the rapid evolution of geriatric problems.

In 2020, there were 342,361 patients in residential healthcare facilities in Italy; three out of four were people over sixty-five [3]. The prevalence of behavioural and psychological vulnerabilities associated with cognitive deficits, can vary widely between 25% and 90% depending on different studies in the scientific literature. Specifically, over 50% of patients with moderate to severe cognitive deficits cared for at home, have at least one behavioural disorder. In patients admitted to long-term care with severe cognitive impairment, 88% present three or more mental and behavioural disorders, the most frequent of which is depression, followed by anxiety, aggression and various forms of psychosis [4].

In addition to the use of drugs and rehabilitation techniques, it is now known that non-pharmacological therapies, such as music therapy and art therapy, reduce symptoms of anxiety and depression, as well as delaying the deterioration of cognitive functions [5]. As confirmed by a 2019 Review, Animal Assisted Therapy has played, and continues to play, a very important role on a psychological level for chronic degenerative diseases such as dementia but also on comorbidities such as depressive and anxiety disorders [6]. Animal-Assisted Therapy appears to be useful in increasing social and communication skills, facilitating verbal and body language, increasing self-esteem, and reducing anxiety and stress, thereby improving the quality of life. [7] An interesting 2020 article [8] which searches the scientific literature for the beneficial effects of AAT, divides the questions into three themes: psychological outcomes, physiological outcomes and aspects to be analyzed in the care of elderly subjects, concluding that, in all three cases remarkably positive results can be obtained using animal therapy. In a 2018 randomized controlled study [9], which took into consideration a population aged 65 years and over, after a 10-week AAT intervention, a statistically significant decrease in depression measured by the Geriatric Depression Scale was demonstrated.

A Systematic Review that analyses studies conducted from 2018 to today, on patients over 65 with cognitive impairment who have been administered AAT, does not fully corroborate the effectiveness of the treatment, having as its limitations the small size of the samples, the absence of a specific protocol and the lack of methodological rigour but considers the results obtained in a highly positive manner [10]. As a 2020 Review confirms, what is popularly defined as 'Pet Therapy' has played and continues to play a very important role on a psychological level for depression and anxiety [11]. On the premises of the above-mentioned findings, our study, immersed in an institutionalized reality, aimed at identifying whether the presence of the dog could significantly produce noteworthy changes in the psychopathological pictures, determining in which specific dimensions of behavior and mood disorders such effects occurred. The study was carried out in total compliance with the National Guidelines of the Italian Ministry of Health regarding Animal Assisted Interventions [12].

Methods

Overview

The study was conducted from September 2023 to March 2024 at a Healthcare Nursing Facility for the Elderly in northern Italy, accredited and affiliated with the National Health System. At the time, the total population in the facility consisted of 110 patients. Patients selected for the study presented, in addition to cognitive deficits, one or more of the following disorders: generalized anxiety disorder; obsessive compulsive disorder; depression; bipolar disorder or psychotic disorders.

Patients were selected from the overall population using the following inclusion criteria:

- age between 65 and 95
- Mini Mental State Examination (MMSE) score: 9-24
- patients institutionalized for at least one year
- preserved functionality of at least one upper limb to enable sensory tactile interaction with the animal
- presence of cognitive behavioral/mood disorders diagnosed through the administration of standardized tests.

The exclusion criteria were:

- Aphasia
- severe sight impairment or blindness
- severe hearing loss or deafness
- proven or suspected allergy to dog hair
- institutionalized for less than one year
- phobia when interacting with a dog

Of the 110 patients present in September 2023:

- 4 were unable to participate due to temporary relief stays.
- 10 did not reach the minimum required threshold of the MMSE < 9
- 2 had aphasic disorders.
- 3 were bedridden.
- 1 was affected by blindness.
- 10 were excluded due to expressed opposition to the project (reluctance to participate in any activity or evident fear of animals)
- 44 did not meet the psychopathological criteria selected

Thus, 36 patients were selected for participating in the study; each was randomly assigned to one of the two groups by drawing

odd and even numbers from a closed container. The 18 patients in the control group followed the usual activities proposed in the Nursing Home; the 18 patients in the treatment group participated in the Animal Assisted Therapy (AAT) in addition to their normal socio-educational activities. In terms of mobility, eight patients in the treatment group and seven patients in the control group used a wheelchair.

