Comparative effect of needle acupuncture and touch acupuncture stimulation on facial nerve function among Bell's palsy patients at selected acupuncture centers in Chennai.

Section A-Research paper

COMPARATIVE EFFECT OF NEEDLE ACUPUNCTURE AND TOUCH ACUPUNCTURE STIMULATION ON FACIAL NERVE FUNCTION AMONG BELL'S PALSY PATIENTS AT SELECTED ACUPUNCTURE CENTERS IN CHENNAI.

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Abstract:

Objective: The aim of this study is to compare the effectiveness of needle acupuncture compared to touch acupuncture stimulation to improve facial nerve function among Bell's palsy.**Design:** A Quasi Experimental Pre-test Post-test Control Group Design. **Participants**: Subjects diagnosed with Bell's palsy survivors between 15-60. **Setting:** An acupuncture centers inChennai. (Week-0) A total of 50 participants were randomized in to Experimental and Control groups.1st week –Pre-test measurement and demographic variables were taken for all participants **Treatment:** (2-11 weeks) Experimental group received needle acupuncture treatment accompanied by manual twisting of needles and obtaining of 8 Meridian based on acupoints for Bell's palsy were performed 3 days a week for 10 weeks. Control group received touch stimulation standard acupuncture. 8th week – Post-test measurement were given as per pre-test **Outcome Measures**- Facial Nerve Grading Scale (FNGS) were evaluating the improvement of facial nerves movement and expression **Results:** Experimental group had shown significant improvement compared to Control group. Facial Nerve Grading Scale score were all increased apparently in the Experimental group (P<0.001) compared to Control group. **Conclusion:** Present study suggests that needle acupuncture stimulation may induce an immediate effect that improves facial nerve function among facial paralysis.

Keywords: Effectiveness, Needle Acupuncture, Touch Acupuncture, Facial nerve function, Bell's Palsy.

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1. INTRODUCTION

Bell's palsy or facial paralysis is characterized by weakness of the muscles supplied by the facial nerve, due to inflammation and swelling of the facial nerve within the facial route. It is most common in the persons who are over 30 years of age and in both sexes equally. Sudden onset of unilateral total or partial paralysis of the facial muscles, numbness on the affected side, loss of taste and excessive tear production on the affected side are the signs and symptoms. 18 cases of facial paralysis were treated using acupuncture with perpendicular and point to point acupuncture. Among them 11 cases were cured (61.11%) after treatment, symptoms and signs disappear completely, both sides of face are symmetric, and the sensory and motor functions recover completely, 6 cases showed marked effect (33.33%) symptoms and signs disappear, both sides of faces are symmetric, sensory and motor functions return 1 case showed improvement (5.55%) symptoms and signs almost disappear, twitching the nose, inflating the cheeks or laughing, an effective rate of 100%. Based on the theory of traditional Chinese medicine, it is held that wind and cold of external origin invade the channels traversing the face and disrupt the flow of Qi and blood, preventing the vessels and muscles from receiving the necessary nourishment. Treatment is directed towards spreading the Qi through the channels of the face[1][2].Bell's palsy is the most common dysfunction affecting the facial nerves[3] it affects 11–40 persons per 100,000 population each year[4] and 1 in 60 suffers a lifetime risk[5]. More than 60,000 persons were affected by this disease each year in the United States alone[6]. Most patients with Bell's palsy recover normally within 3 weeks, with or without medical intervention[7]. Full restoration may take up to 9 months in some cases and up to 30% of patients are left with complications, such as potentially disfiguring facial weakness or persistent lacrimation, needing further medical therapy[8,9,10].Relevant therapies containing antiviral medicine , corticosteroids [11], surgery and acupuncture treatment [12] are commonly applied to Bell's palsy patients. Acupuncture is a practical and cost-effective intervention with few adverse side effects which is useful for many disorders. The efficacy of acupuncture treatment on Bell's palsy has been examined for many times by meta-analyses [13,14,15] Acupuncture is among the oldest healing practices in the world. In the United States, it has been considered as one of the major therapies in complementary and alternative medicine (CAM) [16].

