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Efficacy of the Praxis-Productive Intervention Program for Phonological Disorders: Giannecchini Model®

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Abstract

Speech is defined as the motor representation of Language, based on the coordination of three neurological processes: organization of concepts, formulation and symbolic expression; programming of the motor act involved in the production of speech and its own motor production. The motor control of speech, which orders muscle contraction for its execution of praxis, includes planning, preparation of movements and execution of plans, with a view to muscle contractions and displacements of structures that will culminate in the articulation of speech. National and international scientific works envision a new field of speech-language pathology for working with altered speech, with the stimulation of non-verbal praxis. The objective of this study is to apply a Praxis-productive Intervention Program, the Giannecchini Model, in 128 children with Phonological Disorder and to demonstrate its effectiveness in the Speech-Language Pathology clinic. The results showed an improvement in speech performance in all subjects, in the time stipulated by the instrument, with higher scores in the evaluative tests of phonology and post-intervention oral praxis, when compared to the pre-intervention scores. The Giannecchini Model proved to be efficient, useful, simple, easy to apply by the speech therapist and well understood by the participants, with favorable responses to the acquisition of phonemes and with proven efficacy in 75% of the subjects.

1. Introduction

Speech is a multifaceted human ability that combines linguistic, cognitive, neurological and motor aspects [1]. It is fundamental for communication and for the construction of social and cultural relationships. The study of speech covers several disciplines, reflecting its complexity and importance in human interaction [2].

Speech is defined as a motor representation of language in which there is the coordination of three neurological processes: organization of concepts, formulation and symbolic expression; programming of the motor act involved in the production of speech; the motor production of speech itself. It requires adequate cognitive and phonological development and total integrity of the neurological system and orofacial structures [3].

In 2004, with a scientific publication in Brain [4], a new brain area for the control of articulatory movements related to speech was described. When studying the brains of subjects with articulatory planning disorder, through imaging tests, the authors observed that the same brain area, the insula lobe, in the left hemisphere, was with infarction, that is, with lesion. From this scientific milestone, this brain area is recognized as Dronker's' area, a new area involved in the motor planning of movements for oral verbal expression [5].

Motor Control, which orders muscle contraction for the execution of speech, includes planning, preparation of movements and execution of plans, aiming at muscle contractions and displacements of structures that will culminate in the articulation of speech [6]. In this sense, phonological acquisition interacts with the development of speech motor control [7].

Scientific studies, representative in international literature, envision a new field of speech-language pathology for working with altered speech. In Brazil, in 1996, a publication on non-verbal praxis appeared for the first time in the scientific scenario [8], whose authors expose the need to stimulate this aspect for clinical work with oral language. Expanding the national discussion, in 2015, authors proved that praxis alterations of the stomatognathic system are present in individuals with phonological disorders, and should be encouraged to correct the clinical picture [9,10].

In the Speech-Language Pathology clinic, there is a consensus on the need to improve intervention programs in the Speech-Language Pathology and Audiology field.

Thus, the proposal of an intervention program, with the number of predetermined sessions, such as the GIANNECCHINI MODEL, whose applicability has already been confirmed in a scientific study [11,12,13], exposes a new material, as a longitudinal and future result of this study, still recent and uncommon in speech-language pathology practices.

The intervention proposal to be presented presupposes the integration of phonological skills with the training of oral praxis. The hypothesis is that the stimulation of non-verbal praxis, i.e., exercises in sequence of lips and tongue, can facilitate the learning of a new phoneme, as previously described in the literature [8,9,11,12,13], by optimizing brain areas intended for the coordination of movements for speech.

In this line of reflection, the objective of this work is to apply a Praxis-productive Intervention Program, the Giannecchini Model, in 128 children with Phonological Disorder and to demonstrate its effectiveness in the Speech-Language Pathology clinic.

2. Methods

This study was approved by the Research Ethics Committee of the School of Dentistry of the University of São Paulo (FOB-USP).

