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# Effect of delayed auditory feedback on stuttering with and without central auditory processing disorders

## *Efeito da retroalimentação auditiva atrasada na gagueira com e sem alteração do processamento auditivo central*

### ABSTRACT

**Purpose:** To verify the effect of delayed auditory feedback on speech fluency of individuals who stutter with and without central auditory processing disorders. **Methods:** The participants were twenty individuals with stuttering from 7 to 17 years old and were divided into two groups: Stuttering Group with Auditory Processing Disorders (SGAPD): 10 individuals with central auditory processing disorders, and Stuttering Group (SG): 10 individuals without central auditory processing disorders. Procedures were: fluency assessment with non-altered auditory feedback (NAF) and delayed auditory feedback (DAF), assessment of the stuttering severity and central auditory processing (CAP). Phono Tools software was used to cause a delay of 100 milliseconds in the auditory feedback. The “Wilcoxon Signal Post” test was used in the intragroup analysis and “Mann-Whitney” test in the intergroup analysis. **Results:** The DAF caused a statistically significant reduction in SG: in the frequency score of stuttering-like disfluencies in the analysis of the Stuttering Severity Instrument, in the amount of blocks and repetitions of monosyllabic words, and in the frequency of stuttering-like disfluencies of duration. Delayed auditory feedback did not cause statistically significant effects on SGAPD fluency, individuals with stuttering with auditory processing disorders. **Conclusion:** The effect of delayed auditory feedback in speech fluency of individuals who stutter was different in individuals of both groups, because there was an improvement in fluency only in individuals without auditory processing disorder.

### RESUMO

**Objetivo:** Verificar o efeito da retroalimentação auditiva atrasada na fluência da fala de indivíduos que gaguejam, com e sem alteração do processamento auditivo central. **Método:** Participaram 20 indivíduos com gagueira, de sete a 17 anos, divididos em dois grupos, cada um com 10 indivíduos: Grupo Gagueira com Transtorno do Processamento Auditivo (GGTPA) e Grupo Gagueira (GG) sem alteração de processamento auditivo central. Os procedimentos foram: avaliação da fluência com retroalimentação auditiva habitual (RAH) e atrasada (RAA), e avaliação da gravidade da gagueira e do processamento auditivo central (PAC). O *software Fono Tools* foi utilizado para provocar o atraso de 100 milissegundos na retroalimentação auditiva. O teste dos *Postos Sinalizados de Wilcoxon* foi utilizado na análise intragrupos, e o teste de *Mann-Whitney*, na análise intergrupos. **Resultados:** A RAA ocasionou no GG redução estatisticamente significante: no escore da frequência das disfluências típicas da gagueira na análise do Instrumento de Gravidade da Gagueira, na quantidade de bloqueios e de repetições de palavras monossilábicas, e na frequência de disfluências típicas da gagueira de duração. O atraso na retroalimentação auditiva não provocou efeitos estatisticamente significantes na fluência do GGTPA, grupo dos indivíduos com gagueira com alteração do PAC. **Conclusão:** O efeito da retroalimentação auditiva atrasada na fala de indivíduos com gagueira foi diferente nos indivíduos com e sem alteração do processamento auditivo central, pois houve melhora da fluência apenas nos indivíduos sem alteração do PAC.

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## INTRODUCTION

Relevant information on the auditory aspects of speech fluency has been demonstrated in the literature<sup>(1-10)</sup>, increasing more and more the interest in this interface, stuttering and hearing, among researchers.

Delayed auditory feedback in individuals who stutter decreases or inhibits stuttering<sup>(11)</sup>, and this effect is not related to the reduction of speech rate, but mainly to altered auditory input<sup>(12,13)</sup>. This fact suggests that auditory input processing could be different in individuals who stutter when compared to fluent individuals<sup>(14,15)</sup>.

