

Changes in social functioning and engagement during canine-assisted intervention for children with neurodevelopmental disorders in the context of an early intervention service

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Abstract

Purpose. The objectives were to evaluate the feasibility of early implementation of a canine-assisted intervention (CAI) for children with neurodevelopmental disorders, and to determine the changes in social functioning and in engagement experienced by the participants.

Materials and methods. A CAI consisting of 24 sessions was piloted in an intra-subject quasi-experimental longitudinal design. The outcome measures were the Assessment of Communication and Interaction Skills (ACIS) and Individual Child Engagement Record-Revised (ICER-R).

Results. No adverse events or side-effects were noted. The sample consisted of 44 participants (median age 37 months). A total of 33 children (75%) attended all sessions. Main results showed that after completing the intervention, the overall ACIS score improved significantly ($p < 0.001$); the effect size was large. There was a significant improvement in the scales of the ICER-R from baseline to the final assessment: overall engagement ($p < 0.001$), frequency of repetitive

behaviours ($p < 0.001$), frequency of interaction between the child and adults ($p < 0.001$), and the quality of this interaction ($p < 0.001$); the effect sizes ranged from medium to large.

Conclusions. The early application was feasible. The results in the areas of social functioning and engagement suggest that this CAI may be a useful complementary strategy in early therapeutic intervention with these children.

Keywords

Autism spectrum disorder; Canine-assisted intervention; Early therapeutic intervention; Engagement; Global developmental delay; Occupational therapy; Social functioning

1. Introduction

Neurodevelopmental disorders are a significant issue among children. They comprise various health conditions that begin during the developmental stage, usually early, characterised by deficits in the child's development, with negative repercussions in their personal, academic, social and occupational functioning (American Psychiatric Association APA, 2013). This diagnosis group includes relatively common childhood conditions, such as global developmental delay (GDD) and autism spectrum disorder (ASD) (American Psychiatric Association (APA), 2013, Bellman et al., 2013, Boyle et al., 2011). GDD falls within the scope of intellectual disabilities and is reserved for children who do not manage to reach expected developmental milestones in several areas of intellectual functioning before the age of 5, when reliable systematic evaluations of clinical severity cannot be conducted, for example because the children are too young to take part in standardised tests such as formal intelligence tests (American Psychiatric Association APA, 2013). ASD is diagnosed when an individual persistently evidences social communication and interaction deficits alongside a restricted and repetitive pattern of behaviours and interests (American Psychiatric Association APA, 2013). Both health conditions may limit social interactions and the acquisition of basic psychosocial skills for engaging with the community (American Psychiatric Association (APA), 2013, Shevell, 2008, World Health Organization, 2019). Current scientific advice highlights the positive results of comprehensive and multidisciplinary approaches focused on

maximising each child's potential as early as possible (Bellman et al., 2013, Brown et al., 2020, Merino and Coghill, 2021, Politte et al., 2015). A key principle in the management of children with neurodevelopmental disorders is early intervention, beginning in the preschool stage, since it is a stage of development characterized by higher brain plasticity (Dawson, 2008, Merino and Coghill, 2021, Politte et al., 2015).

The use of strategies based on activities with specifically trained animals (especially dogs) as an intervention approach complementary to conventional therapies is becoming increasingly frequent among non-pharmacological programmes for children with neurodevelopmental disorders (Hardy & Weston, 2020). Animal-assisted intervention is defined as a “structured intervention that intentionally includes or incorporates animals in health, education and human services for the purpose of therapeutic gains in humans” (International Association of Human-Animal Interaction Organizations, 2018). Recent scientific evidence has underscored the positive potential of canine-assisted intervention (CAI) in children with ASD. A 2020 systematic review examined the state of research on therapies with dogs for children with ASD (Hardy & Weston, 2020). Only five works (mostly intra-subject designs) met the criteria proposed, and they all evidenced the benefits of this intervention in relation to the frequency and duration of appropriate social behaviours, although the studies had significant methodological limitations in aspects such as sample size, which prevented the implementation of a meta-analysis (Hardy & Weston, 2020). Similarly, a systematic review of the effects of CAI on children with ASD was published in 2019 (Hill, Ziviani, Driscoll, & Cawdell-Smith, 2019). This analysed 13 studies, all characterised by small sample sizes (between 1 and 26 subjects), and the average age of participants was 10. Despite identifying improvements in communication and social functioning, the authors noted that research is at an initial stage, with more methodologically rigorous studies required in order to confirm these preliminary results (Hill et al., 2019). These conclusions are consistent with O’Haire’s review (2017) based on five studies on CAI, the majority of which were intra-subject designs, where the participants’ mean age was close to 9 and the average sample size consisted of less than 4 participants (O’Haire, 2017).