No significant differences were found in the pre-treatment assessments between the two groups (see Results section) and no statistically significant difference was found in the mean age, specifically:

- Study group: consisted of 18 patients including 14 women and 4 men aged between 65 and 95 years. Average age: 84.4
- Control group: consisted of 18 patients including 15 women and 3 men aged between 75 and 95 years. Average age: 85 years.

Just before the end of the study one patient died and therefore post-treatment values for this subject could not be recorded.

Assessment

The study was conducted by a multidisciplinary team as required by the National Guidelines for Animal Assisted Interventions of the Italian Ministry of Health [12]. The Facility's part of the team consisted of a Geriatrician, a Psychologist specialized in Psychology of Aging, a Professional Educator and a Physiotherapist. The Animal Assisted Intervention's team consisted of an Animal Assisted Intervention's licensed Veterinary Surgeon, a Clinical Supervisor, 4 Professional Dog Handlers, 9 Golden Retrievers and one Samoyed dog specifically trained and in possession of the legal and health certifications to practice as Therapy Dogs in AAT. All the criteria of the guidelines of the Italian Ministry of Health were respected. All patients received specific information on their participation in the project; the informed consent and the Right to Privacy legislation was compiled by them or their legal guardians as required by the Italian law. The study was approved by the ORPEA ethical committee and complies with the Declaration of Helsinki 2013.

The psychological tests chosen by the multidisciplinary team were among those most sensitive and specific for institutionalized subjects and scientifically validated. Cognitive deficits were measured through MMSE together with CDR to determine the severity of cognitive deterioration. These scales were administered at the time of selection and within 14 days from the end of the therapeutic process by two healthcare professionals from the Facility.

The following tests were used:

- Mini Mental State Examination (MMSE) [13].

- UCLA Neuropsychiatric Inventory (NPI, 12 items 144 score) [14].
- General Anxiety Disorder-7 (GAD-7) [15].
- Cambridge Behavioral Inventory Revised (CBI-R) [16].
- Hospital Anxiety and Depression Scale (HADS-A and HADS-D) [17].

The individual sessions took place weekly, with an average of 13 sessions per patient, each lasting approximately 30 minutes depending on the patients' tolerance. Each session included the patient, a dog handler and the dog, as well as a healthcare professional involved in the project. During the sessions the following activities were implemented: sensory and tactile interactions with the dog; grooming including brushing and combing the dog's fur; verbal commands and non-verbal cues towards the animal; goal-oriented actions such as retrieving, feeding and giving water; rally-obedience activities using verbal and non-verbal commands based on pre-prepared visual prompts.

Statistical Analysis

The statistical analysis was performed using the Real Statistics statistical analysis software (Release 8.9), www.real-statistics.com. Our principal investigation was to determine whether there is a significant benefit gained from AAT. This was measured based on comparing the gain on each of the six psychological instruments (MMSE, UCLA-NPI, GAD-7, CBI-R, HADS-A, and HADS-D) between the Treatment and Control groups. Here "gain" for each instrument is equal to the post-treatment score minus the pre-treatment score. In addition, we compared the scores post-treatment with the scores pre-treatment for both the Treatment and Control groups.

We used a two independent sample t-test to compare the Treatment and Control groups. We used a paired sample t-test to compare the pre- and post-treatment scores for the Treatment group, as well as the Control group. Where the normality assumption was violated, we substituted a Signed-rank test for the paired t-test, and a Mann-Whitney test for the two-sample t-test (confirmed with a Brunner-Munzel test). Since multiple tests were performed, we took this fact into account when determining whether a result was significant. Cohen's *d* was used as the standard measure of effect size. We used d_{av} (based on the average of the pre- and post-treatment score variances).

Because of the limited number of previous AAT studies, we were not able to evaluate these effect sizes based on previous studies. As such, we used the usual guidelines that $d = .20$ represents a small effect, $.50$ a medium-sized effect, and $.80$ a large effect. Confidence intervals of the effect size were also calculated using a noncentral t distribution approach. We also used a variation of the correlation coefficient r as a measure of effect size (especially the rank-serial correlation for the nonparametric tests). Here we

used the usual guidelines that $r = .10$ represents a small effect, $.30$ a medium-sized effect, and $.50$ a large effect. Since we knew that sample sizes were limited, we also performed statistical power analysis prior to analyzing the data to determine what size effect could be detected in the significance testing.