Some variables can interfere in the obtained results with delayed auditory feedback, such as age, gender, delay time, stuttering severity, typology of disfluencies, among others. However, it is worth emphasizing that fluent speech occurs from the interaction of the acoustic aspects. The auditory system simultaneously and continuously monitors the external sounds of the acoustic environment during speech, as well as providing feedback of the own voice. Therefore, among the auditory aspects, it is believed that auditory abilities represent important variables that influence the effects of alterations in auditory feedback in stuttering.

The results of behavioral auditory tests of individuals with stuttering showed inferior performance in relation to the controls<sup>(1-4)</sup>. The temporal imprecision in speech perception and the decrease in auditory processing abilities can be related to disfluencies<sup>(2,8)</sup>, since fluent speech occurs from the interaction of the acoustic aspects and the alteration of these can be related to the inability to maintain fluency.

The manner that speakers process auditory information, mainly related to speech perception, is fundamental to understand possible difficulties presented in expressive language, including stuttering<sup>(3)</sup>. Children who stutter present central auditory discrimination impaired by less precise representation of speech sounds in relation to fluent children<sup>(8)</sup>. The results of an investigation with 27 children with stuttering and 28 controls suggest that the auditory-motor circuits and thalamic-cortical of the basal ganglia develop differently in children who stutter<sup>(16)</sup>. These peculiarities in these circuits can affect the processes of speech planning and execution, necessary to reach the motor control of the fluent speech<sup>(16)</sup>.

Although the theoretical reference about the importance of hearing in the stuttering, in the compiled literature, comparative studies of the effect of delayed auditory feedback on individuals who stutter, with and without auditory processing disorder were not found. It is believed that the effect of auditory feedback depends on the integrity of central auditory processing, since auditory abilities are used to process, analyze and interpret the auditory message.

This research aims to verify the effect of delayed auditory feedback on speech fluency in individuals who stutter, with and without auditory processing disorder. It will be analyzed: i) quantitative measures, such as percentage of stuttering-like disfluencies, other disfluencies and total of disfluencies; ii) the flows of syllables and words per minute; iii) qualitative

measures, such as the typologies of disfluencies, and iv) the stuttering severity.

## METHODS

This is a prospective observational cross-sectional study with comparison between groups, approved by the Research Ethics Committee (119809/2015) of institution. All ethical criteria were fulfilled according to the regulations of the National Commission of Ethics in Research (CONEP), including the signing of an Informed Consent Form (ICF) by the parents/family members responsible for the participant, and an Assent Term, when appropriate, signed by the own participant.

### Sample

Data were collected in the period between December 2015 and August 2016. The sample was composed of 20 individuals of both genders, aged between seven and 17 years and 11 months (Mean = 11.1, SD = 3.68) and diagnosis of persistent developmental stuttering, from a laboratory linked to a Clinical School of a public university. Participants were divided into two groups:

- Stuttering Group with Auditory Processing Disorder (SGAPD): 10 individuals with stuttering with auditory processing disorder (mean of 10.30 years, standard deviation of 3.60);
- Stuttering Group (SG): 10 individuals with stuttering without auditory processing disorder (mean of 11.80 years, standard deviation of 3.90).

The groups were similar in age. The Mann-Whitney test was applied to verify possible difference between the ages of the participants of the groups, and the result showed the  $p$  value = 0.421.

The inclusion criteria were: i) being native speakers of Brazilian Portuguese; ii) chronological age between seven and 17 years and 11 months; iii) diagnosis of persistent developmental stuttering by a specialist in the area; iv) a minimum of 3% of stuttering-like disfluencies; v) a minimum score of 11 points (from seven to 16 years and 11 months) or 18 points (over 17 years) in the Stuttering Severity Instrument - SSI-3<sup>(17)</sup>, excluding cases of very mild degree of stuttering, and vi) pure tone audiometry within normality patterns and tympanometric curve type A.

Two criteria differentiated the participants between the groups: those who presented auditory processing disorder, in the Stuttering Group with the Auditory Processing Disorder (SGAPD) and those who did not present auditory processing disorder, for the participants of the Stuttering Group (SG).