The literature has emphasised that CAI brings promising benefits to children with ASD. However, scientific evidence mostly stems from small-size samples, which represents a significant methodological weakness. As for children with GDD as their principal

diagnosis, no studies were located on the efficacy of this mode of intervention. At the same time, we must highlight the absence of research specifically aimed at quantifying the impact of early application (that is, in the early stages of development) of CAI in children with neurodevelopmental disorders. In 2020 we published the results of a novel study conducted in an early intervention unit on the impact of CAI in children with ASD aged between 2.5 and 6 (Ávila-Álvarez, Alonso-Bidegain et al., 2020). The participants showed a significant improvement in most of the communication and social interaction skills analysed. Despite the meaningful findings, it should be noted that the sample size included in this study was small ($n = 19$). Another limitation was the variability in the number of sessions (the median was 9 sessions). Therefore, more research is required to confirm the findings of our pilot study, as well as to determine the effects of early application of this intervention in children with GDD. In order to address the limitations discussed above, in this study we have included children with GDD among a relatively large sample of participants with neurodevelopmental disorders and implemented a longer intervention with a fixed number of sessions in an early intervention setting. Its objectives were to evaluate the feasibility of early implementation of CAI consisting of 24 weekly sessions for children with neurodevelopmental disorders, as well as to determine the changes in various areas of social functioning and in engagement experienced by the participants throughout the intervention, comparing the results in children with GDD and in those with ASD.

2. Material and methods

2.1. Study design

A CAI was piloted in Spain in an intra-subject quasi-experimental longitudinal study.

2.2. Setting and participants

The research was carried out at the Child Rehabilitation and Early Care Unit of the A Coruña University Hospital Complex in the Spanish city of A Coruña. This community unit belongs to the public healthcare system. It is a unit that specialises in comprehensive therapeutic care and rehabilitation for children with developmental disorders and/or

disabilities. One of the key programmes that it implements is the Early Intervention service, which offers a personalised intervention plan aimed at children in their early years, between birth and the age of 6, with the aim of addressing as soon as possible the biopsychosocial needs of children with developmental challenges to facilitate their autonomy and acquisition of skills for engaging with the community. It includes a set of preventive and therapeutic actions, built on the basis of the individualised profile of each child's circumstances and developmental priorities. Interventions with children with neurodevelopmental disorders are common. They usually attend a weekly therapy session aimed at the comprehensive stimulation of their development as early as possible, guided by a specialist therapist and lasting 45 min.

A minimum target of 40 participants was sought, in accordance with the argumentation described in a 2005 work for feasibility studies (Julious, 2005). A consecutive sampling method was used. The study had to be interrupted due to the health emergency and lockdown derived from the SARS-CoV-2 pandemic in March 2020, resuming in October the same year with new participants. The recruitment took place between the months of April 2017 and 2021. The research was conducted two days a week (Mondays and Wednesdays). All children with ASD or GDD who were admitted to the unit for therapeutic intervention during this 4-year period were invited to participate in succession. In order to be included in this study, participants had to fulfil the following inclusion criteria: (a) aged from 30 months to 6 years; (b) a formal ASD or GDD primary diagnosis, confirmed by a specialist clinician in accordance with the definitions of the *Diagnostic and Statistical Manual for Mental Health Disorders—5th edition* (American Psychiatric Association APA, 2013); (c) no severe motor, visual, or auditory impairments; (d) no known history of allergy to or phobia of dogs; and (e) not having previously participated in CAI sessions. We did not include children with asthma, respiratory disease with an obstructive component or in an immunosuppressive state, nor those who showed excessive fear, anxiety or discomfort in the presence of a dog (the absence of these responses was verified by the therapist). Participants were excluded from the study if they exhibited aggressive behaviours towards the dog. We also excluded all those children who did not receive at least five CAI sessions. Demographic information and clinical data were collected at the beginning of the research (Table 1). The current ownership of pets (dogs and cats) was also examined.

Prior to commencing this research, written ethical approval for this study was sought and granted by the hospital's research ethics committee (identification code 2015/669). Each child's parents or legal guardians received full verbal and written information about the research. Subsequently, they signed an informed consent form.

2.3. Intervention

This intervention is a complementary therapeutic strategy, incorporated into a community environment of early intervention with the aim of promoting social participation of children with neurodevelopmental disorders by practising, acquiring and stimulating various types of psychosocial skills needed for interaction and daily life, such as initiating and following up social relationships, posing questions and requests to others, conveying emotions (e.g. smiling or hugging) and sharing information, following social norms, respecting turns or cooperating with other individuals to achieve a shared goal. It uses the relationship and meaningful activities with a therapy dog as an intervention method, with the mediation of a trained therapist. The intervention was designed to fulfil individual objectives. The supplemental material lists various examples of treatment objectives (Table S1). The intervention consisted of 24 sessions. The results were evaluated through direct observation of the child during CAI sessions (without interrupting their ordinary course) longitudinally in three evaluation periods: at the beginning of the study (baseline), after completing 12 intervention sessions (T1) and after completing the 24 sessions (final assessment or T2). Sessions were held on a weekly basis and lasted approximately 15–20 min, since this was considered to be the appropriate duration for conducting interventions with therapy dogs at a paediatric hospital, in accordance with the prior experience gathered by the researchers in the implementation of CAI programmes at this hospital (Ávila-Álvarez et al., 2020, Ávila-Álvarez et al., 2020). In our pilot study on the early application of CAI in children with ASD, the mean duration of the sessions was 19.9 min (SD 5.8) (Ávila-Álvarez, Alonso-Bidegain et al., 2020). The sessions took place in a therapy room of the study unit (28 m²), with natural light coming in from several windows, between 09:00 and 12:00.