Results

Comparing Treatment and Control groups Pre-treatment

Before we compared the effectiveness of the treatment, we wanted to make sure that the Treatment and Control groups have similar characteristics and so the results of our study wouldn't be biased.

Age: First, we note that the 36 participants were randomly assigned to the two groups. Next, we compared the ages of the participants as shown in (Table 1). As noted previously, for three of the psychological instruments the Treatment group excludes the one participant who died prior to taking this post-treatment psychological test. Since the data in the Treatment group was not normally distributed, we used a Mann-Whitney test to determine

whether there is a significant difference between the two groups. We found that there was not a significant difference, and the effect size was close to zero (p -value = $.86$, rank-serial correlation effect size = $.07$). Thus, we were satisfied that the random assignment into the two groups was not biased based on age.

Psychological Instruments: Next, we compared average pre-treatment scores for each of the six psychological instruments. We used the Shapiro-Wilk and D'Agostino-Pearson's tests to determine whether the pre-treatment scores for each of these instruments were normally distributed in both the Treatment and Control groups. We used the two-independent sample t-test for all instruments for which both the Treatment and Control data were normally distributed. Otherwise, we used the Mann-Whitney nonparametric test instead. The data in both the Treatment and Control groups for MMSE and CBI-R are normally distributed based on both normality tests. The data from the Control group for UCLA-NPI is not normally distributed based on both tests. For the Treatment group, the data for GAD-7, HADS-A, and HADS-D are normally distributed based on both normality tests, the situation is mixed for the Control group.

Table 1: Age of Treatment and Control Groups.

	Orig Treat	Treat	Control
Count	18	17	18
Mean	84.4	83.9	85
Median	86.5	86	85
Standard Deviation	8.3	8.2	5.0
Minimum	65	65	75
Maximum	93	93	93
Frequency	Orig Treat	Treat	Control
65-79	3	3	3
80-89	10	10	12
90-99	5	4	3

Descriptive statistics (sample size, mean, median, etc.) for Treatment group (both the original group and the group after one participant died) and Control group. Plus, frequency counts for ages 65-79 years, etc.

Our judgement was that we could use the two-independent sample t-test for all the instruments except for UCLA-NPI. For this instrument we relied on the Mann-Whitney test. In any case, we report on both tests for all six instruments. This is done in (Table 2). For the t-test we report the p -value and Cohen's d and r effect sizes based on unequal variances between the two groups (even though the values for the homogeneity of variances version are almost the same). For the Mann-Whitney test we report the p -value and the rank-serial correlation effect size r .

The p -values of all the tests are greater than $.05$ apart from the t-test for MMSE. There is a significant difference for MMSE although it is close ($p = .04$); this test shows at least a medium-

sized effect ($d \approx .5$ and $r \approx .3$). The only others that are close are UCLA-NPI ($p = .08$, $r = .27$) and CBI-R ($p = .13$, $d = .51$, $r = .26$). None of these tests is significant when experiment-wise error using a Bonferroni correction is taken into account (as explained later).

When we determined whether there is a significant difference between the Treatment and Control groups for each of the instruments, we tested the difference of the "gain" (i.e. the average post-treatment score minus the average pre-treatment score). In fact, this approach should consider any pre-treatment differences observed above.

Table 2: Comparing Treatment and Control group scores pre-treatment.

	MMSE	NPI	HADS-A	HADS-D	GAD	CBR-I
Control	21.87	4.78	5.78	5.78	7	33.22
Treatment	18.80	7.50	5.82	6.00	6.94	42.78
t-test p	0.043787	0.128524	0.975366	0.854321	0.967557	0.133678
Cohen d	0.698171	0.519493	0.010458	0.062061	0.013671	0.51266
r effect	0.338961	0.260084	0.005485	0.033164	0.007903	0.259766
mw p	0.071253	0.077979	0.802987	0.75218	0.690266	0.124768
r effect	0.300644	0.274385	0.023957	0.095539	0.047773	0.255844

Control and Treatment rows show average scores for each instrument pre-treatment. Two-sample t-test conducted comparing control and treatment scores (p-value, Cohen’s d and r effect sizes provided). A Mann-Whitney (mW) non-parametric test was also conducted comparing control and treatment scores (p-value and r effect sizes provided). MMSE: Mini-mental state evaluation; NPI: UCLA Neuropsychiatric Inventory; HADS-A and HADS-D: Hospital Anxiety and Depression Scales; GAD: General Anxiety Disorder-7; CBR-I: Cambridge Behavioral Inventory.