The construction of the Praxis-productive Intervention Program was demonstrated in 2016 by researchers in the area [14]. The justification for including the praxis aspects to be carried out within the program was followed by a scientific study [8], which provides a theoretical overview of this stimulation in the speech-language pathology clinic. The intervention program contained 12 sessions of combined stimulation of phonological aspects with the non-verbal praxis of the lips and tongue, in addition to stimulation of auditory skills, phono articulatory awareness and oral proprioceptive stimulation of articulatory points and modes.

The application of the program had the participation of 128 children, aged between 5 and 9 years, students from the private elementary school network in the city of São Paulo, who sought speech therapy care, by spontaneous demand in private clinics. Children of both sexes were submitted to the Program proposed in the GIANNECCHINI MODEL (GM) consisting of 14 sessions, performed by a speech therapist trained to handle the procedure. A speech therapist only selected the subjects with tests that will be described below, as inclusion criteria. After being selected, other speech therapists, including the researcher, applied the GM to the subjects.

The inclusion criteria of the subjects were listed as follows: Audiological evaluation without peripheral alteration; without alteration in another aspect of language: pragmatic, syntactic and semantic; No oromiofunctional alteration; no apraxia of speech; with proven phonological alteration, i.e., phonological disorder; No type of speech therapy at the time of evaluation.

To verify whether the subjects were included in the study, the following procedures were applied, respectively: audiological evaluation – audiometry, logoaudiometry and immittance testing; language evaluation of morphosyntactic, semantic and pragmatic aspects; oromiofunctional evaluation to rule out the alteration, history of anamnesis to rule out cases of apraxia of speech, evaluation of phonology by the application of the ABFW[15] Phonology Test for the diagnosis of Phonological Disorder, with the Imitation and Naming tests, requirement that the target audience not have been attended in any Speech Therapy service, nor exposed to interventions to solve speech disorders.

The ABFW Phonology Tests were used to evaluate speech and 1 separate test to evaluate the different aspects of Orofacial Motricity, parameters for analyzing the results with the stimulation of the proposed praxis-productive program.

For the use of the ABFW, the children were analyzed in terms of the number of phonological processes existing at the beginning of the intervention and compared with the same number at the end of the sessions.

The Orofacial Motricity test applied was The Orofacial Praxis Test [16], which asks the child to perform (1a) sonorized praxis, (1b) orofacial praxis, (2) Sequence of Movements and (3) parallel movements, upon request or imitation (Appendix A).

Appendix A: The Orofacial Praxis Test (Bearzotti, Tavano e Fabbro, 2007)

Orofacial Praxia Test Items					
1a. Sound Praxias	Request	Imitation	**1b. Orofacial Praxias**	Request	Imitation
Making the cow sound — "moo"			Stick out your tongue		
Making the sound of the sheep — "bée"			Grit your teeth		
The noise of the train			Biting the lower lip		
Saying "a" with your mouth open			Blow		
Cough			Encher as bochechas		
Slugging			Touch the cheek with the tongue		
Tongue clicking			Smile		
Blow a raspberry			Yawn		
Asking for silence ("Shhhhhhh")			Biting your tongue with your teeth		
Buzz a tone			Breathing through your nose		
Whistle			Raise eyebrows		
Throw a kiss			Blink		
Total					
2. Sequence of Movements			**3. Parallel movements**		
Opening and closing the mouth			Close your eyes and open your mouth		
Sticking out your tongue and closing your mouth			Closing teeth and raising eyebrows		
Puffing your cheeks and blowing your nose			Bite your tongue, close your mouth and say "Mm-mm"		
Showing your teeth, opening your mouth and closing your eyes			Open your mouth, protrude your tongue and say "ahhh"		
Blowing, biting the lower lip and filling the cheeks			Close your eyes, close your mouth and breathe through your nose		
Stick out your tongue, touch your cheek with your tooth and blow a kiss					

To characterize phonological stimulation, we chose to stimulate the auditory abilities of central auditory processing [17]. For the stimulation of phono articulatory awareness, the CONFIART [18]-based program was used, and for the proprioceptive activation of articulatory points and modes, normative data about the phonemes of the Brazilian Portuguese 19 were considered [19].