OBJECTIVES

1. To compare the effectiveness of needle acupuncture and touch acupuncture on five point facial nerve scale its respect to facial nerve function among Bell's palsy patients.
2. To compare the effectiveness of needle acupuncture and touch acupuncture on selected demographic variables among Bell's palsy patients

HYPOTHESES

H1: There is a significant difference between the needle acupuncture and touch acupuncture on five point facial nerve scale its respect to facial nerve function among Bell's palsy patients.

H2: There is a significant association between the needle acupuncture and touch acupuncture on selected demographic variables among Bell's palsy patients

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Theoretical Model
The theoretical framework adapted for this study is based on Orem's Self-Care Deficit Theory [17].

2. MATERIALS AND METHODS

An evaluate approach with quasi experimental pretest-posttest control group design was adopted for the current study .The target population was right and left hemiplegic stroke who attended in acupuncture centers in Chennai. The study was conducted in federation of acupuncture centers located in the City of Chennai (Valasaravakkam and Pallikaranai). The data collection Process done for 12 weeks by using purposive sampling method. The tool is prepared based on the objectives of the study. Permission is obtained and registered from federation of acupuncture centers in Chennai, Tamil nadu, India. After obtaining approval and clearance from the Institutional Ethics Committee.50 subjects who met the inclusion and exclusion criteria were included in the study. Anonymity, confidentiality, and professional secrecy were maintained for all the study subjects. The study was conducted from January 2021 to March 2021. Detailed history of Bell's palsy was obtained. The inclusion criteria for selection of patients who are already diagnosed to have with facial paralysis. People with first-ever Bell's palsy confirmed by CT or MRI. Patients who are able to read and understand and English or Tamil. Age group above 15 to 60.Patients who are visit in Acupuncture centers. Severe and unstable clinical disorders. Unable to follow or respond to treatment. Lactation, Pregnancy or intend to be pregnant within 6month.Pacemaker or Implantable cardioverter defibrillator carriers and needle phobia were excluded. Content validity of the instruments was obtained from two medical experts and three nursing experts in the field of medical surgical nursing. The reliability of the tool was elicited by using test-retest method

Data collection procedure
Ethical permission for conduction of the study was obtained from Acupuncture centers in Chennai. Prior to the collection of data; the investigator introduced self to the patients and established rapport with them. The treatment was explained to the patients and a written consent was obtained prior to initiation of the intervention. The purpose of the study was explained to each subject in the language known to them (Tamil/English).Adequate privacy was ensured throughout the study.**Allocation Baseline assessment and randomization (Week-0).**Totally 50 subjects were enrolled for this study and divided in to two groups with simple randomization method. They have been enrolled for this study after screening based on inclusion criteria. The subjects were assigned the experimental group received needle acupuncture (n=25) the control group received routine touch acupuncture (n=25). **Pre-test – (Week-1)** Demographic Variables, Facial Nerve Grading Scale (FNGS) were given.**Treatment (Weeks-2-11)** Experimental group received needle acupuncturethe needle used for the treatment is simple foliform shortest needles of 0.5 inch length and the acupuncture points are all located only on the surface of the skin. Locations of acupuncture points for Bell's palsyGB 1, GB 20, ST 7, ST 8, LI 4, LI 11, ST 19 and ST 36 (Total Meridian points are 8). Total Locations of acupuncture points includes 14 Channels.The control group has received the routine touch acupuncture which has standard acupuncture treatment stimulating a point by the touch of the finger, instead of needle and the tip of the right index finger is used for the touch treatment without intervention from the

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researcher. Both group received acupuncture for the period of 20minutes.A total of 3 sessions, per week performed for a period 10 weeks and explain the acupuncture process and possible sensations during acupuncture therapies to the participants before administration of acupuncture treatment. Immediately after each acupuncture session vital signs such as pulse, blood pressure, respiration rate and body temperature were assessed and recorded, brief interviews conducted to record participants. Feedback about the treatment these forms will be checked regularly by the investigator for consistency across different licensed acupuncture practitioner.**Compliance assessment via phone calls (week-8) Follow-up.Post-test(Week-12)** given same as pre-test. **Outcome Measures and Evaluations.** The outcome measures in the changes in the movement and expression of Five point Facial Nerve Grading Scale (FNGS) [18].