With the aim of promoting animal welfare, the sessions were individual in nature, with the participation of a therapy dog, a therapist and at least one of the father, mother or legal guardian. All participants had a ten-minute preliminary session with the therapy dog to

ensure they were not unduly anxious. The animals met predefined specific criteria (see supplementary material, Table S2). Nine therapy dogs were used. Supplementary material details the characteristics of the dogs (Table S3) and the strategies used to promote animal welfare (Table S4). All dogs were trained as therapy dogs and introduced into the unit by a professional dog handler from a specialised external centre (Montegatto). During the intervention sessions, the handler was responsible for the safety, overall well-being and care of the dog. This professional was instructed not to interfere in the interaction between child and dog. The handler continuously supervised the dog's responses (behaviour and emotions). All sessions could be interrupted if this canine professional notes that the therapy dog was not comfortable (e.g. when the dog showed stress signals or the behaviour of children presented safety concerns for the dogs).

The intervention was conducted by an occupational therapist who had specialised training and extensive experience in AAI. Each child interacted with the same therapist in all sessions. The therapist played a key role throughout the intervention. The role of the therapist was to present the repertoire of intervention activities and the elements of each session (dog, tools and toys). In addition, through verbal, gestural and pictographic prompts, the therapist acted as a mediator and facilitator in the interaction between the participant and the dog. This health professional encouraged the child's active participation during each CAI session and the involvement of their parents through the individualised use of behavioural strategies such as feedback, positive reinforcement or modelling. The therapist promoted the generation of multiple opportunities for communication and interaction with the dog and with adults and motivated the child towards the attainment of the highest possible degree of autonomy in the psychosocial skills trained.

A fundamental principle of the intervention was that it was individually tailored to the abilities, needs and interests of the participant. Therefore, this CAI strategy was not based on a prescheduled framework of activities. A semi-standardised approach was taken, characterised by designing the therapeutic sessions based on the needs and desired choices of each child. The intervention was first and foremost based on the active involvement of the child in the selection of activities during the session. The intervention included a wide range of activities, mainly interactive and social in nature, grouped into four broad domains as described in Table 2. All participants received an individualised

combination of all types of CAI domains, adapted on a case-by-case basis. The therapist tailored the intervention. All sessions included the initial procedure of greeting the dog and the therapist and a goodbye at the end, through hugs, hand gestures (e.g. hand waving or “high-fiving”) and/or kisses. The first sessions were introductory in nature and were aimed at encouraging the child to get interested in the dog, explore it and begin a relationship with the animal based on closeness, bonding and friendliness through activities included in the “Getting acquainted with the dog” and “Interacting with the dog” domains (Table 2). Subsequently, the therapist progressively introduced the activities in the groups “Taking care of the dog”, focusing on the responsibility to care for the animal’s health and well-being, and “Playing with the dog”, characterised by an interactive and recreational approach, encouraging the participant to explore the dynamics of each activity, practice their performance and establish their preferences (Table 2). Once the four activity domains had been presented, i.e. having completed the more structured part of the intervention, the child was encouraged to gradually become more involved in the choice of activities, taking into account their own pace, so that they could have increasing control over the structure and time allocation of each therapy session. In addition, instances of free play with the animal were permitted, as well as periods of rest in the company of the dog.

2.4. Instruments and data collection

The variables studied were the changes in social functioning and engagement levels of the children during the CAI. Various domains of social functioning were evaluated: communication and social interaction skills, frequency of repetitive behaviours and frequency and quality of child-adults interaction. Two observation-based tools were used as outcome measures. The standardised instruments for measuring results were the *Assessment of Communication and Interaction Skills* (ACIS), version 4.0 (Forsyth et al., 1999, Forsyth et al., 1998), and the *Individual Child Engagement Record–Revised* (ICER-R) (Kishida, Kemp, & Carter, 2008). All assessments were carried out by an independent assessor with experience and training in the assessment of children with neurodevelopmental disorders.

The ACIS (Forsyth et al., 1998, Forsyth et al., 1999) is an observational rating scale designed to measure changes in the domain of communication and social interaction

skills, which are defined as observable actions used to communicate intentions or needs and to interact successfully with other people in daily activities and social contexts (Forsyth et al., 1999). It includes 20 items distributed in three domains: physicality (six items), information exchange (nine items) and relations (five items). Each item is rated on a four-point scale, from 1 (severe deficit that causes an unacceptable delay or breakdown of social interaction) to 4 (a competent skill that supports ongoing social action). The items are summed and the total score ranges from 20 (severe deficit) to 80 (competent performance). This widely used instrument has demonstrated adequate validity and reliability (Forsyth et al., 1999). In a study with a 117-subject sample, characterised by a broad diversity of diagnoses and disabilities on a psychosocial level, many-faceted Rasch analysis was used to determine the psychometric data of this scale. The Rasch fit statistics supported the ACIS construct and internal validity and its intra- and inter-observer reliability (Forsyth et al., 1999). The ACIS was able to discriminate the different levels of skills in an expected hierarchical order. In our study, each assessment was performed for two days. The baseline evaluation consisted of observing the child in the first two CAI sessions. The same procedure was followed for the T1 and T2 assessment. Evaluation T1 was carried out after observing sessions 11 and 12. Evaluation T2 was based on the last two sessions of the study.