The efficacy of speech-language therapy may vary depending on factors such as the severity of the problem, the therapeutic approach used, the quality of the therapeutic relationship, the frequency and duration of sessions, and the patient's adherence to treatment [20,21]. To calculate the efficacy of GM, data analysis and comparison of pre- and post-therapy results were performed using statistical analysis (Student's t-test), and the percentage of improvement in each area evaluated was calculated and it was also observed, through the interpretation of the results, whether the improvements recorded were clinically significant and resulted in practical changes in patient communication [22].

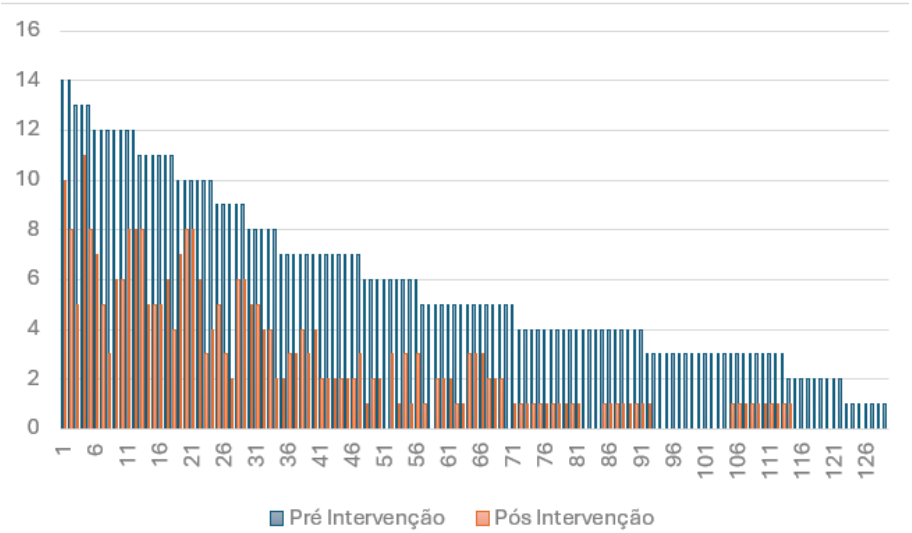
At the end of this evaluation, the parents of the children who met the inclusion criteria were informed that GM would be started for 12 weeks and that, at the end, the child would be reevaluated and then continue the treatment. Children who did not meet the inclusion criteria were referred directly to traditional treatment. The parents who agreed to participate in the study signed the informed consent form and the child started the praxis-productive intervention program.

3. Results

The Intervention Program entitled GIANNECCHINI MODEL was composed of 14 sessions. Of this total, 2 sessions were aimed at the evaluation of Phonology and orofacial praxis, with 1 session before stimulation and another session after the application of GM, as mentioned in the method. It was decided to hold a weekly session within the program, with extra exercises at home.

The sample of this research was composed of 128 subjects, aged between 5 years and 2 months and 9 years and 1 month, 86 males and 42 females. The data of their pre- and post-intervention Phonology evaluations can be found in Appendix B, characterizing the number of altered phonological processes per subject.

Appendix B: Characterization of Phonological Processes by subjects Pre- and Post-intervention in the Praxis-productive Intervention Program – Giannecchini Model



Legend: Number of altered phonological processes (maximum = 14) X study subjects scorers (n=128)

Regarding the evaluations to which the subjects were submitted, the results obtained before and after the speech-language pathology intervention with the MG were analyzed below.

The results showed significant data when the subjects' performances in all tests were compared with each other, that is, in imitation and naming in the initial, medial and final times (Tables 1 to 2).

