To Study the Intervention of Bell's Palsy by Video Self Modelling through Kinect Azure : A Research Protocol

Madhura R. Darware[1], Divya Jethwani[2]

[1]Final year student, Ravi Nair Physiotherapy College, Datta Meghe Institute of Medical Sciences,Wardha,Maharashtra,India, [2]Associate Professor, Department of Neuro-Physiotherapy, Ravi Nair Physiotherapy College, Sawangi(M), Wardha

Abstract

Background: Bell's palsy is the common acute mono-neuropathy, and is commonly associated with facial paralysis or weakness of facial nerve. It is unilateral facial nerve paresis or paralysis. The cause of Bell's palsy is suspected to be herpes simplex virus infection of nerve.The nerve get swollen because of this viral infection and is compressed in its canal as it passes through the temporal bone. Grading systems for the assessment of movements and asymmetry of face in Facial palsy are divided into computer-based and traditional grading systems. The program that uses Kinect Azure provides assessment method for evaluation of asymmetry of face at rest and the rating of facial palsy during voluntary activity of various areas over face. This study aims to investigate the intervention of facial palsy by video self modelling with the use of Kinect Azure.

Methods: 20 participants will be selected. Each group will include 10 subjects. Group A will receive conventional treatment, electrical muscle stimulator(EMS) ,and visual feedback.

Group B(Experimental group) will receive conventional treatment ,electrical muscle stimulator and video self modelling. Each participant would be presented with their own videotape of video self-modeling, which included the best attempts at their evenest acts (smiles).Following 2 weeks of tape viewing the actions will be assessed. The outcome of the treatment will be assessed by Kinect Azure.

Discussion: Traditional methods for documentation of treatment effect have been through scales and questionnaires which at times are little complex and also difficult for patients to interpret. Hence this experimental and comparative study aims at focusing on the effective use of Kinect to document outcome for bell's palsy.

Key words: *Bell's palsy,physical therapy, Kinect.*

Introduction

Bell's palsy is the common acute mono-neuropathy, and is commonly associated with facial paralysis or weakness of facial nerve. It is unilateral facial nerve paresis or paralysis. This disorder causes complete or partial inability of the paralysed side of face to voluntarily move facial muscles. The paresis or paralysis of face in Bell's palsy result in inability to close the eyelid and temporary oral incompetence resulting in possible injury to the eye. ([1]) Annual incidence of palsy is 15 to 30 per 100,000 people, with equal numbers of women and male affected. Any side of the face has no predilection. The palsy of Bell was identified in patients of all ages, with peak incidence in the 40s. It occurs more frequently in diabetes patients and pregnant females. ([2])

The cause of Bell's palsy is suspected to be herpes simplex virus infection of nerve.The nerve get swollen because of this viral infection and is compressed in its canal as it passes through the temporal bone.([3]) Symptoms typically begin in the first week, and then gradually resolve over 3 to 3 months. It is in patients with diabetes, and while it can affect people of any age, incidence peaks in 40s([2]) Paresis is the most disturbing symptom of Bell's palsy; up to three quarters of affected people assume they have had a stroke or an intracranial tumour. The palsy frequently starts unexpectedly and

progresses quickly, with maximum facial weakness occurring within two days. Hyperacusis, reduced tear production, and altered taste may be associated with symptoms. Patients may also report otalgia or aural fullness, and facial or retroauricular pain, usually mild and preceding palsy. Severe pain indicates herpes zoster virus, and can lead to a vesicular eruption and progression to Ramsay Hunt syndrome. Features can lead to a mild polyneuropathy. A gradual progressive paralysis with other cranial nerve defects or headache increase the neoplasm possibility [4].

Video self-modelling is used with movements of face affected by facial nerve palsy(Lower Motor Neuron type). Although self-modeling patients view video clips of themselves engaging only in the correct, adaptive behavior and so the treatment relies on the patient being able to generate the desired form of behavior at least once. The action, or movement pattern, is recorded, edited into a short set of images by only choosing the best presentation and then given to the patient to watch again before replaying. Analyzing one's best attempts at a desired reaction has been used to promote motor learning in a variety of therapeutic settings, and it improves the degree of success that integrates previously unachievable abilities. vBecause an successful smile provides the audience with a powerful emotional input, this study was designed to examine the use of video self-modeling as a method of adapting the smiles after facial nerve palsy.[5]

Evaluation of paralysis of face and quantitative grading of asymmetry is important to measure the severity of the disorder as well as to monitor its progression or improvement. As such, a precise quantitative grading system is needed which is easily understand , cheap and has minimum variability. As there is clearly a need for a clinically feasible tool that can assess the severity of the disease and the resultant loss of function from Facial palsy and can also calculate the efficacy of medical care or surgery. Such a tool should be qualitative, standardized, depending little or no on the observer, and cost-efficient.