The ICER-R tool (Kishida et al., 2008) was designed to evaluate the level of engagement of children with disabilities in their early years and was used on samples with various neurodevelopmental disorders (Kemp et al., 2013, Kishida and Kemp, 2009, Kishida et al., 2008). Its authors defined engagement as the amount of time within the sessions in which the child is involved in and interacting with their environment (other individuals or materials) in a way that is appropriate to the activity and the context/situation through the manipulation of materials and/or vocalisation (Kemp et al., 2013, Kishida and Kemp, 2009, Kishida et al., 2008). We used the revision published in 2008, which has been proven to be a simple tool whose use requires a short training period (approximately 4 h), validated by acceptable reliability and validity levels (Kishida et al., 2008). The inter-observer reliability was examined. Good overall percentage agreement (above 80%) and kappa (scores > 0.60) coefficients were achieved. The E-Qual III (McWilliam & Kruif, 1998) was used as a criterion measure to examine concurrent validity. A large and statistically significant correlation was found between total engaged behaviours as

measured by the E-Qual III and by the ICER-R ($r = 0.976$, $p < 0.001$) (Kishida et al., 2008). Professionals in paediatrics have characterised this scale as easy to use and useful for their practice (Kishida & Kemp, 2010). The ICER-R scale was used for measuring the engagement, repetitive behaviours and interaction with adults domains. Four Likert-type rating scales were applied, immediately after observing the initial session (baseline) and the sessions corresponding to weeks 12 (T1) and 24 (T2): (i) “overall engagement”, evaluated on a five-point scale (1 = nonengaged, 2 = poorly engaged, 3 = engaged, 4 = highly engaged, and 5 = very highly engaged); (ii) “frequency of repetitive behaviours” (1 = never, 3 = sometimes, and 5 = all the time or very often); (iii) “frequency of interaction between the child and adults” (1 = never, 2 = rarely, 3 = sometimes, 4 = most of the time, and 5 = all the time), the concept of interaction including verbal and non-verbal communication attempts by the child directed at another individual and the child’s responses to communication attempts by the adult; and (iv) “quality of interaction between the child and adults” (1 = negative, 3 = neutral, and 5 = positive). The initial evaluation was based on observing the first session; the T1 evaluation was based on session 12 and T2 was based on the last session.

2.5. Statistical methods

Data were described using frequencies and percentages for categorical variables. The Shapiro–Wilk test was used to determine the normal distribution. The variables that followed a normal distribution were reported using the mean and the standard deviation (SD); those that did not follow the normal distribution and the ordinal variables, through the median and the first and third quartiles (Q1 – Q3). In order to identify significant differences in the duration of sessions based on the principal diagnosis group (GDD vs. ASD) we used an independent samples Student’s *t*-test. The changes in outcome measures, defined as the difference between the final (T2) score and the baseline, were calculated for the participants who completed the 24 intervention sessions, and these changes were compared based on principal diagnosis using the Mann–Whitney *U*-test. Friedman’s non-parametric analyses were conducted to test for differences in the two standardised instruments (ACIS and ICER-R scales) from baseline to T2, and the Wilcoxon’s signed-rank test was used as a post hoc procedure to test for differences between the three time points (baseline, T1 and T2). Bonferroni corrections for multiple

comparisons (0.05/3) were applied to prevent type I errors. Regarding the ACIS items, the changes in the scores between the baseline and T2 assessments were tested for significance by means of the Wilcoxon's test. In this research, the effect size (r) [ES(r)] was calculated through the method of Cohen (1988) (Cohen, 1988). An ES(r) of 0.10 constitutes a small effect, 0.30 a medium effect, and 0.50 a large effect (Cohen, 1988). For all tests except the Wilcoxon post hoc test, the level of statistical significance was set a priori at a p value of < 0.05 and all tests were two-sided. Statistical data analysis was conducted using the IBM SPSS version 27 software.

3. Results

During the period studied, a total of 52 children met the inclusion criteria. All parents/guardians authorised their participation in the study. Of the 52 children initially enrolled, eight participants (15.4%) were excluded due to taking part in less than five sessions. The reasons for non-completion of the minimum number of sessions were discharge from the unit due to change of home address ($n = 1$) or due to worsening of health ($n = 2$) and interruption of the study as a consequence of lockdown due to the SARS-CoV-2 pandemic ($n = 5$). Thus, the final sample consisted of 44 participants. A total of 33 children (75%) attended all 24 intervention sessions and thus underwent all three evaluations of the study. The remaining 11 children underwent evaluation T1 but not T2, since they attended a minimum of 12 sessions but had not completed 24 sessions at the end of our research due to the following causes: the interruption of the study as a result of the situation caused by the SARS-CoV-2 pandemic ($n = 8$), discharge from the unit in order to receive therapeutic care at another treatment centre ($n = 2$) and medical reasons related to worsening health ($n = 1$).