In the initial imitation, the mean number of altered phonological processes was 3.25, while in the final imitation this number was 1 (Friedman's test - Repeated measures and analysis of variance) with p = < 0.001 (Table 1). The subjects had more altered phonological processes in the initial Imitation than in the Final Imitation, characterizing performance improvement.

Table 1: Comparison of performance in the ABFW Phonology Test – Imitation at the beginning, middle and end of the Giannecchini Model

Name Of The Test Applied	N	Average	Standard Deviation
Initial Mistry	128	3.25	1.865
Medical Imitation	128	2.25	1.055
Ultimate Imitation	128	1	1.279

Legend: N: number of participating subjects; p = < 0.001

In the initial nomination, the mean number of altered phonological processes was 3.25, while in the final nomination, this number was 1.16, with a statistically significant difference of p = < 0.001 (Friedman) (Table 2). This finding shows that the subjects had more altered phonological processes in the initial Nomination than in the Final Nomination.

Name of the test applied	N	Average	Standard deviation
Initial Appointment	128	3.25	1.865
Medial Appointment	128	2.167	1.467
Final Appointment	128	1.167	1.267

Legend: N: participating individuals, p = < 0.001;

In The Orofacial Praxis Test, the performance of the subjects in each of the evaluations, pre and post-intervention, was analyzed. The results were separated into 4 variables, by number of correct answers: pre-intervention request, post-intervention request, pre-

intervention imitation and post-intervention imitation. The statistics applied were from the paired test, which showed significant results for all variables.

In the pre- and post-intervention request, the change in performance that occurred with treatment was statistically significant (p = <0.001). In the pre-intervention request, the average of the exercises performed was 10.167, while in the post-intervention period, this number increased to 25.167, indicating an increase in the number of exercises performed, upon request, with improved performance in this test. (Table 3).

Table 3: Request for movements in The Orofacial Praxis Test - Pre and post-intervention of the Giannecchini Model

Name of the test applied	N	Average	Standard deviation
PRE Request	128	10.167	7.004
Post-Request	128	25.167	5.374
Difference	128	-15	4.221

Legend: N: number of participating individuals; p = < 0.001

In the pre- and post-intervention imitation, the change in performance achieved with the treatment was statistically significant (p = <0.001). In the pre-intervention Imitation, the average of the exercises performed was 19.417, while in the post-intervention period, this number decreased to 8.167, indicating a decrease in the number of exercises performed through imitation, since the same exercises were performed only under the requested command (Table 4).

Table 4: Imitation of movements in The Orofacial Praxis Test - Pre and post-intervention of the Giannecchini Model

Name of the Test Applied	N	Average	Standard deviation
Imitation-PRE	128	19.417	4.944
Imitation-POWDERS	128	8.167	5.078
Difference	128	11.25	4.267

Legend: N: number of participating individuals; p = < 0.001

Ensuring the quality of home exercises during the implementation of the Giannecchini Model for addressing speech sound disorders involved several key strategies aimed at maximizing engagement, understanding, and effectiveness:

1. Home exercises were carefully structured to align with the four foundational pillars of the Giannecchini Model. Each exercise targeted specific auditory, motor, and sensory aspects of speech production, ensuring that they were not only relevant but also progressively challenging. This structured approach allowed caregivers and clients to follow a clear path toward achieving speech goals.

2. Comprehensive instructional materials were provided to caregivers and clients. These materials included detailed explanations of each exercise, objectives, and expected outcomes. Visual aids, such as diagrams or video demonstrations, can enhance understanding and ensure that exercises are performed correctly.

3. Training sessions for parents or caregivers were essential to ensuring the quality of home exercises. Educating them about the principles of the Giannecchini Model, as well as providing them with strategies to encourage their child, fosters a supportive home environment. Empowered caregivers can facilitate practice sessions more effectively, reinforcing learning in a naturalistic setting.

4. Caregivers were encouraged to document their child's progress and any observations during home practice. This documentation served multiple purposes: it allowed tracking improvements over time, identified areas needing further focus, and provided valuable insights during therapy sessions.