Exclusion criteria for both groups were: presence of neurological alterations, genetic syndromes, conductive or sensorineural hearing loss, attention deficit hyperactivity disorder (ADHD) or psychiatric conditions. The parents of the participants were submitted to the anamnesis and the procedures of the audiological and speech-language assessments were applied to the participants to raise the exclusion criteria.

## Procedures

The procedures consisted of assessment of the speech fluency and basic audiological assessment and specific auditory processing assessment.

The fluency assessment was performed from the spontaneous speech samples collected in two different listening conditions: non-altered and delayed. The sequence of recording of the tasks was the same for all participants: first, spontaneous speech with non-altered listening; then spontaneous speech with delayed auditory feedback.

The recordings were performed with the participant sitting in a quiet environment, with the headphones (with microphone) adjusted and connected to a computer, in which a specific software was used to cause the delay of 100 milliseconds (Fono Tools, version 1.5h, CTS Informatic). The audiovisual record of spontaneous speech was carried out by means of a Sony digital camera (HDR - CX 350) and a tripod. The spontaneous speech samples collected in both auditory feedback conditions (non-altered and delayed) were transcribed in a total of 200 fluent syllables for each sample. The Stuttering Severity Instrument-SSI-3 was used to classify the severity of stuttering<sup>(17)</sup>.

The basic audiological assessment was based on pure tone audiometry (thresholds ranging from 250 to 8.000 Hz in an acoustic booth with a GSI-61 audiometer), acoustic immittance through tympanometry (with a 226 Hz probe tone); the acoustic reflex threshold (contralateral and ipsilateral, at 500, 1.000, 2.000 and 4.000 Hz) was performed using the AT-235 immitanciometer.

The assessment of auditory processing was performed to assess the auditory abilities through the behavioral tests, in an acoustically treated booth, with a two-channel clinical audiometer (GSI-61), connected to a DVD Player. The selected tests were: Dichotic Digit Test (DDT), Duration Pattern Recognition Test (DPT), Frequency Pattern Recognition Test (FPT), Random Gap Detection Test (RGDT) and Gaps In Noise (GIN).

## Data analysis

The properly tabulated data were sent for statistical treatment in SPSS software version 23.0. The descriptive analysis was performed using mean, median, minimum value, maximum value and standard deviation. Statistical analysis of the data was performed with the Wilcoxon Signed-Rank test for intragroup analysis and the Mann-Whitney test for intergroup analysis. The significance level adopted was 5% and the significant results were marked with an asterisk.

## RESULTS

Initially, it is important to emphasize that the groups were homogeneous in relation to the fluency parameters in the non-altered listening condition, that is, there were no statistically significant differences for the frequencies of disfluencies and for the flow of syllables and words per minute (Tables 1 and 2). The delayed auditory feedback did not provoke significant effects in any of the investigated groups in relation to the frequency of disfluencies (Table 1) and the speech rate (Table 2). However, it can be observed a statistical tendency of the stuttering group (SG) to present a reduction of the stuttering-like disfluencies ( $p=0.058$ ) (Table 1). The stuttering group with auditory processing disorder (SGAPD) presented a statistical tendency of reduction of the flows of syllable ( $p = 0.051$ ) and words per minute ( $p = 0.051$ ) (Table 2).

In terms of the stuttering severity, the groups showed similarities in the non-altered listening condition (Table 3). The delayed auditory feedback caused a significant decrease in the frequency of stuttering-like disfluencies (SLD) in SG, that is, in the participants of the stuttering group without auditory processing disorder (Table 3).