Statistical Power and Sample Size

For comparisons between the Treatment and Control groups (using a two-sample t-test), because of the small sample sizes (17 and 18), we could only expect to detect an effect of size .98 or more with power of .80 or an effect of 1.13 or more with power of .90. For pre/post-treatment tests (using a paired t-test) for the Treatment group, we could only expect to detect an effect of size .73 or more with power of .80 or an effect of .84 or more with power of .90. Since the Control group has one more participant, we could only expect to detect an effect of size .70 or more with power of .80 or an effect of .81 or more with power of .90. In summary, given the modest sample sizes, we could expect to detect only a very large effect (based on Cohen’s d) for the Treatment/Control comparisons and a large effect size for pre/post-treatment tests.

Comparing the Treatment and Control groups

As stated above, we determined whether there is a significant difference between the gain of the Treatment and Control groups. The sample size for the Control is 18, while the sample size for the Treatment group is 18 for the MMSE and CBI-R instruments, but 17 for the other four instruments (Tables 3,4). The data in both the Treatment and Control groups for MMSE, HADS-D and CBI-R

are normally distributed based on both normality tests. The data for the Control group for the GAD-7 is not normally distributed based on both tests. For the Treatment group, the data for UCLA-NPI are normally distributed based on both normality tests, but the situation is mixed for the Control group. For HADS-A the situation is mixed for both the Treatment and Control groups. Our judgement was that we could use the two-independent sample t-test for all the instruments except for GAD-7. For this instrument we relied on the Mann-Whitney test. In any case, we report on both tests for all six instruments. This is done in (Table 5). For the t-test we report the p-value and Cohen’s d and r effect sizes for the case where the variances of the two groups are different (even though the values for the homogeneity of variances version are almost the same). For the Mann-Whitney test we report the p-value and the rank-serial correlation effect size r. Here, the mean represents the mean gain for the Treatment group minus the mean gain of the Control group. There are significant differences between the two groups for the HADS-D (p = 0.000303) and GAD-7 (p = .0000253). Note that with six tests, we can use a Bonferroni correction to obtain a revised significance level of $\alpha = .05/6 = .008333$. Even after this correction, HADS-D and GAD are significant. The results are not significant for the other four instruments.

Table 3: Gain for Treatment Group.

	MMSE	NPI	HADS-A	HADS-D	GAD	CBI-R
Count	18	18	17	17	17	18
Mean	1.227778	5.5	-1.47059	-1.88235	-3.11765	-5.66667
Variance	9.665654	100.5	5.139706	2.860294	8.110294	186.8235
Min	-5	-15	-5	-5	-11	-35
Max	6	30	5	1	1	28

Count: # of participants in Treatment group who took indicated psychological test both pre- and post-treatment. Mean: average gain (i.e. average post-treatment score minus average pre-treatment score) for each instrument. Variance: variance of the gain. Min/Max: smallest/largest gain for any participant in Treatment group. MMSE: Mini-mental state evaluation; NPI: UCLA Neuropsychiatric Inventory; HADS-A and HADS-D: Hospital Anxiety and Depression Scales; GAD: General Anxiety Disorder-7; CBR-I: Cambridge Behavioral Inventory.

Table 4: Gain for Control Group.

	MMSE	NPI	HADS-A	HADS-D	GAD	CBI-R
Count	18	18	18	18	18	18
Mean	-0.03333	6.055556	-0.27778	0.277778	0.777778	-5.5
Variance	11.62706	45.58497	1.271242	2.094771	3.124183	102.8529
Min	-4.1	-2	-3	-2	-2	-28
Max	8.6	20	1	3	6	15

Count: # of participants in Control group who took indicated psychological test both pre- and post-treatment. Mean: average gain (i.e. average post-treatment score minus average pre-treatment score) for each instrument. Variance: variance of the gain. Min/Max: smallest/largest gain for any participant in Control group. MMSE: Mini-mental state evaluation; NPI: UCLA Neuropsychiatric Inventory; HADS-A and HADS-D: Hospital Anxiety and Depression Scales; GAD: General Anxiety Disorder-7; CBI-R: Cambridge Behavioral Inventory.

