Clinical Trial for Stuttering Treatment: pilot study about dog participation in the therapy session

Ensaio Clínico de Tratamento da Gagueira: estudo piloto com variável monitorada, participação do cão na sessão de terapia

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ABSTRACT

Purpose: To verify the effect of dog intervention on the regular session of speech therapy for developmental stuttering in adults. **Methods:** The study involved young adults and adults with developmental stuttering. The study sample was composed of eight participants, six males and two females, ranging in age from 16 to 45 years. Participants were divided into two groups: G1 – those who underwent treatment for stuttering with the presence of a dog-therapist in the therapy room and G2 – those who underwent treatment for stuttering without the presence of the dog therapist. We included a control group, G3, composed of fluent participants, matched in age and sex to G1 and G2 to control the natural variability of speech fluency. **Results:** Comparative results between the groups indicated that the group that performed the treatment without the presence of the dog achieved better performance, evolution and efficacy rates. **Conclusion:** for the population in this study, the dog intervention on speech therapy did not improve treatment.

RESUMO

Objetivo: Verificar o efeito da intervenção do cão na sessão regular de terapia fonoaudiológica para a gagueira do desenvolvimento em jovens adultos. **Método:** Foram selecionados jovens adultos e adultos com diagnóstico de gagueira do desenvolvimento. Concluíram o estudo oito participantes, seis do sexo masculino e dois do sexo feminino, com idades variando entre 16 e 45 anos. Os participantes foram divididos em dois grupos: G1 – que realizou o tratamento para gagueira com a presença de um cão terapeuta em sala de terapia e G2 – que realizou o tratamento para gagueira sem a presença do cão terapeuta. Foi incluído um grupo controle, G3 – composto por participantes fluentes, pareado em idade e sexo ao G1 e G2, para controle da variabilidade natural da fluência da fala. **Resultados:** A análise comparativa entre os grupos indicou que o grupo que realizou o tratamento sem a presença do cão alcançou melhores índices de performance, evolução e eficácia. **Conclusão:** Para a população pesquisada neste estudo, não foi observado efeito da intervenção do cão na terapia fonoaudiológica.

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INTRODUCTION

Stuttering is a neurodevelopmental, multifactorial disorder characterized by involuntary disruptions of the speech flow from the non-coordination between neural commands and effector muscle action[1].

Although without the strict methodology of a clinical trial, the stuttering treatments validated with efficiency control publications are those based on speech restructuring; breath regulation; stimulus-response; cognitive-behavioral models, and hearing feedback[2]. There are several international publications on treatments for stuttering, and most authors concluded that patients improve immediately after treatment and lose some of this improvement over 12 months in a late evaluation. These studies are heterogeneous and inconsistent, without replicable methodologies, without conclusions and reliable evidence, making meta-analyses unfeasible[3].

Clinical trial designs represent the methodological evolution to prove diagnostic and treatment protocols. Treatment clinical trials are those in which an intervention is applied, and its effects are controlled. Classic clinical trials are conducted with drugs. In the speech therapy area, efforts are the possible adaptations for the application of this method in therapeutic processes. In clinical trials, the primary concern is the safety and effectiveness of the treatment offered to the patient. In the group design, care should be taken that one group receives the intervention to be tested and the other group receives a comparative intervention or the same intervention without a test variable (marker), for example. The number of participants in each group is important to identify a population that is feasible to generate an outcome effect. In the randomization of the participants, the groups are distributed equally by random variation, that is, intentional or unintentional factors are prevented from influencing the study results. As for blinding, those responsible for evaluation and outcome measures should not be the same researchers who know the participants, and the participants distribution in the groups is important. This measure aims to protect the study from personal and circumstantial biases[4-11].

In a clinical treatment trial, it is important to outline the variables that will be measured to determine the effect of the intervention. In the case of stuttering, due to its multifactorial characteristics and the diversity of therapeutic approaches - many of these approaches are poorly described - the only indicator accepted by most researchers for scientific purposes is the percentage of stuttered syllables per minute. Venkatagiri[12] presented a study describing the difficulty to find a measure to evaluate the effectiveness of stuttering treatments. The author assessed the indicators produced by people who stutter, who had completed their stuttering treatments and asked them to define what they considered to be their success in the therapy. The two most prevalent definitions were: the ability to manage to stutter (but lazy to do so all the time), and freedom (realizing that they would always suffer frustration and embarrassment, but did not want to change their attitudes and emotions to adjust to a pattern).

