**INTRODUCTION**

The use of animals for therapeutic purposes dates back, although it only became popular after the 1960s. Animal assisted therapy (AAT) is commonly incorporated into therapy programmes for elderly subjects and patients with dementia as AAT sessions can bring about normalisation of blood pressure and induce neurochemicals associated with relaxation and bonding.

At present, contact with animals is part of many programmes for care of the elderly, particularly those with cognitive disturbances. Some facts in favour of this approach are:

a) animals are active living beings;

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1 Prof. Aldo V. Bono, coordinator of the study, died on 24 August 2014. He had just prepared and circulated the draft of the manuscript to the co-authors that wish to acknowledge the great passion of Aldo V. Bono for Medical Research and his ability to involve and motivate his coworkers.
b) they interact with humans;
c) they willingly accept humans;
d) they are able to proffer emotional support and;
e) to stimulate feelings of responsibility toward other people^2^-^4^.

In a controlled clinical study in subjects without cognitive impairment but resident in geriatric care institutions, three groups were compared: contact for three months with either a canary or a house plant, and control group^6^. At the study end, the group in contact with birds showed a significant improvement in Brief Symptom Inventory ^7^ and core Quality of Life tests compared to the house plant and control groups.

A number of reports suggest that AAT, also termed Pet-Therapy, set up with a variety of animals, may be beneficial to older people^3^-^8^-^12^.

AAT has mostly primarily been carried out with dogs, and is often used in various clinical settings with subjects who display cognitive impairment and dementia and somewhat satisfactory outcomes have been observed^2^,^4^,^5^,^12^.

Unfortunately, reports on the efficacy of AAT in cognitive impairment are frequently flawed due to poor methodological design, an absence of correlative data between efficacy and the level of dementia, concomitant drug treatments, reports using small sample sizes and anecdotal positive results^13^.

Consequently, conclusive evidence for the efficacy of this kind of therapeutic support is still lacking^14^.

Nevertheless dog-AAT does seem to decrease aggressiveness and psychotic symptoms^3^ and, quite frequently, to bring about a reduction in “mental stress”^14^.

In most instances, dog-AAT is administered bi-weekly in one-hour sessions for six to eight weeks^15^.

While most dog breeds can be involved in AAT, not all animals possess the suitable traits to be eligible; in fact candidate dogs should be friendly and non-aggressive, confident, patient, calm, gentle and receptive to training.

Following these considerations, aim of the present study was to verify the clinical effect of a medium term dog-AAT applied for eight months to non-hospitalised patients affected by low/mild stage cognitive impairment due to Alzheimer’s disease (AD) versus a control group.

MATERIAL AND METHODS

The controlled, parallel group, randomised study was approved by the Ethical Committee of Molina Foundation, site of the study.

A Veterinary Committee (AP and EV) selected three dog breeds, Border Collie, Golden Retriever and Weimaraner, due to their calm demeanor, gentle disposition, and friendliness to strangers. Candidate animals all belonged to the group of animals selected by the European Institute of Psychology for various activities intended for disabled people. They were housed in human families when they were 60 days old and then gradually exposed to various situations such as contact with humans (adults, children, elderly individuals, etc.), and trained to learn to live together with other dogs and taught basic commands. The dogs were then examined by the Committee, who assessed their health, their behaviour when placed in contact with humans and their ability and suitability (in terms of obedience) for involvement in the study. Then the selected dogs were submitted to specific training with their trainers (EV, MP, TP, VC) in compliance with the Institutional Care and Use of Animals Committee of Molina Foundation and of European Institute of Psychology. The animals finally selected for the study were: 1 male Golden Retriever (age: 3 years), two female Border Collies (age 2 years) and one female Weimaraner (3 years old).

Outpatients diagnosed with minor-to-mild AD (Group A1 and 2 class of DMS-IV-TR) at the Neurology Department of University Hospital (Alzheimer Evaluation Unit) were examined in our Memory Office by a Psychologist’s team (RC, PC, CM) and classified by means of Mini-Mental State Examination (MMSE)^16^.

Patients with MMSE scores between 24 and 16 were judged eligible for the study (by CM) if they had not been pet-owners or in contact with dogs during their life, if no general illness was evident or, in case of co-morbidity, the disease was controlled by a therapy taken at home.