Locations of Acupuncture Points for Bell's Palsy
1.GB 1 (Tongzilliao)
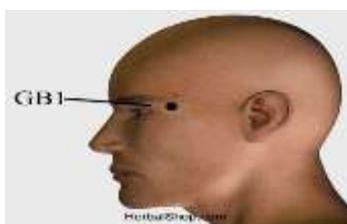
0.5 cun lateral to the outer canthus, in the depression on the lateral side of the orbit.
2. GB 20 (FengChi)
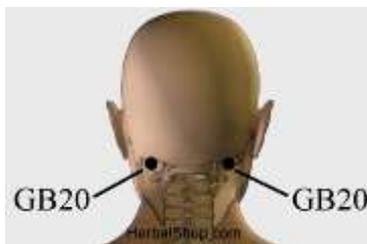
Gall Bladder **20**. **Location**: On the nape, below the occiput, at the level of DU 16, in the depression between the upper portion of m. sternocleidomastoideus and m. trapezius.
3.ST 7 (Xiaguan)
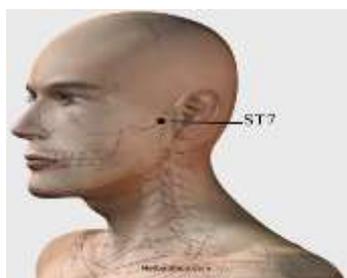
Location: On the lateral face, in the depression at the lower border of the zygomatic arch, anterior to the condyloid process of the mandible. **ST 7** is **located** with the mouth closed.
4. ST 8 (Touwei)

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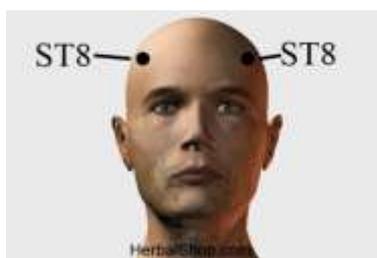
Location: On both sides of the scalp, .5cun above the hairline at the corner of the forehead, 4.5 cun lateral from the midline of the head.

INSTRUMENTS

Section A - Socio demographic: The data included the demographic variable of Bell's palsy consisting of age, sex, occupation, family history of Bell's palsy and dietary history.**Section B-** Facial Nerve Grading Scale (FNGS)**:** Scale measures the passive movement and expression on a 5-point scale (levels 0,1,2,3,4) respectively are awarded. The scale consists of normal, slight paralysis,moderate paralysis,severe paralysis and total paralysis. Activities are 1. At rest, 2. Wrinkle forehead, 3. Blink, 4, Slight closure of eye, 5. Tight closure of eye, 6. Closure of eye on the involved side only, 7. Wrinkle nose, 8. Whistle, 9. Grin (a wide smile), 10. Depress lower lip. This test is designed to assess the return of function following facial paralysis and neurological impairment. The test looks at a patient's ability to move with low tone or in a synergistic pattern and finally move actively out of that pattern into normal movement and expression.

STATISTICAL ANALYSIS

The data obtained from the study was computed using a frequency distribution to describe the demographic characteristics and chi-square test was carried out to find the homogeneity. Both parametric and non parametric test were done for the comparison of the effectiveness of needle and touch acupuncture.Mean and median were used for statistical analysis by means of parametric and nonparametric tests.Two-way RM ANOVA with Bonferroni multiple comparison test were used for comparison of pre and post test difference from between and within groups.A probability of 0.05 or less was taken as statistically significant. The analysis and plotting of graph were carried out using Sigma Plot 13.0 (Systat Software Inc.,USA).