The delayed auditory feedback did not cause significant effects on the different stuttering-like disfluencies manifested by participants from SGAPD (Figure 1). Intragroup analysis of the frequency of typologies of stuttering-like disfluencies showed

**Table 1.** Intra and intergroup analysis of the Stuttering Group with Auditory Processing Disorder and Stuttering Group in relation to the percentage of disfluencies in both listening conditions, non-altered and delayed

		Stuttering Group with Auditory Processing Disorders (SGAPD)					Stuttering Group (SG)					p Value
		Mean	Median	Minimum	Maximum	SD	Mean	Median	Minimum	Maximum	SD	
<b>SLD</b>	<b>NAF</b>	6.60	4.50	3.00	17.50	4.64	7.55	6.25	3.00	19.50	5.30	0.760
	<b>DAF</b>	7.85	4.50	2.50	22.00	7.01	6.20	4.75	1.50	20.00	5.30	0.677
<b>p value</b>		0.944			0.058							
<b>OD</b>	<b>NAF</b>	6.95	6.25	3.50	14.50	3.43	6.80	5.00	3.00	15.00	4.37	0.568
	<b>DAF</b>	5.95	6.25	2.00	9.50	2.09	8.10	7.00	3.50	13.00	3.08	0.094
<b>p value</b>		0.722			0.172							
<b>TD</b>	<b>NAF</b>	13.55	11.75	6.50	32.00	7.63	14.35	11.50	7.50	27.70	7.28	0.733
	<b>DAF</b>	13.80	11.00	7.00	29.00	7.13	14.30	12.75	5.00	27.50	6.29	0.343
<b>p value</b>		0.513			0.683							

Statistical difference  $p < 0.05$  - Wilcoxon Signed-Rank test the intragroup analysis and Mann-Whitney test in the intergroup analysis

**Caption:** NAF = Non-altered Auditory Feedback; DAF = Delayed Auditory Feedback; SD = Standard Deviation; SLD = Stuttering-Like Disfluencies; OD = Other Disfluencies; TD = Total of Disfluencies

that delayed auditory feedback caused a significant reduction in the amount of blocks ( $p = 0.010$ ) and monosyllabic word repetitions ( $p = 0.042$ ) in SG (Figure 2).

Table 4 presents the comparison between duration disfluencies (block, prolongation and pause) and repetition disfluencies

(word, part-word and syllable repetition) manifested by the two groups assessed, under listening conditions with non-altered and delayed auditory feedback. The Stuttering Group (SG) presented a reduction of the stuttering-like disfluencies of duration under the effect of delayed auditory feedback.

**Table 2.** Intra and intergroup analysis of the Stuttering Group with Auditory Processing Disorder and Stuttering Group in relation to the speech rate in the two listening conditions. non-altered and delayed

		Stuttering Group with Auditory Processing Disorders (SGAPD)					Stuttering Group (SG)					p value
		Mean	Median	Minimum	Maximum	SD	Mean	Median	Minimum	Maximum	SD	
<b>SPM</b>	<b>NAF</b>	161.30	168.50	30.00	240.00	58.37	154.04	150.95	48.00	266.66	59.98	0.596
	<b>DAF</b>	136.95	150.21	33.00	219.52	54.86	156.34	157.03	100.00	260.86	46.29	
<b>p value</b>		0.051					0.878					
<b>WPM</b>	<b>NAF</b>	97.55	107.18	20.00	124.40	32.97	92.82	86.66	28.00	157.33	35.70	0.520
	<b>DAF</b>	83.99	88.26	20.00	133.68	32.74	93.30	92.07	58.50	133.04	22.90	
<b>p value</b>		0.051					0.878					

Statistical difference  $p < 0.05$  - Wilcoxon Signed-Rank test the intragroup analysis and Mann-Whitney test in the intergroup analysis