Exclusion criteria were the use of concomitant specific drug therapies or alternative medicine interventions such as music therapy, shiatsu massage, etc. A detailed and fully informed consent was signed by the participant, care-giver or legal representative. The study was carried out according to the Principles of the Helsinki Declaration (1975, rev. 2000) and to the guidelines of PHS and of NIH for the care and use of animals and followed the US Gov. Principles for the utilization and care of animals used in testing, research and training. Informed consent was obtained by patients/ caregivers that were
made aware about the possibility that the AAT could be interrupted in about a quarter of cases, as this must be expected when planning dog AAT in dementia patients. Participants were centrally randomised into two groups: AAT (AAT group) and Controls (C group). AAT consisted of bi-weekly one-hour sessions for 8 months, and the control group was followed at home at the same intervals. Participants were allowed to postpone the sessions of AAT or control visits for no more than one week.

The AAT sessions were run at Memory Clinic where participants were individually put in contact with animals and their tutors, doing specific and standard activities that can be summarised as follows:

1. Cognitive stimulation (spatial-temporal orientation, mnemonic stimulation, dog “introduction” to the patient (contact, name, profiling of the animal), identification of the dog breed looking at illustrations, recalling of personal events with animals, learning basic commands, remembering some play with the animal);
2. Communication (learning the body language of the animal, stimulating relationship with other participants);
3. Motor activity (strolling with dog; petting the dog; throwing a small ball; grooming the dog; stimulation of manual skills);
4. Wellbeing and entertainment.

At baseline and after 8 months, the psychologist's team assessed Barthel index 17 to evaluate daily activities, ADAS test (Alzheimer disease assessment scale) 18 sensitive instrument to characterise symptoms of cognitive impairment scored from 0 non abnormality to 70 max abnormality and Cornell Scale 19 in both groups of subjects.

At 3 and 5 months, compliance with the protocol and any factors possibly impacting on patient attendance of the sessions were checked. These could include medical contraindications such as intervening deterioration of cognitive disturbances or worsening of general conditions or practical issues such as the onset of logistical problems hampering transportation from home to the clinic. The sample size of 12 subjects for each group was calculated expecting an objective response in 50% of AAT cases (literature reports AAT is beneficial in all cases of minor or mild AD) 2, with a power of 80% and alpha = 0.01 (one-tail test).

The statistical analysis was performed comparing the two groups by the Mann-Whitney U-test for non-parametric independent data on 8-month absolute differences versus baseline, which were established as the endpoint of the study.

Data management was performed by MB and CR and statistics by CB. The study was coordinated by AVB and CB.

RESULTS

Thirty-two AD outpatients with minor/mild cognitive disturbance, living at home with family members or caregivers enjoying standard, good quality home care, were enrolled into the study, 16 in each group. Mean MMSE test score at baseline was 17.26 ± 3.66 SD. Eight cases, 4 in AAT and 4 in C group, withdrew from the study because of: intercurrent disease in 2 cases on AAT (1 femoral fracture and 1 cerebral-vascular accident), referral to another institution because of onset of behavioural disturbances (1 case) or logistic problems or refusal to continue the study for the remaining 5 cases. Therefore, 24 patients (12 AAT and 12 C) were finally considered eligible for the analysis. In both groups there were 8 females and 4 males, the mean age was 82.1 years ± 6.2 (SD) for AAT and 78.3 ± 10.3 in the C group.

None of the dogs showed signs of stress (such as frequent lip and nose licking or yawning, pinned back ears, etc.) when working for the study.

In 29.2% of cases (7/24) no drug was taken by the patients during the study period, whereas in 17 (70.8%) some kind of therapy was regularly taken, consisting of multi-drug therapy in 41.6% (10/24), mostly to address mild hypertension or mild CV diseases. None of patients required specific Alzheimer's or other drugs active on CNS during the study period.