Based on these considerations, this research aimed to develop a clinical treatment trial that associated the objectivity and consistency of scientifically proven techniques for the reduction of stuttering with a variable that softens the implicit seriousness and formality paradigm in the therapy. The variable would make the therapy session more serene and welcoming. Thus, we introduced the concept of the animal-assisted intervention.

Animal Assisted Intervention (AAI) is a therapeutic approach that aims to systematically incorporate animals into therapeutic rehabilitation contexts in health, education and social work, according to the International Association of Human - Animal Interactions Organizations (IAHAIO). This type of intervention includes the active participation of animals to provide therapeutic benefits. Animal Assisted Intervention consists of three subcategories: Animal Assisted Therapy (AAT), Animal Assisted Education (AAE), and Animal Assisted Activity (AAA). Thus, Animal Assisted Therapy is an alternative for treatments in the area of rehabilitation increasingly used[13].

Some studies in the literature indicate that AAT can have positive therapeutic results in different rehabilitation areas, such as treating adults with schizophrenia, depression, alcohol and drug addiction, heart problems, arthritis, osteoporosis, depression, cancer, Alzheimer's and victims of domestic violence[14]; in the treatment of children with autism or mental disorders[15], and in the reduction of stress in the hospital context[16,17].

Some reports showed that the interaction with the animal makes individuals more motivated to interact, communicate, and express needs, information and feelings. In the national literature, two master dissertations[18,19] on the topic with positive qualitative results were found. In both studies, there was no comparative verification with a control group.

We found three publications specific to speech therapy in the international literature, with case studies of aphasia and specific language disorder[20-22]. In these case reports, there was no formal quantitative or qualitative assessment. The idea of the reports was the AAT proposition for difficult cases in which patients were in severe or much unmotivated clinical conditions. Also, two personal experiences of speech therapists were found in the monthly ASHA (Leader) journal, who volunteered with therapist dogs and introduced these dogs to their clinics with some patients who they thought could benefit from the experience[23,24].

The clinical trial developed in this research aimed to verify the effect of dog intervention in the regular speech therapy session for stuttering. The clinical treatment trial methodology was used to verify the outcome effect of dog participation, identifying its effectiveness, and estimating its magnitude. The hypothesis of the monitored variable - dog presence – was that the dog's interaction with the patient provided a therapeutic depathologization environment, enabling greater patient involvement with the techniques used during therapy sessions. The basic treatment adopted for the clinical trial was the Speech Therapy Program to Promote Fluency I (STPPF 1)[25], which is currently in phase V of its validation as a treatment model, that is, it has already been validated in all clinical stages, and today it is applied throughout Brazil and South America, as being considered efficient, safe and gold standard in its proposal.

METHODS

The Research Ethics Committee of the Institution approved the study (CEP-1,856,900). Data collection procedures only began after signing the informed consent form by all the research participants.

Participants

As shown in the flowchart (Figure 1), the study sample included eight participants among the 48 adult individuals who spontaneously sought specialized care for stuttering at the Fluency, Speech, and Dysphagia Laboratory of the Department of Physiotherapy, Speech Therapy, and Occupational Therapy from the Faculty of Medicine of the Universidade de São Paulo. Study participants were diagnosed with developmental stuttering based on the following criteria: speech disruption onset during language acquisition and development phase (mainly between 18 and 60 months old); current persistence of symptoms; Speech Fluency Profile score[26] outside the reference values for their age[27], and at least MILD stuttering level according to the Stuttering Severity Instrument - 3 (SSI-3)[28]. All study participants are native speakers of Brazilian Portuguese; without additional complaints related to communication (language, voice, articulation, oral motor skills, and hearing); without history of neurological and/or neurodegenerative diseases, and education of at least 12 years (equivalent to complete high school).

The eight participants were divided into two groups: Group 1 (G1) and Group 2 (G2). Each group had four individuals, three male, and one female, aged 16 to 45 years old (mean 25.6 years old and standard deviation 21.76 years old). For inclusion in G1, two additional specific criteria were adopted: no fear or phobia of dogs, and no dog hair and/or saliva allergy.

A third group was also recruited for comparison, composed of four fluent individuals (Group 3 - G3). Their speech fluency of these subjects was assessed before inclusion in the study. All of them had the scores on the Speech Fluency Profile[26] within the reference values for their age[27] and with less than 10 points on the Stuttering Severity Instrument - 3 (SSI-3)[28], indicating normality for speech fluency. Participants included in G3 are all native speakers of Brazilian Portuguese, without communication-related complaints (language, voice, articulation, oral motor skills, and hearing) and history of neurological and/or neurodegenerative diseases. G3 participants were matched to participants in Groups 1 and 2 by age, gender, and education level.