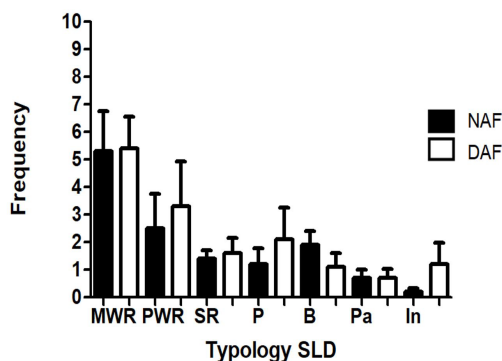
**Caption:** NAF = Non-altered Auditory Feedback; DAF = Delayed Auditory Feedback; SD = Standard Deviation; SPM = Syllables Per Minute; WPM = Words Per Minute

**Table 3.** Intra and intergroup analysis of the Stuttering Group with Auditory Processing Disorder and Stuttering Group in relation to the scores of the Stuttering Severity Instrument

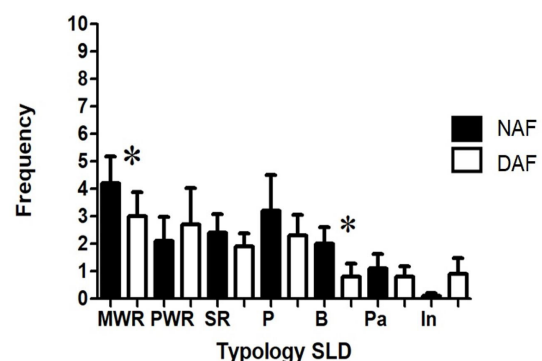
		Stuttering Group with Auditory Processing Disorders (SGAPD)					Stuttering Group (SG)					p value
		Mean	Median	Minimum	Maximum	SD	Mean	Median	Minimum	Maximum	SD	
<b>FS</b>	<b>NAF</b>	11.00	10.00	8.00	16.00	2.87	11.60	11.00	8.00	16.00	3.24	0.689
	<b>DAF</b>	11.20	10.00	6.00	18.00	3.79	9.50	9.50	4.00	16.00	3.37	
<b>p value</b>		0.914					0.048*					
<b>DS</b>	<b>NAF</b>	6.40	6.00	6.00	8.00	0.84	6.40	6.00	4.00	10.00	2.27	0.668
	<b>DAF</b>	6.20	6.00	4.00	10.00	1.99	6.40	6.00	4.00	10.00	2.46	
<b>p value</b>		0.705					>0.999					
<b>PCS</b>	<b>NAF</b>	4.20	3.50	3.00	7.00	1.55	5.20	5.50	0.00	10.00	2.62	0.216
	<b>DAF</b>	4.60	4.00	3.00	9.00	2.01	5.10	5.00	0.00	9.00	2.77	
<b>p value</b>		0.684					0.833					
<b>TS</b>	<b>NAF</b>	21.60	19.00	17.00	29.00	4.67	23.20	23.00	14.00	32.00	7.10	0.471
	<b>DAF</b>	22.00	19.00	13.00	35.00	7.06	21.00	19.00	11.00	31.00	6.61	
<b>p value</b>		0.811					0.256					

\*Statistical difference  $p < 0.05$  - Wilcoxon Signed-Rank test the intragroup analysis and Mann-Whitney test in the intergroup analysis

**Caption:** NAF = Non-altered Auditory Feedback; DAF = Delayed Auditory Feedback; SD = Standard Deviation; FS = Frequency Score of stuttering-like disfluencies; DS = Duration Score of stuttering-like disfluencies; PCS = Physical Concomitants Scores; TS = Total score of the test



**Caption:** NAF = Non-altered Auditory Feedback; DAF = Delayed Auditory Feedback; MWR = Monosyllabic Word Repetition; PWR = Part-Word Repetition; SR = Sound Repetition; P = Prolongation; B = Block; Pa = Pause; In = Intrusion. **Figure 1.** Distribution of the means of the different stuttering-like disfluencies manifested by the Stuttering Group with Auditory Processing Disorders in two listening conditions, non-altered and delayed. Mean  $\pm$  standard error of the mean frequencies of stuttering-like disfluencies.