Table 5: Testing the Gain for Treatment vs. Control group.

	MMSE	NPI	HADS-A	HADS-D	GAD	CBI-R
Δ gain	1.261111	-0.55556	-1.19281	-2.16013	-3.89542	-0.16667
t-test p	0.25457	0.846744	0.058819	0.000303	4.46E-05	0.967127
Cohen d	0.369844	-0.08228	-1.05793	-1.49249	-2.20387	-0.01643
d- lower	-0.27598	-0.58897	-0.01466	0.62649	0.872475	-0.63958
d-upper	1.043425	0.718031	1.349881	2.107926	2.418448	0.667077
r effect	0.195035	-0.03343	-0.32707	-0.57786	-0.64841	-0.00712
mw p	0.116473	0.886625	0.010812	0.000663	2.53E-05	0.899216
r effect	0.308642	0.030864	0.496732	0.666667	0.830065	0.027778

Δ gain: Average gain (average score post-treatment minus average score pre-treatment) for Treatment group minus average gain for Control group. Two-sample t-test conducted comparing these gains (p-value, Cohen’s d effect size, 95% confidence interval on Cohen’s d, and r effect sizes provided). A Mann-Whitney (mw) non-parametric test was also conducted to compare these gains (p-value and r effect sizes provided). MMSE: Mini-mental state evaluation; NPI: UCLA Neuropsychiatric Inventory; HADS-A and HADS-D: Hospital Anxiety and Depression Scales; GAD: General Anxiety Disorder-7; CBI-R: Cambridge Behavioral Inventory.

We also observe that the effect size for HADS-D ($d = -1.49$, $r = -.58$) and GAD ($r = -.83$) is very large. The effect size for HADS-A is also large based on Cohen’s d ($d = -1.06$) and medium-sized based on the r effect size ($r = -.33$). The effect size for the other three instruments is small or near zero. Note too that a 95% confidence interval for Cohen’s effect size for HADS-D is (.63, 2.11) and (.87, 2.42) for GAD, which represent large effects even at the lower end of the confidence interval. For GAD, we could also use a Brunner-Munzel non-parametric test. We again obtain a highly significant result: $p = 6.8E-10$ with an effect size of $r = .92$ and a 95% confidence interval of (.82, 1.00). Finally, we note that although the mean score of UCLA-NPI for the Treatment group increased by 73.3% (see Table 6) and that of the Control group by 126.7% (see Table 7) over the timeframe of the pet therapy, there isn’t a significant difference between the two groups ($p = .85$) and the effect size is close to zero ($d = .08$). Clearly there was a degeneration in the UCLA-NPI scores for both groups that was not made better by pet therapy.

Comparing Pre/Post for the Treatment group

Our goal was to compare the mean difference between the post- and pre-treatment scores for the Treatment group for each of the six instruments. The data for all the instruments are normally distributed based on the Shapiro-Wilk test and fail for the D’Agostino-Pearson test only for the HADS-A and GAD instruments. To stay on the cautious side, we used the Signed-Rank nonparametric test for these two instruments and the paired t-test for the other four. As usual, we report the findings of both statistical tests for all six instruments, as shown in (Table 6). We obtained a significant result for UCLA-NPI ($p = .033$), HADS-A ($p = .0163$), HADS-D ($p = .00030$), and GAD ($p = .00074$). Since we used six tests, we employed a Bonferroni correction whereby the significance level became $\alpha = .05/6 = .008333$. On this basis, only HADS-D and GAD showed a significant difference between the pre- and post-treatment scores. We also observe that the effect size for HADS-A ($r = .71$) and GAD ($r = .96$) are very high, as well

as the effect size for HADS-D ($d = -0.68, r = -.75$) and UCLA-NPI (73% increase, $d = .75, r = .49$). The effective size for MMSE and CBI-R is small Even at the low end of the Cohen's d confidence interval, GAD has at least a medium-sized effect.