Speech fluency assessment and re-assessment procedures

Data were collected within six months. All study participants (Groups 1, 2 and 3) were assessed following the same methodology in two moments: initial assessment at the time of study inclusion and re-assessment after 12 weeks from the initial assessment.

Speech fluency was assessed and analyzed in both moments according to the methodology proposed by Andrade in 2004[26]. Speech samples from each participant were collected using a digital camcorder (SONY DRC-SR62). Participants were instructed to speak freely about a visual stimulus for five minutes. If necessary, the examiner could perform small interventions to stimulate their speech production.

Speech samples were transcribed and analyzed by a speech therapist with experience in stuttering and blind to the study. Orthographic transcriptions of the first 200 syllables expressed
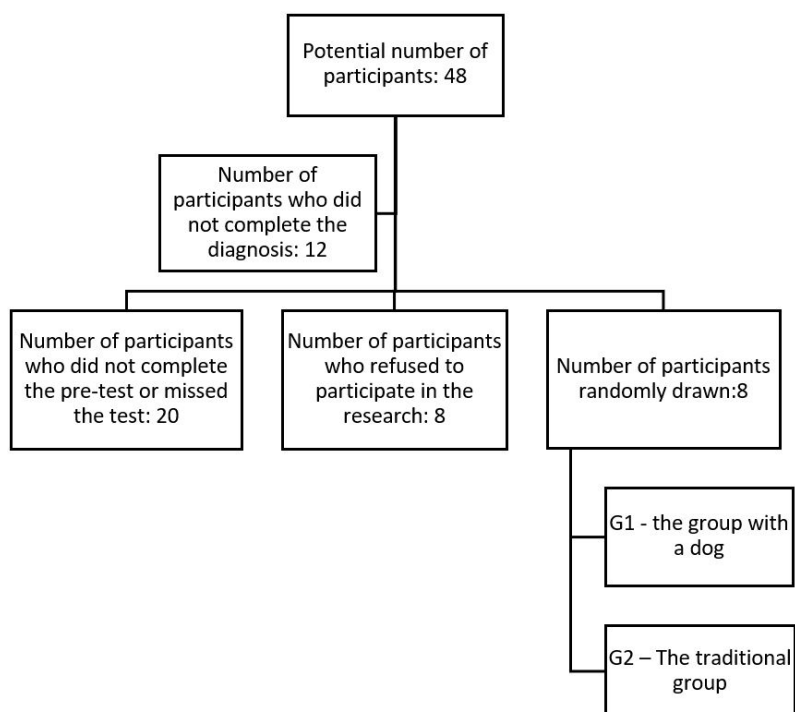

Figure 1. Participant Distribution Flowchart

in each of the speech samples were performed, in which the speech disruptions presented by the participants were identified and counted. Monosyllabic answers such as "yes" and "no" were excluded from syllable counting. Speech disruptions were classified as stuttering disruptions (repetition of sounds and syllables, prolongation of sounds and blocks) or common disruptions (repetition of words, repetition of sentences, interjections, reviews and repetition of segments).

Speech therapy treatment

During the 12-week interval between assessments, participants in G1 and G2 underwent the same cognitive (conscious, perceived as a person, a speaker, and as a stutterer) and a motor-based speech therapy (motor program activation of command, sensory consequence, and the result of movement). The presence of the dog in G1 was considered as the monitored variable for outcome potentiating effect.

Individual therapeutic sessions with all participants in Groups 1 and 2 were conducted by a speech therapist specializing in stuttering. The basic treatment used for both G1 and G2 was the Speech Therapy Program to Promote Fluency (STPPF)[25]. The STPPF has 50-minute sessions during 12 weeks, structured and based on the stimulation of four areas, which are worked out sequentially: body proprioception and location of tension; breath and voice; proprioception and articulatory tension, and specific techniques for reducing speech disruption. The program is structured in modules with progressive levels of complexity. This modality of cognitive therapy modifying articulatory pressure and temporalizing speech movements aims to smooth the movement of the articulatory organs and promoting a fluent speech pattern. All participants in Groups 1 and 2 were instructed to apply the techniques learned in therapy continuously and daily at all times of social interaction involving speech. Participants with two or more absences during the therapeutic process were removed from the research.