3. RESULTS

Table 1 :	Comparison between the Experimental and Control groups as regard Socio Demographic data (N=50)			
Demographic variables	**Experimental Group(25)**		**Control Group (25)**	
	Frequency	**Percentage**	**Frequency**	**Percentage**
1. Age in years				
1. 15-25	2	9%	2	8%
2. 26-35	15	40%	14	39%
3. 36-45	5	30%	6	33%
4. 45-60	3	21%	3	20%

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2. Sex				
1.Male	19	71%	22	80%
2.Female	6	29%	3	20%
3. Occupation				
1.Working	22	85%	23	90%
2.Non working	3	15%	2	10%
4. Family history of Bell's palsy				
1.Father	13	40%	12	40%
2.Mother	7	30%	8	31%
3.Sibling	3	20%	4	24%
4.Paternal grand parent	2	10%	1	5%
5.Maternal grand parent	0	-	0	-
5. Dietary History				
1.Non-Vegetarian	21	86%	23	90%
2.Vegetarian	4	14%	2	10%

Table-1 reveals that the Demographic variables of Patients indicated that 40% of the patients in experimental and 39% were in control group in the age group 26-36.In the experimental group 71% were in male 29% were in female, whereas in the control group 80% in male 20% in female. In the experimental group 85% were working, 15% were non-working whereas in the control group 90% were working 10% were non-working. Family history of Bell's Palsy 40% of them had fathers in the experimental and control group respectively. 86% and 90% were non –Vegetarian in the experimental and control group.

Table 2 : Comparison of Facial Nerve Grading Scale Measures (N=50)

Parameters	Groups	Mean	SD	Median Percentile	P- Value	Statistical Inference
Facial Nerve Grading Scale (FNGS - A) (At rest)	Control group pre-test	5.94	1.53	6.0(5.0-7.0)	P< 0.001	Greater Significant
	Control group post-test	12.58**	4.46	12.0(8.0-15.75)		
	Experimental group pre-test	6.21	1.37	6.0(5.0-7.0)		
	Experimental group post-test	20.23**	1.74	20.0(19.0-22.0)		
Facial Nerve Grading Scale (FNGS - B) (Wrinkle forehead Blink	Control group pre-test	5.08	1.32	5.0(4.0-6.0)	P< 0.001	Greater Significant
	Control group post-test	12.58*	3.94	13.0(9.0-16.0)		
	Experimental	5.12	1.62	5.0(4.0-6.0)		

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Slight closure of eye Tight closure of eye Closure of eye on the involved side only)	group pre-test					
	Experimental group post-test	17.08**	1.70	17.0(16.0-18.0)		
Facial Nerve Grading Scale (FNGS - C) (Wrinkle nose Whistle Grin(wide smile) Depress lower lip)	Control group pre-test	3.66	1.41	4.0(2.0-5.0)	P< 0.001	Greater Significant
	Control group post-test	6.23*	1.76	7.0(5.0-7.75)		
	Experimental group pre-test	4.23	1.11	4.0(4.0-5.0)		
	Experimental group post-test	7.28**	1.27	7.5(6.0-8.0)		
Facial Nerve Grading Scale (FNGS - T) (Total components of Facial Nerve Grading Scale)	Control group pre-test	14.75	3.11	14.0(13.0-17.75)	P< 0.001	Greater Significant
	Control group post-test	31.41*	9.57	32.0(22.0-39.75)		
	Experimental group pre-test	15.56	3.13	14.0(13.0-17.0)		
	Experimental group post-test	44.60**	3.32	46.0(42.0-47.0)		

Table 2: reveals that the Comparison of Facial Nerve Grading Scale Measures Mean,SD and p value shows that compare to pre test post test experimental group have Greater Significant

Table 3: Within-group comparison for FNGS - A and FNGS – B (N=50)				
S. no	**Parameter**	**Paired test**	**t-test value**	**P-value**
1.	Facial Nerve Grading Scale (FNGS - A) (At rest)	Control group (Pre to Post)	t = 13.201	< 0.001
		Experimental group(Pre to Post)	t = 27.857**	< 0.001
2.	Facial Nerve Grading Scale (FNGS - B) (Wrinkle forehead Blink Slight closure of eye Tight closure of eye Closure of eye on the involved side only)	Control group (Pre to Post)	t = 16.867	< 0.001
		Experimental group(Pre to Post)	t = 26.907**	< 0.001

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t and P values are by Two-way RM ANOVA Boneferroni multiple comparision test
Within group comparison for FNGS-A and FNGS-B on pre test to post test of t and P value were shown greater significance for the experimental group over the control group (P < 0.001).
** Significantly different from the respective control group (Within group)