Table 6: Pre/Post Testing for Treatment group.

	MMSE	NPI	HADS-A	HADS-D	GAD	CBI-R
mean	1.227778	5.5	-1.47059	-1.88235	-3.11765	-5.66667
% change	6.50%	73.30%	-25.30%	-31.40%	-44.90%	-13.20%
t-test p	0.112133	0.032538	0.016616	0.000303	0.000353	0.096575
Cohen d	0.256473	0.75081	-0.4536	-0.67923	-1.22457	-0.36711
lower d	-0.05897	0.061306	-0.81496	-1.04509	-1.89087	-0.7892
upper d	0.564987	1.421328	-0.08067	-0.30049	-0.53477	0.064819
r effect	0.376468	0.491607	-0.55583	-0.75383	-0.74841	-0.39239
sranks p	0.107935	0.025942	0.016286	0.001322	0.000738	0.060992
r effect	0.463235	0.620915	0.708333	0.941667	0.963235	0.508772

Mean: average gain (i.e. average post-treatment score minus average pre-treatment score for those in the Treatment group) for each instrument. % change: Percentage gain. Paired t-test conducted comparing pre- and post-treatment scores (p-value, Cohen's d , 95% confidence interval for Cohen's d , and r effect sizes provided). In addition, a Signed-Rank (srank) non-parametric test comparing pre- and post-treatment scores (p-value and r effect sizes provided). MMSE: Mini-mental state evaluation; NPI: UCLA Neuropsychiatric Inventory; HADS-A and HADS-D: Hospital Anxiety and Depression Scales; GAD: General Anxiety Disorder-7; CBR-I: Cambridge Behavioral Inventory.

Table 7: Pre/Post Testing for Control group.

	MMSE	NPI	HADS-A	HADS-D	GAD	CBI-R
mean	-0.03333	6.055556	-0.27778	0.277778	0.777778	-5.5
% change	-0.20%	126.70%	-4.80%	4.80%	11.10%	-16.60%
t-test p	0.967401	0.001415	0.310544	0.426753	0.079258	0.034328
Cohen d	-0.00736	0.67708	-0.05861	0.066679	0.144495	-0.27463
lower d	-0.35518	0.254602	-0.16942	-0.09631	-0.01659	-0.52238
upper d	0.340671	1.085549	0.053849	0.227758	0.301747	-0.01991
r effect	-0.01006	0.67821	-0.24574	0.193746	0.412479	-0.4873
sranks p	0.647198	0.001108	0.327489	0.495131	0.076336	0.033882
r effect	0.128655	0.933824	0.377778	0.242424	0.533333	0.610294

Mean: average gain (i.e. average post-treatment score minus average pre-treatment score for those in the Control group) for each instrument. % change: Percentage gain. Paired t-test conducted comparing pre- and post-treatment scores (p-value, Cohen's d , 95% confidence interval for Cohen's d , and r effect sizes provided). In addition, a Signed-Rank (srank) non-parametric test comparing pre- and post-treatment scores (p-value and r effect sizes provided). MMSE: Mini-mental state evaluation; NPI: UCLA Neuropsychiatric Inventory; HADS-A and HADS-D: Hospital Anxiety and Depression Scales; GAD: General Anxiety Disorder-7; CBR-I: Cambridge Behavioral Inventory.

Comparing Pre/Post for the Control group

Here we compare the mean difference between the post- and pre-treatment scores for the Control group for each of the six instruments. Since the Control group didn't get any AAT or substitute treatment, we didn't expect any significant or even sizable effect, except as may be obtained due to the ageing process or progression of any illnesses. In any case, such an effect should be a component of the Treatment group as well, and so may be (at least partially) eliminated in the Treatment vs. Control group analysis. The data for all the instruments are normally distributed based on the D'Agostino-Pearson test, except for GAD, which also

fails the Shapiro-Wilk normality test. HADS-A and HADS-D also fail the Shapiro-Wilk test. To stay on the cautious side, we used the Signed-Rank nonparametric test for GAD, HADS-A, and HADS-D and the paired t-test for the other three. Once again, we report the findings of both tests for all six instruments, as shown in (Table 7). We see from Table 7 that there is a significant difference for UCLA-NPI ($p = .0014$) and CBI-R ($p = .034$). Only UCLA-NPI is significant when the Bonferroni correction is used, whereby $\alpha = .05/6 = .008333$. UCLA-NPI shows a large effect (127% increase, $d = .68, r = .68$) as does GAD ($r = .53$). CBI-R likely shows a medium-sized effect ($d = -.27, r = -.49$).