The treatment applied to participants in G1 was adapted to accommodate the presence of the therapist dog, who participated in all sessions with activities previously outlined. Two dog therapists from the organizations *Instituto Cão Terapeuta* and *Amor Canino Terapia*, Golden Retrievers and with experience in working in health and education participated in this study. The animals underwent periodic veterinary medical follow-up to control flea, tick and/or other skin parasites infestation and perform protocol examinations for digestive parasites. Vaccination of animals against rabies, V8, V10, giardia and canine cough was also by the veterinary calendar[29].

Before the inclusion in this study, the dogs were tested and exhibited desirable reactions in response to unknown people; loud sounds; unpredictable visual and sound stimuli; aggressive human voice; threatening gestures; places with a large concentration of people; vigorous and clumsy cuddles (such as strong hugs), and/or the presence of other animals. Both dogs were also tested and approved beforehand for their ability to obey commands such as sitting, lying down, and standing still[29].

During the sessions, the dogs were taken by their tutors, both professionals trained in Psychology and experienced in Animal Assisted Intervention. Thus, the following were present in the room during the animal-assisted therapy sessions: one of the G1 participants, the speech therapist, one of the therapist dogs, and their respective handler. The same dog handler, chosen at random, participated in all sessions with each participant.

In some therapeutic sessions, the dog's participation was passive: the animal was wearing a vest containing pictures, words, and phrases that should be drawn by participants and used as a speech stimulus during specific speech-language exercises. In other sessions, the dog's participation was active: the animal selected an object among some possibilities that the participant should also use as speech stimulus during the exercises proposed by the speech therapist. Participants were allowed to interact with the dog voluntarily during all sessions.

The dogs followed the same routine before the interactions throughout the treatment. This routine involved coat bathing and brushing 24 hours before the therapeutic sessions, regular nail grooming, and weekly cleaning of the collars and leashes. Also, the study participants, the speech therapist and the dog handler cleaned their hands before and after all interactions with the animals[29].

The handler was free to stop the dog-participant interaction immediately if the animal manifested any behavior of fear or aggression. The interaction could also be suspended immediately in the event of signs and symptoms of illness, such as vomiting, diarrhea; urinary and/or fecal incontinence; cough; sneeze; skin lesions and/or alterations, and otitis[29]. However, there were no complications that would require suspension of care.

Data analysis

The collected data were submitted to statistical analysis using the SPSS version 25 software. Nonparametric tests were used for all inferential analyses, with a significance level of 1% due to the number of participants in the sample. Descriptive analyses (mean and standard deviation) and inter and intragroup comparisons (initial assessment × re-assessment) were performed using Fisher's Exact Test.

The results of the initial fluency assessment and re-assessment are shown in Table 1. For G1, we observed a significant difference between the initial assessment and the re-assessment for the SSI-3 score. There was no variability in the percentage of stuttered syllables. G2 showed a significant difference between the initial assessment and the re-assessment, both for the percentage of stuttered syllables and the SSI-3 score. As expected, G3 showed no significant difference between the two data collection occasions, indicating that speech fluency does not suffer statistically significant variability over the established control time.

The comparison between groups indicated no significant differences between Groups 1 and 2 for any of the parameters analyzed in the initial assessment (percentage of stuttered syllables - $p = 0.054$; total score according to the SSI test - $p = 0.550$) and the final assessment (percentage of stuttered syllables - $p = 0.660$; total score according to the SSI test - $p = 0.448$), according to Fisher's Exact Test.

The comparison between G3 and Groups 1 and 2 showed significant differences for all parameters analyzed at the initial assessment (percentage of stuttered syllables - $p = 0.017$ for G1 and $p = 0.001$ for G2; total score according to the

SSI test - p < 0.001 for G1 and p = 0.026 for G2), and for all parameters in the final assessment (percentage of stuttered syllables - p = 0.001 for G1 and p = 0.007 for G2; total score according to the SSI test - p <0.001 for G1 and p = 0.001 for G2), according to Fisher's Exact Test.

We also analyzed the performance calculation before and after treatment[30] due to the number of participants. This calculation allows quantifying the individual measurement of the phenomenon under study. The calculation of the performance rate is established by the relationship between the result obtained by the individual in the pretreatment assessment (numerator) and the mean reference value (denominator) for his age and gender. This numerical relationship expressed the degree of

deviation between the participant and his peers. The closer the ratio is to 1, the lower the degree of deviation.

As a complement, we performed the Evolution Calculation[30], established by varying the individual performance to increase the sensitivity of quantifying treatment effect. The evolution calculation is determined by the relationship between the participant's performance value obtained in his pretreatment assessment (numerator) and the value obtained in his post-treatment assessment (denominator). This relationship increases the accuracy to represent the effective personal gain obtained with the treatment.