The baseline characteristics of the 44 participants are shown in Table 1. The median age was 37 months. Most participants were male participants without verbal language. Regarding the primary diagnosis, more than half the sample (52.3%) had a formal diagnosis of GDD. More than 10% of the participants had a secondary diagnosis of attention-deficit/hyperactivity disorder (11.4%). At the start of the study, more than 30% of the participants had at least one dog or cat in their home (pet ownership group).

Regarding the intervention, the mean duration of the CAI sessions was 17.6 min (SD 2.2). The participants did not attend a median of 2 sessions (Q1 – Q3 = 1 – 3). No statistically

significant differences were found in the average duration of sessions when comparing participants based on their principal diagnosis (GDD vs. ASD). No participant was withdrawn from the study at the request of the parents/guardian. No adverse events or side-effects were noted. No issues of allergic reaction to the dog were reported. The therapist verified that no participant evidenced discomfort, anxiety or fear in the presence of the dog during the intervention sessions. No events were recorded of aggressions towards the participants on the part of the therapy dogs, damage to the room's furniture, aggressive behaviours towards the dog or complaints from the hospital staff.

3.1. Outcome measures

3.1.1. ACIS instrument

Among the participants who completed 24 intervention sessions, their overall ACIS score improved by 8 points over the period studied (median; Q1–Q3 = 6–11.5). There were no statistically significant differences in the change in this overall score from the baseline to T2 when comparing children with GDD with those who had ASD as their principal diagnosis ($n = 33$). Friedman's analysis showed a statistically significant improvement in the total score of this instrument from baseline to T2 (Table 3, $n = 33$). Regarding this total score, all post hoc comparisons reached statistical significance, with effect sizes greater than 0.6 (Table 4).

With respect to the 20 items of the ACIS, Table 5 shows the changes in the scores between the baseline of the study and the T2 assessment ($n = 33$). The score improved significantly in a total of 15 items and the effect size ranged from medium [$ES(r) = 0.30$] to large. The largest effects were obtained for the following items: "Contacts" [$ES(r) = 0.64$], "Manoeuvres" [$ES(r) = 0.60$], "Orients" [$ES(r) = 0.59$] and "Expresses (affect/attitude)" [$ES(r) = 0.59$].

3.1.2. ICER-R instrument

Table 3 presents changes in the four scales of this tool during the study period. Among the participants who underwent all three evaluations of the study ($n = 33$), their scores improved on all scales over the period studied. There were no statistically significant differences between the children with GDD and those with ASD in regard to the changes

in score on these four scales from the baseline to T2 ($n = 33$). Friedman's analyses showed a statistically significant improvement in the four scales of this tool from baseline to T2 (Table 3, $n = 33$). In relation to these scales, Table 4 details the level of significance and the $ES(r)$ of the changes identified in the post hoc procedures. All post hoc comparisons reached statistical significance, with effect sizes that ranged from medium [$ES(r) = 0.30$] to large [$ES(r) = 0.55$] (Table 4). The largest effects were obtained for the "Overall engagement" scale.

4. Discussion

This pilot study supported the feasibility and positive impact of CAI in a population consisting of children with neurodevelopmental disorders in the earliest stages of their life, with similar proportions of participants with GDD and ASD and significant social interaction and communication deficits. Our research was pioneering in the development of this form of actions in an early intervention service for children with these health conditions. Its findings provided valuable preliminary evidence, bearing in mind that the recruitment of the sample, the collection of information and the implementation of the intervention were feasible. Unanimity in consent for participation and the absence of requests for the withdrawal of their child once the study had begun demonstrated its acceptability among parents/guardians. Also, it was not necessary to interrupt the programme due to fear or anxiety caused by the presence of the dog and the rate of participants who completed the intervention was high. Although our research lasted four years, the main reason for not completing the intervention was the unexpected interruption of our study due to the lockdown derived from the SARS-CoV-2 pandemic. The absence of adverse events was another reason that supported the feasibility of conducting 24 weekly CAI sessions of a shorter duration than in previous studies (O'Haire, 2017, O'Haire, 2013), indicating the viability of their future replication, for the purpose of progressing in the development of evidence within this field.