Table I shows the results of Barthel index, ADAS test and Cornell scale at baseline and after 8 months. At 8 months, Barthel index was -1.2% in AAT group vs - 2.5% in the control group; ADAS score was + 16.2% in AAT group vs + 36.6% in controls; Cornell scale was + 52.1% for AAT and - 28.4% in controls. The absolute differences between baseline and final values in the AAT group were statistically significant different from the control group.
DiscUssIOn

Our goal was to check whether AAT administered alone could have some influence on the evolution of AD in its early stages as reported in some meta-analysis.

The study confirms the feasibility of a medium-term period of AAT with dogs in persons with low or mild AD not receiving pharmacological treatment, even if this experience shows that dog AAT can be carried out with some difficulty, because unexpected events may hamper the smooth progress of the AAT sessions, yielded some reliable results. They can be summarised as follows.

Barthel index evaluates daily activities, where higher values correspond to a less deteriorated daily life. The less reduced Barthel index in AAT group may mean a lower impairment of daily life activities.

As high ADAS scores have positive correlation with high cognitive impairment, the statistically lower increase of ADAS in AAT group versus C may represent a slowing down of cognitive impairment in Alzheimer’s disease.

The Cornell scale score remained below 9 in both groups during the study period and this outcome demonstrates the absence of a depressive syndrome, when patients can rely on regular and periodical assessments which also consist of interviews with psychologists who administer the tests, but at the same time also give support to the patients and caregivers.

Some methodological consideration can be underlined for a better interpretation the data. To minimise dropouts during the study the patients were considered eligible if no general illness was evident or, if a co-morbidity was present, when the disease was controlled by a therapy taken at home.

Reliability of our data is assured by the selection of the appropriate dog breeds, identifying the best eligible animals characterised by calm demeanour, gentle disposition, and friendliness to strangers as suggested by the Veterinary Committee.

The three dog breeds used in the study were selected among the ones suggested by the Pet Therapy Group of the European Institute of Psychology.

Dog size could influence the relationship between dogs and patients (Marx) as some people are not comfortable with dogs of larger breeds (Matuszek).

The contact with animals never exceeded one hour, as this is the maximum time during which our animals are able to provide a coordinated activity, and it is inadvisable to tire participants to prolonged sessions not to compromise their capability to collaborate.

Lengthening the AAT therapy trial period to 12 months or more could probably enhance the improvements in the objective findings and show, in some cases, a more significant slowing down in the progression of cognitive disturbance. This appears to be difficult within a controlled trial considering the high drop-out rate due to logistical problems. One possibility could be to offer dog-AAT at the patient’s home (with obvious difficulties) or to arrange it at Memory Clinics, as our Association is currently doing since the completion of the present study.

An extensive multicentre controlled study is required to reach a higher statistical power, even if objective difficulties of keeping homogeneity (dog selection, characteristics of activities, etc.) make such a project unfeasible.
Objectives. Animal assisted therapy (AAT), also termed Pet-Therapy, may be beneficial particularly to older people with cognitive disturbances. Efficacy evaluation of AAT in cognitive impairment is frequently biased by poor methodological design, and conclusive evidence is still lacking. Aim of this study was to verify the clinical effect of a medium term dog-AAT in non-hospitalised patients affected by mild cognitive impairment due to Alzheimer’s disease (AD) versus a control group.

Methods. The controlled study included out-patients diagnosed with early stage or mild AD and centrally randomised into two groups: AAT treatment with dogs and Controls (C) both followed for eight months. At baseline and after 8 months, Barthel index (functional status), ADAS test (AD Assessment Scale for cognitive status) and Cornell Scale (depression condition) were assessed. The statistical analysis was performed by the Mann-Whitney U-test for non-parametric independent data.

Results. Twelve patients for each group (aged 82.1 and 78.3 years in AAT and Controls) were evaluable at 8 months. In AAT group, Barthel index showed less deterioration in daily life activities, ADAS test indicated a slowing of the progression of AD, and Cornell scale showed the absence of a depressive syndrome.

Discussion. This study confirms the feasibility of AAT with dogs in low-mild AD. AAT lead to a lower impairment of daily life activities, and cognitive deterioration. An extensive multicentre controlled study is required to reach a higher statistical power, even if objective difficulties of keeping homogeneity (dog selection, characteristics of activities, etc.) make such a project unfeasible.

Key words: Animal assisted therapy, Cognitive impairment

REFERENCES