The results of the individual achievement calculations are shown in Table 2. For both G1 and G2, there was a positive

Table 1. Descriptive individual results of initial speech fluency assessments and re-assessment

ID	Group	Percentage of stuttered syllables		Total score SSI-3	
		IA	RE	IA	RE
11	1	8.5	5.5	28	20
12	1	4.0	3.0	21	16
13	1	4.5	4.0	22	19
14	1	14.0	6.0	33	24
Mean (± SD)		**7.8 (± 4.6)**	**4.6 (± 1.4)**	**26.0 (± 5.6)**	**19.8 (± 3.3)**
p-value			*0.166*		*0.020**
21	2	8.5	4.5	26	17
22	2	3.5	1.5	16	10
23	2	7.5	2.0	25	14
24	2	7.0	4.0	25	21
Mean (± SD)		**6.6 (± 2.2)**	**3.0 (± 1.5)**	**23.0 (± 4.7)**	**15.5 (± 4.7)**
p-value			*0.017**		*0.017**
31	3	0.0	0.0	0	0
32	3	0.0	0.0	0	0
33	3	0.0	0.0	0	0
34	3	0.5	0.0	0	0
Mean (± SD)		**0.1 (± 0.3)**	**0.0 (± 0.0)**	**1.0 (± 0.0)**	**0.0 (± 0.0)**
p-value			*0.391*		*1.000*

*Significant difference according to Fisher's Exact Test
Caption: IA = initial assessment; RE = re-assessment after 12 weeks; SD = standard deviation

Table 2. Performance and Evolution Gain Calculation Table for Quantifying Stuttered Syllables per Minute

ID	Group	Performance Assessment	Post-treatment Performance	Gain by the Evolution	Evolution Gain Percentage
11	1	3.89	2.52	1.54	54%
12	1	1.33	1.0	1.33	33%
13	1	4.01	3.57	1.12	12%
14	1	10.37	4.44	2.33	133%
Mean	1	4.05	2.88	1.40	**40%**
21	2	3.89	2.06	1.88	88%
22	2	1.16	0.5	2.32	132%
23	2	6.69	1.78	3.75	275%
24	2	5.18	2.98	1.75	75%
Mean	2	4.23	1.82	2.32	**132%**
31	3	0	0	0	0
32	3	0	0	0	0
33	3	0	0	0	0
34	3	0.37	0	0.37	0
Mean	3	0.09	0	0.09	0

difference in the participants' performance between the initial assessment and the re-assessment. As expected, Group 3 revealed no difference in speech performance between the two data collection occasions. In the individual analysis of the participants, the result of the G1 participants was lower than the result of the G2 participants.

DISCUSSION

This study aimed to verify the effect of dog intervention on regular speech therapy session for developmental stuttering in young adults and adults. The clinical treatment trial methodology was used to verify the therapeutic effect of dog participation, identifying its effectiveness and estimating its magnitude. The hypothesis of the monitored variable - dog presence - was that the dog's interaction with the patient provided a therapeutic depathologizing environment, enabling greater patient involvement with the techniques during therapy sessions. The test variable did not produce a predictive effect. Comparative results indicated that G2 (the group that performed the treatment without the dog) achieved better individual performance, evolution, and outcome indices, either as a group or as participants alone.

This study adopted a clinical treatment trial methodology[4-11]. By the number of participants, it was a pilot clinical trial, having followed all the necessary criteria for it. The study was an intervention study with monitored variable control, and the outcome measure was the reduction in the percentage of stuttered syllables per minute in the post-treatment assessment. Participants were allocated to G1 and G2 randomly. A blinded researcher transcribed the analyzes of pre and post-treatment speech samples from both G1 and G2, that is, a researcher who was unaware of the participants and the groups they were allocated.

Due to the nature of the proposed clinical treatment trial, both the therapeutic proposal and the control measurement were strictly objective, numerical, and aimed at reducing bias and sampling errors. We are fully aware that the outcome of the study is limited to the methodological conditions in which it was performed. New analyses, with different characteristics from those performed here are necessary and may contribute with additional important information. A different type of speech therapy treatment, which may be modulated as a clinical trial, may also result in different results from those obtained here.

The clinical trial should be considered as part of an evolving research program. Confirmatory results and repeated studies by other researchers are essential, replicating the conditions described, and producing the evidence for the advancement of science.

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Author contributions