Another strength was the quantitative documenting of the outcomes of early implementation of therapy dog-based strategies. The participants significantly improved their ACIS and ICER-R scores at the end of the CAI and the size of these improvements ranged from medium to large. Significant changes were identified upon completion of the first half of the intervention, although the effect was smaller in size. When comparing the

baseline with the findings after 24 sessions, the greatest improvements were identified in communication and interaction skills (i.e. the most basic level of analysis), followed by the degree of involvement of the child in the sessions through “engagement” in contextually appropriate relationships with their environment, and the frequency of interaction with adults. The notable improvement in the overwhelming majority of skills can be used to explain the good results obtained in the child’s interaction with their surroundings, since these skills are simple observable actions defined as key units for social participation (American Occupational Therapy Association, 2020, Forsyth et al., 1999) and a competent performance in social settings requires their acquisition and mastery (Forsyth et al., 1998, Kielhofner, 1995). The greatest improvements in skills were observed in “physicality”, a group related to the use of the body as a facilitating means (Forsyth et al., 1998): the children perfected their skills for establishing socially appropriate physical contact, actively moving their body in relation to others and orienting their head towards the focus of social activity. Conveying affection through facial expressions, smiles or tone of voice and the ability to focus their attention and behaviour on the interaction for an appropriate amount of time without getting distracted were other skills that underwent important changes. The skills that did not display significant changes corresponded to levels of greater complexity in the hierarchical classification empirically validated by the authors of ACIS (Forsyth et al., 1999). Future research is needed to confirm whether a higher number of sessions influences the development of these more demanding skills. On the other hand, there were no differences in the size of the improvements when comparing the changes between children with GDD and ASD, which is consistent with the existence of characteristics common to both diagnoses and their inclusion in the group of neurodevelopmental health conditions (American Psychiatric Association (APA), 2013, World Health Organization, 2019). Both share an early onset and significant difficulties in functions related to language or socialisation due to central nervous system dysfunctions (Choo et al., 2019, Kim et al., 2020, World Health Organization, 2019). The results extend the existing evidence base for this intervention modality. The originality of this research lies in the fact that it was the first to implement a CAI in children with GDD, hence there are no previous studies on this population. With regard to children with ASD, research on the effect of therapy dogs has grown in the last decade (Hill et al., 2019). An analysis of the available evidence

allows us to conclude that the findings of this study are consistent with the previous literature, whose conclusions have noted the positive effects of CAI in the areas of verbal and non-verbal communication and social skills, repeated behaviours and social interaction (Hardy and Weston, 2020, Hill et al., 2019, O’Haire, 2017, O’Haire, 2013). However, comparisons between our study and the literature are limited by the existence of differences in the characteristics of the samples and the heterogeneity of methodologies and settings.

We believe that several positive characteristics of the evaluated intervention contributed in part to explaining the results. These include the gradual forging of a bond with the dog and the therapist and the sequential progression of activities from basic relationships based on visual inspection, physical contact and simple demands typical of the early sessions to the achievement of a pleasurable and relaxed context, optimal for the repetition of activities, sequences and interactions in an leisurely, predictable and soothing environment that is auspicious for the child to display more receptiveness towards the acquisition of social behaviours and skills (Funahashi et al., 2014, Martin and Farnum, 2002, Viau et al., 2010). Other key aspects were the involvement of the child in the selection of activities (a feature that favours their motivation and adherence) (Koegel et al., 2010, Stevenson et al., 2015) and the active participation of parents in all sessions. This is not a usual factor in this type of programmes (O’Haire, 2013), but it increased the repertoire of opportunities for interaction with adults and facilitated training more complex aspects of social functioning such as cooperation with other individuals to achieve shared goals and the development of affection, friendship and camaraderie, resulting from sharing the activity between the child, the dog, the therapist and the parents (Fung and Leung, 2014, Nimer and Lundahl, 2007). Various authors have postulated that the behaviour of these dogs (simple, predictable and characterised by offering unconditional support) and their non-verbal communication style (easy to understand, based on their own body) are other factors to consider in the argument for the therapeutic basis of human-animal interaction (Berry et al., 2013, Prothmann et al., 2009, Solomon, 2010, Stevenson et al., 2015). Similarly, the calming effect of interaction with dogs has been demonstrated in children with ASD through an objective diminution in cortisol levels (cortisol is a biological indicator of stress) (Viau et al., 2010). In addition to the above is the natural tendency of humans to search for a connection with other living

beings in their environment, be they human or animal. This is the basis and main hypothesis of research in the field of anthrozoology (Wilson, 1984).

The results of this study should not be interpreted without taking some limitations into account. The absence of a control group was an important concern. Due to the uncontrolled design, the reader must keep in mind that the changes that occurred during the study cannot be attributed to the effects of the CAI alone. Additionally, important descriptive data, such as the degree of severity of the primary diagnosis or the pharmacological treatment, were not recorded in our study. Another limitation was the representativeness of the sample. The sample did not consist of a random selection of children and the study was conducted at one site only. We recruited children who received care at a single therapeutic unit which serves a small geographical area. Therefore, generalisation of the findings to other Spanish children with neurodevelopmental disorders should be made with caution. The participants were mainly boys, although the lower representation of girls is common in the literature on this subject in populations with ASD (Hill et al., 2019). The inclusion of participants with different ages and a heterogeneous evolution profile made it difficult to start the interventions from the same point, limiting the comparisons between groups. Finally, we did not perform a long-term follow-up. Thus it is impossible to conclude from this research whether the observed changes in the outcomes were sustained after the intervention was terminated. This study's findings encourage us to begin an experimental design with randomisation and a control group with the aim of confirming these benefits. For the comparison group, a sample of children belonging to the same population as the one studied but who receive the standard care at the unit could be recruited. Although our sample size is large compared to similar studies on CAI in children with ASD (Hardy and Weston, 2020, Hill et al., 2019, O'Haire, 2017), the large-scale implementation of experimental designs, with a larger and broader sample from several early care services, would favour the generalisability of the results. The follow-up of participants over a time period is advantageous to determine the extent to which the intervention effects are maintained. Future research should also explore the effects on the child-guardian bond and the impact of this type of intervention on the daily life of the families.