5. Regular assessments of the child's speech development were integrated into the home exercise framework. By setting measurable goals and evaluating progress periodically, clinicians could ensure that the home exercises were yielding the desired results and could make necessary adjustments to the intervention strategy.

By implementing these strategies, the quality of home exercises within the Giannecchini Model was effectively ensured, fostering an environment conducive to speech development and supporting positive outcomes for children with speech delays.

3. Discussion

Speech is a complex phenomenon that involves the production and perception of linguistic sounds, allowing verbal communication between individuals. It is the result of a complex neural network that integrates sensory, motor, and cognitive information [6,7]. Speech production involves complex cognitive processes, including word selection, sentence formation, and articulation. This requires the activation of specific areas of the brain and the coordination of motor skills [23]. It is often mediated by working memory, which allows speakers to hold and manipulate temporary information during conversation [24].

Studies around Speech and Language signal the need to apply validated models and evidence-based practices to ensure the effectiveness of interventions in Phonological Disorders.

The GIANNECCHINI MODEL proved to be easy to apply, with the necessary details for its execution. The sessions were organized according to the criteria described and the individuals with phonological disorders had no difficulties in understanding the orders given by the speech-language pathologist trained with the instrument.

The subjects' answers were marked on their respective note sheets, generating the data that were statistically worked. The surveys always took place after 3 intervention sessions and brought relevant answers to measure the baseline of the progress of the sample subjects, as well as their difficulties and point out the effectiveness of the program.

It can be inferred that the program with determined sessions was beneficial to the subjects, in relation to the time they were exposed to speech-language stimulation. In the literature, reports of therapy time for phonological disorders [20,21] and a document from the Brazilian Society of Speech-Language Pathology and Audiology (SBFa), entitled "Markers of Treatment Time in Speech-Language Pathology and Audiology" [25]. In the articles cited above, there is a reference to extensive therapy times, directly related to the severity of the phonological disorder, with an average of 18 therapy sessions. In the SBFa document, which includes speech in language disorders, in the subtitles of specific articulation disorders, periods longer than 1 year are foreseen for the solution of the present alterations, with 2 weekly sessions of 45 minutes each. The program proposed in this study prioritized the aspects to be stimulated, and, in 12 sessions, generated favorable results in all subjects, confirming the hypothesis that motor learning in 12 sessions can be achieved.

Thus, a praxis-productive program was proposed, considering as a priority:

- The union between the stimulation of phonological aspects and the motor aspects of speech.
- Praxis-productive stimulation in 12 sessions, based on the principles of muscle motor programming.

The sum of the 2 aspects contributed to the overcoming of phonological disorders in the subjects of the study sample, or, at least, to the reduction of phonological processes expected for a given age.

Several studies have proven the occurrence of praxis alterations of the stomatognathic system in speech disorders [7,9,26]. Other authors [27,28,29] point out that linguistic disorganization in phonological disorders may be influenced by motor disability or by praxis difficulty in performing phonemes. Regarding the stimulation of non-verbal praxis, in agreement with literature [9], the program diagnosed praxis alterations in subjects with phonological disorders. Such data were significant to support the elaboration of the GM and justify the insertion of non-verbal praxis stimulation in the clinical work of speech-language pathology in speech disorders.

The objective to be achieved by this study has practical implications in the speech-language pathology clinic, when it discusses the usability of the program. The data collected in the pre- and post-intervention evaluations, regarding the performance of the subjects, serve as theoretical support to justify the role that the program can gain in clinical practice.

Regarding the efficacy of the GIANNECCHINI MODEL, the findings pointed to the sufficient collection of data to prove it, at least to a moderate degree, which indicates that 75% of the subjects obtained positive results, with noticeable improvements in many cases, but with individual variations and the need for follow-up. However, studies with more subjects and meta-analyses in different populations are still needed. Numerical data were used and will be discussed to score the usability of GM in the various clinical scenarios of speech disorders.