S. no	Parameter	Paired test	t-test value	P-value
1.	Facial Nerve Grading Scale (FNGS - A) (At rest)	Control group (Pre to Post)	t = 0.542	0.589
		Experimental group (Pre to Post)	t = 15.458**	< 0.001
2.	Facial Nerve Grading Scale (FNGS - B) (Wrinkle forehead Blink Slight closure of eye Tight closure of eye Closure of eye on the involved side only)	Control group (Pre to Post)	t = 0.079	0.937
		Experimental group (Pre to Post)	t = 9.955**	< 0.001

Table 4: Between-group comparison for FNGS-A and FNGS-B (N=50)

t and P values are by Two-way RM ANOVA Boneferroni multiple comparison test
Between group comparison for FNGS-A and FNGS-B on pre test to post test of t and P value were shown greater significance for the experimental group over the control group (P < 0.001).
** Significantly different from the respective control group (Between group)

Table 5: Shows that the Association between Post-test of Socio Demographic Variables and Acupuncture treatment among Study and Control groups (N=50)

Demographic Variables	Socio Demographic Variables and Acupuncture treatment					
	Experimental Group		Chi-square & P-Value	Control Group		Chi-square & P-Value
	N	P		N	P	

1.Age in years
    1. 30-40
    2. 41-50
    3. 51-60
    4. 61-70
	1
	7
	17
	0
		5
		30
		65
		-
			4.177
			>0.05
				2
				6
				16
				1
					20
					25
					50
					5
						4.187
						>0.05

2.Sex
   1.Male
   2.Female
	20
	5
		85
		15
			0.027
			>0.05
				23
				2
					90
					10
						0.025
						>0.05

3.Educational status
   1.Elementary
   2.High School
	2
	3.5
		10
		20
			2.395	1
				6
					5
					25
						2.465

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3.Higher Secondary	9	30	>0.05	12	40	>0.05
4.Degree	10.5	40		6	30	
4.Occupation						
1.Working	12.5	50	0.58	12.5	50	0.54
2.Non working	12.5	50	>0.05	12.5	50	>0.05
5.Monthly family income						
1.<5000	3	25	4.387	5	20	4.286
2.6,000-10,000	8	30	>0.05	7	30	>0.05
3.>11,000	14	45		13	50	
6.Family history of Bell's Palsy	17	70		16	60	
1.Father	6	20	4.178	7	30	4.234
2.Mother	2	10	>0.05	2	10	>0.05
3.Sibling	0	0		0	0	
4.Paternal grand parent	0	0		0	0	
5.Maternal grand parent						
7. Dietary History						
1.Non-Vegetarian	23	95	0.344	24	96	0.322
2. Vegetarian	2	5	>0.05	1	4	>0.05

Table-5 reveals that there was significant association between Socio Demographic Variables with the post-test and Acupuncture treatment among Study and Control groups in relation to Age, Sex, Educational status, Occupation, Monthly family income, Family history of Bell's Palsy and Dietary history.

4. DISCUSSION

This study was conducted to find out the effects of needle acupuncture among Bell's palsy patients. Present study was aimed to improve facial nerve function among Bell's palsy. After post test treatment of needle acupuncture the study group had greater significant improvement compared to the control group. This study hypothesized that 4 weeks acupuncture treatment would improve neuro- muscular recruitment and will result positively in the movement of facial nerves. Acupuncture can cause multiple biological responses, including circulatory and biochemical effects. These responses can occur locally or close to the site of application, or at a distance. They are mediated mainly by sensory neurons to many structures within the central nervous system. This can lead to activation of pathways affecting various physiological systems in the brain as well as in the periphery. Acupuncture is widely used to improve motor, sensation, speech, and other neurological functions in patients with stroke. (1-4).The present study reveals that the both the groups as per mean, standard deviation on Five point facial nerve grading Scale total aspects in the post test experimental group shown (M=44.60, SD=3.32) was higher than that of in the post test control group(M= 31.41, SD=9.57).The difference was found to be statistically significant at P<0.001 level which indicates the effectiveness on needle acupuncture to improve facial nerve function This study results depicted that the demographic variables of patients indicated that 40% of the patients in experimental and 39% in control group were in the age group 26-35. Comparison of Facial Nerve Grading Scale (FNGS) in pre test and post test values are mean ± SD