5. Conclusion

This pilot study was a first step in the study of the effectiveness of non-pharmacological interventions based on therapy dogs in community early intervention units for children with neurodevelopmental disorders. The study design accomplishes its explorative aim as a preliminary step for a definitive randomised clinical trial. It was the first to implement this mode of intervention in children with GDD in the first years of their life. The intervention appears feasible and the results in the areas of social functioning and engagement are promising. The findings suggest significant improvements of a medium to large size in the domains of communication skills and social relations, engagement levels, frequency and quality of interaction with adults and repetitive behaviours after 12 and 24 weekly CAI sessions. Thus it could be a useful complementary strategy in early therapeutic intervention with these children.

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CRediT authorship contribution statement

Adriana Ávila-Álvarez: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Funding acquisition. **Miguel Alonso-Bidegain:** Conceptualization, Methodology, Writing – review & editing, Visualization, Supervision, Funding acquisition. **Daniel Ramos-Veiguela:** Validation, Investigation, Resources, Writing – original draft. **Elba Iglesias-Jove:** Software, Investigation, Resources, Data curation. **Iván De-Rosende-Celeiro:** Conceptualization, Methodology, Software, Formal analysis, Data curation, Writing – original draft, Writing – review & editing, Visualization, Project administration.

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Declarations of interest

None.

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Table 1. Baseline characteristics of study sample (n = 44).

Baseline characteristics	Values ^a
Gender	
Male	35 (79.5)
Age (months)	
Median (Q1 – Q3)	37 (33.2 – 47.2)
Range	30 – 54
Primary diagnosis	
Global developmental delay	23 (52.3)
Autism spectrum disorder	21 (47.7)
Secondary diagnosis	
Attention-deficit/hyperactivity disorder	5 (11.4)
Verbal ability	
Presence of verbal language ^b	12 (27.3)
Current pet ownership	
At least one dog or cat	14 (31.8)
Dog ownership	12 (27.3)
Cat ownership	4 (9.1)

Q1 – Q3, first and third quartile.

^aData are presented as n (%) unless otherwise stated.

^bAs defined by the Autism Diagnostic Interview-Revised.

Table 2. Overview of the topics within each of the four activity domains of the canine assisted intervention.

Domain	Description
Getting acquainted with the dog	<p>Calling the dog by its name</p> <p>Main parts of its body</p> <p>Physical characteristics and exploration of its coat</p> <p>Behavioural patterns and movements of the dog</p> <p>Its response to various human actions</p> <p>Asking questions to the adults about the dog</p> <p>Sharing thoughts and impressions about the animal with adults</p>
Interacting with the dog	<p>Greeting and saying goodbye to the dog</p> <p>Introducing oneself and paying attention to introductions</p> <p>Talking to the dog</p> <p>Physical/tactile contact with the dog</p> <p>Conveying positive emotions to the dog</p> <p>Hugging, stroking and snuggling with the dog</p> <p>Observing and following the animal's actions and responses</p> <p>Giving the dog commands; praising it</p> <p>Interactive obedience activities (“sit”, “down”, “shake”, “fetch”)</p> <p>Enjoying the company of the dog and relaxation at its side, as a “friend” and “companion”</p> <p>Interaction shared with adults</p>
Taking care of the dog	<p>The responsibility of taking care of the dog</p> <p>Basic feeding habits</p> <p>Preparing and giving it food and water</p> <p>Basic hygiene and health habits (e.g. brushing and bathing, mouth and nail care, etc.)</p> <p>Holding the dog, guiding it and going with it for walks</p> <p>Rest and sleep needs</p> <p>Responsibility sharing: cooperating with adults in caring for the animal</p> <p>Putting away, cleaning and organising the necessary materials</p>
Playing with the dog	<p>Experimenting with different games and structured recreational activities with the dog</p>

Examples: throwing a ball and telling the dog to pick it up and bring it back, games related to searching for objects, going through a tunnel following a system of turns, exploring itineraries with obstacles, etc.

Interests: choosing a favourite game

Giving clear instructions and making requests for the development of the game

Comaraderie: cooperating and sharing the game with adults and the dog

Respecting turns

Sharing toys and materials

Fun and enjoyment with the dog

Periods of free play with the animal

Putting away, cleaning and organising the toys used

Table 3. Outcome measures along the three assessment times of the study.