When the performance of the research subjects was compared in relation to the Phonology – Naming and Imitation tests, it was found that all of them presented phonological processes that were inappropriate for their age, and were, therefore, included in the program (see tables 1; ANNEX B). After the 12 stimulation sessions, all subjects reduced the number of inappropriate phonological processes, and 32 subjects had their oral productions generalized and, therefore, normalized. (Tables 1 and 2) indicate an improvement in performance in the tests, i.e., less occurrence of significant errors among all evaluations, being greater when comparing the initial tests with the final ones. Thus, evaluating the subjects during the program, as a baseline, was effective in measuring changes in speech, which is important for clinical practice and significant for scoring the effectiveness of the proposed program. It is important to mention that the subjects included in the research presented alterations in different phonological processes and all of them obtained positive results, with partial or total elimination of the alterations, signaling the possibility of using MG for various forms of presentation of phonological disorder.

The Oralfacial Praxis Test analyzed the performance of the subjects in each of the assessments, pre and post-intervention. For 4 variables studied, namely, pre-intervention request, post-intervention request, pre-intervention imitation and post-intervention imitation, the results were statistically significant, indicating better performance of the subjects (Tables 3 and 4). It is pertinent to emphasize that some of the movements required by the tests were not specifically worked on in session, that is, the improvement achieved in these executions was due to the training of the non-verbal praxes that made up the program.

What should be reported, in relation to the program, is that the coordination of the exercises increased qualitatively, measured by the pre- and post-intervention tests, proving the applicability of GM for children with phonological disorders.

Confirming the hypothesis that phonological acquisition interacts with speech motor control7, the program proposed in this study proved to be an instrument that, by considering such aspects, offers stimulation so that phonemic acquisition is facilitated. The sum of phonological stimulation with motor stimulation [13,29] was also shown to be more effective in the application of the program for overcoming articulatory alterations.

It is important to point out that the MG proposed stimulation of several neurological pillars for speech adequacy.

It is pointed out that the findings of this study, regarding the inclusion of the stimulation of non-verbal praxis in the clinical work with speech, especially with children with phonological disorders, are unprecedented, denoting scientific relevance and theoretical basis for its execution. Meeting the clinical demands of phonological disorders is part of the responsibilities of the speech-language pathologist and this program presents itself as a viable and useful tool for the re-establishment of function. It is reiterated that the use of GM can be expanded to various forms of presentation of phonological disorder. The program, which proposed the intervention for subjects who had alterations in different phonological processes, provided positive results in all participants.

The applicability of GM can only be considered in the sum of the auditory and motor aspects, ensuring the stimulation of the stages of reception and realization of Language [30].

The Giannecchini Model proposes a robust and scientifically grounded theoretical approach to speech acquisition and the mitigation of phonological disorders, based on four main pillars. These pillars are designed to be universal and not restricted to a specific language, allowing their application in diverse geographic and linguistic contexts, regardless of the dominant language. The model's pillars emphasize the importance of three essential components in learning new phonemes: auditory, motor, and sensory aspects [7,14]. Auditory stimulation is crucial, as it allows the individual to recognize and discriminate the sounds of the new language [17]. Motor practice is equally important, as correct articulation of phonemes requires fine motor coordination and muscle control [4,7,16]. Finally, sensory aspects are fundamental for the learner to develop phonological awareness, which aids in the perception and production of sounds [29]. Thus, the Giannecchini Model is applicable to a variety of languages, promoting the generalization of its techniques as an effective therapeutic tool for speech-language pathologists worldwide. The universalization of the proposed matrix is based on the premise that the fundamental skills of speech perception and production transcend linguistic barriers. Furthermore, the proposal suggests that no cultural factors interfere with the successful application of the model. This is because the neurophysiological processes involved in speech learning are intrinsic to the human condition and are not limited by cultural or

linguistic variations. Therefore, adopting the Giannecchini Model can significantly contribute to global therapeutic practices, providing a consistent and effective framework for the treatment of phonological disorders in any language.