Other Testing Approaches

There are two other commonly used approaches for carrying out the Treatment vs. Control and Pre- vs. Post-treatment analysis: Repeated-measure ANOVA (or alternatively repeated-measures MANOVA) and ANCOVA.

For repeated-measures ANOVA, we have one within-subjects

factor (pre/post) and one between-subjects factor (group). We need a separate ANOVA for each of the six instruments. Since there are only two levels for the within-subjects factor, sphericity = 1, and so there is no need to test for sphericity. For this reason, we decided that there was no need to look at the MANOVA approach. For the UCLA-NPI instrument, the output from the repeated measures ANOVA is as shown in (Figure 1).

ANOVA	SS	df	MS	F	P value	P Eta-sq
Between Subjects	3409.944	35				
- Rows	107.5556	1	107.5556	1.107347	0.300081	0.031542
- Error	3302.389	34	97.12908			
Within Subjects	1844	36				
- Columns	600.8889	1	600.8889	16.45313	0.000276	0.326107
- Interaction	1.388889	1	1.388889	0.03803	0.846544	0.001117
- Error	1241.722	34	36.52124			
Total	5253.944	71	73.99922			

Figure 1: Repeated-measures ANOVA (UCLA-NPI).

The p-value for the Interaction of the between-subjects and within-subjects factors in the repeated measures ANOVA is equal to the p-value for the two independent samples t-test between the Treatment and Control groups (under the equal variances assumption). In the ANCOVA approach, we treat the pre-treatment scores as the covariant. Once again, we need a separate ANCOVA model for each instrument. For the UCLA-NPI instrument, the parallel slopes assumption is violated, and so we didn't pursue this approach further.

Discussion

Based on the data collected in the study and the comparison of the results obtained, we noted that Animal Assisted Therapy significantly increases the patient's state of well-being thanks to a decrease in states of anxiety and depression in patients with cognitive deficits in an institutionalized setting. The behavioural and cognitive aspects studied through the administration of UCLA- NPI, CBR-I and MMSE did not show significant differences in the pre and post treatment. It should though be noted that even if the increase in the UCLA-NPI in the post treatment assessment shows a large effect size in both groups: (127% increase, $d = .68$, $r = .68$ in the control group) (73% increase, $d = .75$, $r = .49$ in the treatment group) the lower increase in the treatment group of core symptoms is interesting from a clinical perspective suggesting that AAT may 'buffer' overt psychopathological sequelae and thus be worthy of further investigation. There are some potential limitations to the generalizability of these findings. The groups were selected from a single nursing care facility, even

if it should be noted that the facility is a National Health Service accredited clinical institution where patients from highly diverse socio-economic and socio-cultural backgrounds are represented, suggesting that the findings have broad relevance. Another potential limitation is that all patients are of Italian origin and each sample presents a higher percentage of female patients with respect to males. This distribution is consistent though with the Italian population where individuals over 65 account for 23 % of the total population and about 60 % are women with a four year longer life expectancy than males.

Conclusion

This study concludes though that Animal Assisted Therapy can be a valid, effective and useful non-pharmacological treatment modality in the implementation of the biopsychosocial model for institutionalized elderly by enabling patients to better face a fragile phase of their life [18,19] The improved psychophysical well-being of the group that participated in the AAT sessions should be investigated over time to evaluate the duration of the effects detected by our study and further research is recommended to investigate in greater depth the behavioural and cognitive disorders in the institutionalized patients having received dog-mediated Animal Assisted Therapy.

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Disclosure statements:

The study was carried out in total compliance with the National Guidelines of the Italian Ministry of Health regarding Animal Assisted Interventions. Informed consent to participation to the study was obtained by the patients or their legal guardians in accordance with Italian law, art.1 law 219/2017. The Authors have no potential conflicts of interest or funding to disclose. Data concerning the study are available on request. The study was approved by ORPEA ethical committee and complies with the Declaration of Helsinki 2013.

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