	Baseline (<i>n</i> = 44)	T1 (<i>n</i> = 44)	T2 (<i>n</i> = 33)	
Outcome measures	Median (Q1 – Q3)	Median (Q1 – Q3)	Median (Q1 – Q3)	<i>p</i> -value ^a
Assessment of Communication and Interaction Skills				
Total score	27 (23 – 34.5)	30.5 (26 – 39)	35 (29 – 45)	<i>p</i> < 0.001 ^b
Individual Child Engagement Record – Revised				
Overall engagement	2 (1 – 2)	2 (2 – 3)	2 (2 – 3)	<i>p</i> < 0.001 ^b
Repetitive behaviours				
Frequency	3 (1 – 3)	3 (1 – 3)	1 (1 – 3)	<i>p</i> < 0.001 ^b
Interaction between the target child and adults				
Frequency	2 (1 – 2)	2 (1 – 2)	2 (2 – 3)	<i>p</i> < 0.001 ^b
Quality	3 (3 – 3)	3 (3 – 5)	5 (3 – 5)	<i>p</i> < 0.001 ^b

Q1 – Q3, first and third quartile; T1, assessment following 12 weeks of intervention; T2, assessment following 24 weeks of intervention.

^a Results from Friedman’s test (*n* = 33).

^b Indicates statistical significance (*p* < 0.05).

Table 4. Outcome measures: post hoc procedures ($n = 33$).

Outcome measures	Baseline versus T1		T1 versus T2		Baseline versus T2	
	<i>p</i> -value	ES (<i>r</i>)	<i>p</i> -value	ES (<i>r</i>)	<i>p</i> -value	ES (<i>r</i>)
Assessment of Communication and Interaction Skills						
Total score	$p < 0.001^a$	0.60	$p < 0.001^a$	0.62	$p < 0.001^a$	0.62
Individual Child Engagement Record – Revised						
Overall engagement	$p < 0.001^a$	0.43	$p < 0.001^a$	0.44	$p < 0.001^a$	0.55
Repetitive behaviours						
Frequency	0.014 ^a	0.30	0.008 ^a	0.33	$p < 0.001^a$	0.44
Interaction between the target child and adults						
Frequency	0.014 ^a	0.30	$p < 0.001^a$	0.41	$p < 0.001^a$	0.51
Quality	0.003 ^a	0.37	0.004 ^a	0.36	$p < 0.001^a$	0.48

ES(*r*), effect size; T1, assessment following 12 weeks of intervention; T2, assessment following 24 weeks of intervention.

^a Indicates statistical significance after Bonferroni correction ($p < 0.017$).

Table 5. Changes in communication and interaction skills from initial to final (T2) assessment ($n = 33$).

	Baseline	T2		
Outcome measure: ACIS	Median (Q1 – Q3)	Median (Q1 – Q3)	<i>p</i> -value	ES (<i>r</i>)
Physicality				
Contacts	2 (2 – 2)	3 (2 – 3)	$p < 0.001^a$	0.64
Manoeuvres	2 (1 – 2)	3 (2 – 3)	$p < 0.001^a$	0.60
Orients	2 (2 – 2)	3 (2 – 3)	$p < 0.001^a$	0.59
Gazes	2 (1 – 2)	2 (2 – 3)	$p < 0.001^a$	0.52
Gestures	1 (1 – 2)	2 (1 – 2)	$p < 0.001^a$	0.51
Postures	2 (1 – 2)	2 (1 – 2)	0.083	–
Information Exchange				
Expresses (affect/attitude)	1 (1 – 2)	2 (2 – 2.5)	$p < 0.001^a$	0.59
Speaks	1 (1 – 2)	1 (1 – 3)	$p < 0.001^a$	0.44
Engages	1 (1 – 2)	1 (1 – 2)	$p < 0.001^a$	0.41
Shares	1 (1 – 2)	1 (1 – 2)	$p < 0.001^a$	0.41
Asks	1 (1 – 1)	1 (1 – 2)	0.002 ^a	0.39
Articulates	1 (1 – 2)	2 (1 – 2)	0.008 ^a	0.33
Asserts	1 (1 – 2)	1 (1 – 2)	0.014 ^a	0.30
Modulates	1 (1 – 2)	1 (1 – 2)	0.083	–
Sustains	1 (1 – 1)	1 (1 – 1)	0.157	–
Relations				
Focuses	2 (1 – 2)	2 (2 – 3)	$p < 0.001^a$	0.56

Conforms	2 (1 – 2.5)	2 (2 – 3)	$p < 0.001^a$	0.54
Collaborates	1 (1 – 2)	2 (1 – 2)	$p < 0.001^a$	0.52
Relates	1 (1 – 1.5)	1 (1 – 2)	0.083	–
Respects	1 (1 – 1)	1 (1 – 1)	0.317	–

ACIS, *Assessment of Communication and Interaction Skills*; ES(*r*), effect size; Q1 – Q3, first and third quartile; T2, assessment following 24 weeks of intervention.

^a Indicates statistical significance ($p < 0.05$).