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(n= 25 each) FNGS-A (At rest),FNGS-B (Wrinkle forehead,Blink ,Slight closure of eye, Tight closure of eye, Closure of eye on the involved side only),FNGS-C(Wrinkle nose,Whistle,Grin(wide smile),Depress lower lip) and FNGS-T(Total components) shown that Significantly different from the respective control group. Within and Between group comparison for FNGS-A,FNGS-B,FNGS-C and FNGS-T in pre test to post test of t and p value were shown greater significance for the experimental group over the control group (**P<0.001). There is significant association between demographic variables and acupuncture treatment among Bell's Palsy patients (**P < 0.001).The prognosis is on the whole favorable. A study reported that 84% showed satisfactory recovery without any treatment ([19]. One of the largest series of people with Bell's palsy, including those who were not receiving specific therapy, also showed that 85% of participants began to recover within three weeks after onset [20]. Prognostic testing currently involves various electrophysiological tests. Degeneration of more than 90% of the facial nerve carries a poor prognosis for recovery [21]. Logistic regression analysis [22] suggested that the most important predictors of incomplete recovery were complete facial weakness, pain other than in or around the ear, and systemic hypertension. According to Traditional Chinese Medicine (TCM) facial paralysis is known as 'deviated mouth'. In Bell's palsy, acupuncture treatment is thought to regulate channels and collaterals, harmonize qi and blood, strengthen the body's resistance to pathogenic factors, increase the excitability of the nerve, promote regeneration of the nerve fibers and formation of its collateral branches, enhance muscle contraction and blood circulation, and accelerate metabolism and recovery of body functions [23]. A number of studies especially in China have

suggested a good therapeutic effect of acupuncture on facial palsy. The literature reports a lowest cure rate of 37% and a highest of 100%, averaging 81% [24]. This conclusion is from a non systematic review of over 50 articles ([25]. 94 participants between the age of six and 65 were randomly assigned to an experimental or control group. The intervention took place once daily for a total of four courses at two day intervals. The length of one course was five days. The outcome measures were assessed before the start of the intervention and two days after the last intervention. The statistical data showed there was no significant difference between the experimental and the control group in each item of the study outcomes (P > 0.05) [26]. Similar study found that electro acupuncture within the six weeks of facial weakness combined with conventional care may help to reduce spasticity in the facial nerve [27]. Facial nerve impairments and disability significantly affects the facial palsy survivor's social participation and community re-integration and other meaningful life activities [28]. Disability appears to be directly influenced by impairment [29].The impact of physical impairment, specifically decreased strength, poor skeletal muscle endurance and increased fatigue, is well documented in chronic illness [30,31]. Supported studies are reported that facial nerve strength is the important predictor for measuring the level of disability and quality among facial palsy survivors. Studies have shown that individuals who are more dependent on mobility and physical activities experience a greater restriction in participation [32,33,34].The therapeutic effect of acupuncture treatment is to insert a needle into specific acupoints on the body surface, while manually rotating or applying electric pulse stimulation [35,36 37]. Stimulation of peripheral nerves by acupuncture can

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recover and repair a variety of neurological diseases [38].

5. CONCLUSION

From the above it is clear evidence suggests that needle acupuncture is more effective in improving facial nerve function. In summary, different comparisons, acupuncture regimens and disease stages showed opposite results on efficacy of Bell's palsy. Needle therapy is effective in reducing muscular tension and improving facial nerve function.Current study shows that the different was found to be statistically significant at $P<0.001$ level which indicates the post treatment of needle acupuncture is effectiveness among Bell's palsy patients.

Recommendation
The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system was often used to evaluate the quality of evidence. A similar study can be undertaken on a larger scale for more valid generalization. The study can be replicated in different settings. It can be conducted with different audio visual aids like video films, filmstrips on involvement care of Bell's palsy.

Conflicts of Interest
There are no conflicts of interest

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