To assess the sustained outcomes of the Giannecchini Model over the long term, it is essential to implement a systematic follow-up plan that focuses on several key aspects:

1. Scheduled Follow-Up Assessments: Regular follow-up assessments should be scheduled at strategic intervals post-intervention (e.g., 6 months, 1 year, and 2 years). These assessments can evaluate ongoing speech development, and the retention of skills learned during the initial therapy phase.

2. Longitudinal Studies: Conducting longitudinal studies that track participants over extended periods will provide valuable insights into the long-term effectiveness of the Giannecchini Model. This approach can help identify any changes in speech abilities, the need for additional support, or the emergence of new challenges.

3. Parent and Teacher Feedback: Gathering feedback from parents and teachers regarding the child's communication skills in various settings can provide a broader perspective on the sustained impact of the model. This qualitative data can complement quantitative assessments and highlight practical outcomes in everyday situations.

4. Development of a Tracking System: Establishing a tracking system for participants can facilitate ongoing monitoring of speech outcomes. This could involve the use of digital tools or apps that allow clinicians to easily assess progress and document any changes in speech abilities over time.

5. Research Collaborations: Collaborating with academic institutions or research organizations can enhance the rigor of long-term follow-up studies. These partnerships can provide access to larger participant pools and resources for comprehensive data analysis.

By implementing these plans for long-term follow-up, researchers and clinicians can effectively assess the sustained outcomes of the Giannecchini Model, ensuring that the benefits of the intervention continue to be realized in the years following initial therapy.

Future research directions should focus on several key areas to enhance our understanding and validation of the findings from the current study. Conducting comparative studies across diverse populations and settings will help assess the generalizability of the results. This could involve comparing outcomes in different demographic groups or geographical regions to identify any variations that may arise due to cultural or environmental factors. Implementing longitudinal designs will provide insights into the long-term effects of the variables studied. This approach can help to determine causal relationships and the sustainability of the findings over time. Performing meta-analyses of existing literature will allow for a comprehensive synthesis of related studies, enhancing the statistical power and reliability of conclusions drawn. This can help identify trends, inconsistencies, and gaps in research that require further exploration. Encouraging interdisciplinary research that integrates perspectives from various fields can lead to more holistic insights. Collaborations between psychologists, sociologists, and neuroscientists, for example, could provide a richer understanding of the phenomena being studied. Future studies should aim to explore the underlying mechanisms driving the observed effects. This can involve qualitative research methods to gather deeper insights into participant experiences and behaviors. By pursuing these avenues, researchers can build upon the current findings, leading to a more robust and nuanced understanding of the subject matter.

4. Conclusion

The praxis-productive intervention program – GIANNECCHNI MODEL elaborated for children with phonological disorder was composed of 14 sessions, 12 of which stimulated the 4 theoretically predefined pillars (auditory skills, phono articulatory awareness, non-verbal praxis and oral proprioception for articulatory points and modes) and 2 sessions of evaluation of these pre and post-intervention aspects.

The application of the MG showed an improvement in speech performance in all subjects, in the time stipulated by the instrument, with higher scores in the evaluative tests of phonology and post-intervention oral praxis, when compared to the pre-intervention scores, denoting its usability. The MG proved to be useful, simple, easy to apply by the speech-language pathologist and well understood by the sample subjects, with favorable responses to the acquisition of phonemes and, consequently, phonological and

praxis developments. Its efficacy was considered moderate, at least, since 75% or more of the subjects stimulated obtained positive results, with noticeable improvements in many cases, but with individual variations and the need for follow-up. However, studies with more subjects and meta-analyses in different populations are still needed.

It is notorious that future studies with the expansion of the sample, as well as age and different conditions of speech disorders, should be carried out to complement the findings of this study and to develop intervention programs that meet clinical demands.

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