**Caption:** NAF = Non-altered Auditory Feedback; DAF = Delayed Auditory Feedback; MWR = Monosyllabic Word Repetition; PWR = Part-Word Repetition; SR = Sound Repetition; P = Prolongation; B = Block; Pa = Pause; In = Intrusion. \* $p < 0.05$  **Figure 2.** Distribution of the means of the different stuttering-like disfluencies manifested by the Stuttering Group in two listening conditions, non-altered and delayed. Mean  $\pm$  standard error of the mean frequencies of stuttering-like disfluencies.

**Table 4.** Comparison between duration and repetition disfluencies under two different listening conditions, non-altered and delayed

		Stuttering Group with Auditory Processing Disorders (SGAPD)					Stuttering Group (SG)					p value
		Mean	Median	Minimum	Maximum	SD	Mean	Median	Minimum	Maximum	SD	
<b>SLD of duration</b>	<b>NAF</b>	3.80	3.20	1.00	7.00	2.35	6.30	5.00	1.00	18.00	4.85	0.224
	<b>DAF</b>	4.10	2.00	0.00	11.00	4.12	3.90	2.50	1.00	9.00	2.92	0.590
<b>p value</b>		0.905					0.036*					
<b>SLD of repetition</b>	<b>NAF</b>	9.20	6.00	2.00	30.00	8.35	8.70	6.50	0.00	21.00	7.02	0.909
	<b>DAF</b>	10.40	6.00	5.00	33.00	9.24	7.60	4.50	1.00	25.00	7.59	0.092
<b>p value</b>		0.325					0.526					

\*Statistical difference  $p < 0.05$  - Wilcoxon Signed-Rank test the intragroup analysis and Mann-Whitney test in the intergroup analysis

**Caption:** SLD = Stuttering-Like Disfluencies; NAF = Non-altered Auditory Disfluencies; DAF = Delayed Auditory Disfluencies; SD = Standard Deviation

## DISCUSSION

The delayed auditory feedback (DAF) has been used to promote speech fluency in individuals with stuttering, through various electronic devices, among which a software, which presents itself as an easy access technology to both the individual who stutters and the speech-language therapist. However, due to the wide variability of the effects of DAF, there is still no consensus on the subgroup of individuals affected by the disorder who could benefit from the use of this device.

It is believed that auditory abilities play a relevant role in the effects of auditory feedback alterations, this study analyzed the immediate effect of delayed auditory feedback on the fluency of stuttering individuals with and without central auditory processing disorders.

The effect of DAF was assessed by comparison between the means of the groups in relation to the frequency and typology of stuttering-like disfluencies, speech rate and stuttering severity in the non-altered listening condition with the delayed listening condition. The results showed positive effects in individuals with stuttering without central auditory processing (SG) alterations, because the following reductions occurred: i) the frequency score of stuttering-like disfluencies of Stuttering Severity Instrument<sup>(17)</sup>; ii) the amount of blocks and monosyllabic words repetitions, and iii) the total of disfluencies of duration. These data corroborate studies which show a decrease of the disfluencies in individuals who stutter under delayed listening condition<sup>(11-12,18-21)</sup>. This increase in fluency represents a very relevant result for individuals with stuttering, for two main reasons: i) speech is the main form of human communication and its efficiency in transferring information depends on fluency<sup>(22)</sup>, and ii) the percentage of stuttered syllables or stuttering-like disfluencies is considered a counting measure of stuttering gold standard obtained by the speech language therapist<sup>(23)</sup>.

The delay in auditory feedback caused, as an immediate effect, a significant reduction in block and monosyllabic words repetitions in individuals with stuttering without central auditory processing disorders (SG). In relation to the monosyllabic word repetition, this can be explained by the fact that the words repetition is the repetition disfluency considered as stuttering-like disfluencies, whose linguistic unity repeated is greater, that is, the word is greater than syllable and that sound; therefore, it

would intensify the chorus effect, making monitoring of auditory feedback more effective.

The significant reduction in the number of blocks corroborates a previous study that showed a greater reduction of blocks in relation to the prolongations and repetitions<sup>(5)</sup>. It is believed that, because the blocks cause a rupture in speech production, the silence is more audible by delayed auditory feedback. Therefore, during the DAF, the stutterer individual was able to maintain a more continuous flow of oral emission, to avoid inappropriate interruption of the speech caused by the blocks.

The qualitative analysis of the immediate effect of DAF showed that auditory abilities should be considered in the process of indicating the use of this device for individuals with stuttering, because, while five types of disfluencies increased in SGAPD, in SG, there was reduction of five typologies. It can be observed a tendency to the reduction of majority of the disfluencies under the effect of delayed auditory feedback in the Stuttering Group, with the exception of part-word repetition and intrusion, which presented a mild increase in this condition. In individuals with stuttering with auditory processing disorders (SGAPD), there was a tendency to increase in the most disfluencies; it was observed that only the pause remained with the same frequency and occurred the decrease of the number of blocks.

In relation to the speech rate, the effects were not significant in both groups; however, were diverse among individuals with and without auditory processing disorders. There was a small tendency to increase flows of syllable and words per minute in SG, while in SGAPD there was an opposite effect, a tendency to reduce these flows. Individuals with stuttering with central auditory processing disorders showed a reduction of 15.09% in the flow of syllables per minute ( $p = 0.051$ ) and of 13.90% in flow of words per minute ( $p = 0.051$ ).

The effect of decreasing the speech rate is not desirable for individuals who stutter, since the own disorder, due to the excessive amount of disfluencies, causes a reduction in speech rate<sup>(24-26)</sup> or articulatory slowing<sup>(27)</sup>. A study of children with developmental stuttering, speakers of Brazilian Portuguese, showed that readiness in motor speech programming is slowed in relation to the control group of fluent children<sup>(28)</sup>. These findings reinforce the importance of providing a greater number of words per minute in the flow of speech of individuals who stutter. Therefore, one of the desirable effects in therapy is to

increase fluency and, consequently, the flow of information, that is, the number of fluent words per minute.

This research presented relevant results with respect to the DAF on the speech fluency of individuals with stuttering, but it is important to highlight some limitations of the study. The analyzed effects were immediate and, therefore, further studies should be conducted to investigate whether the effects continue in the long term. In addition, the study examined the effect of delayed auditory feedback. Since several investigations were performed with the delay and alteration in the frequency of auditory feedback in individuals with stuttering, it would be interesting to replicate the methodological design of this study, but using both forms of alteration in auditory feedback.

It is also believed that, before indicating the use of the device, the speech-language therapist should perform a therapeutic test to analyze the immediate effects of the DAF in the population of individuals affected by stuttering. The results of speech and audiological assessment need to be considered in the therapeutic conduct in relation to the indication or not of DAF.

## CONCLUSION

The effect of delayed auditory feedback on the speech of individuals with stuttering was different in individuals with and without alteration of central auditory processing (CAP), because there was improvement in fluency only in individuals without alteration of CAP. In this regard, the speech-language therapist should assess auditory abilities before indicating the use of this device.

The group of individuals with stuttering without central auditory processing disorders showed positive results of the delay in NAF, because there was a significant reduction in the amount of blocks and monosyllabic words repetitions, as well as the frequency of stuttering-like disfluencies in the Stuttering Severity Instrument. There was also a decrease in the frequency of stuttering-like disfluencies of duration. It was concluded that delayed auditory feedback for individuals with stuttering without central auditory processing disorders is a viable therapeutic device.

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### Author contributions

*LAP was responsible for project design and collection, sample selection and case diagnosis, tabulation and data analysis, and writing of the manuscript; ACVC was responsible for the study design, data analysis, research coordination and writing of the article; AVC was responsible for collecting and data analysis and writing of the scientific article; CMCO was responsible for the project, study design, discussion of the findings and general orientation of the stages of execution and preparation of the manuscript.*