Grading systems can be divided into conventional and computer based grading systems for determining facial gestures and facial asymmetry in facial palsy[6] Modern approaches include the House-Brackmann grading system (HBGS)-The House and Brackmann grading system is recommended as a common standard for determining the degree of facial paralysis and is a clear and accurate method for evaluating facial function.. [7] Functional disability index – It is a disease-specific, self-reporting functional status instrument that provides an essential component for the evaluation of citizens with facial neuromuscular disorders.[8] Many programs include Burres-Fisch, Nottingham, Sunnybrook, and many others. Computer-based FP grading systems including video recording and image processing are also proposed. [6]

Kinect Azure provides assessment method for evaluation of asymmetry of face at rest and the rating of facial palsy during voluntary activity of various areas over face. This study aims to investigate the intervention of facial palsy by video self modelling with the use of Kinect Azure.

Aim:

This study aims to analyze the intervention of Bell's palsy by visual self-modeling using Kinect Azure.

Methodology

Study setting:

The trial will be carried out in HumEn research lab and Neuro Physiotherapy Department of Ravi Nair Physiotherapy College, DMIMS, Sawangi(Meghe),Wardha, Maharashtra, India ,after approval from Institutional Ethics Committee of Datta Meghe Institute Of Medical Sciences,Deemed to be University.

Study Design and Sample Size:

The design of the study is a single blinded randomized controlled trial of a Kinect Azure for individual diagnosed with bell's palsy and it is an experimental and comparative study.

By using purposive sampling we will select 20 subjects(n=20) and will include 10 subjects in each groups(Group A and B). All topics will be clarified in detail about the research and a written informed consent will be taken. Group A will receive conventional treatment, electrical muscle stimulator(EMS) ,and visual feedback.Group B(Experimental group) will receive conventional treatment ,electrical muscle stimulator and video self modelling. All topics will be clarified in detail about the research and a written informed consent will be taken.The schedule of enrollment ,interventions,and assessments of the study is illustrated in Figure 1.

Figure.1 Schedule of enrolment , interventions and assessments.

TIMEPOINT	Enrolment	Allocation	Intervention	Post-test	tx
			STUDY PERIOD		
	Enrolment	**Allocation**	**Post-allocation**		**Follow-up test**
			Intervention	**Post-test**	**tx**
ENROLLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
{Conventional}			X		
{video self modelling}			X		
ASSESMENTS: House-Brackmann Scale, Facial disability index					
	X				
Outcomes measure :Kinect Azure				X	X

Participants

 The Inclusion Criteria for the participants are as under:

1.   Those who are willing to participate.

2.   Patient affected by acute onset paralysis without detectable cause

3.   Those with Idiopathic facial paralysis

4.   Rehabilitation treatment carried out at our own hospital

5.   Those who have unilateral facial paralysis-LMN type

6. Those who are between 20 to 42 years of age.

7. Those who scored above grade 3 on House brachman scale

8. Those have Normal superficial and deep sensation

The Exclusion Criteria for the participants are as under:

1. Those who are not willing to participate

2. Those with any type of facial fracture

3. Those with Known traumatic, inflammatory, Neoplastic pathology of facial nerve

4. Those with Bilateral facial paralysis

5. Those with UMN type facial palsy

6. Those who have Disease of central or peripheral nervous system

7. Those who scored below grade 3 on House brachman scale.

8. Those with Recent head injury

9. Those who have Psychiatric disease

PARTICIPANT TIMELINE:

The study duration is of 6 months and intervention duration is 2 weeks.

Assessment will be done on 1st day of visit following 2 weeks of tape viewing the actions will be reassessed.

RECRUITMENT: The neurologists and health care practitioners working under DMIMSU are invited to refer the prospective patients to our inpatient department (IPD).Regular visit to Neuromedicine , Neurosurgery wards will be done and contact will be maintain with doctors, record maintaining office for cases that will enrolled in hospital so that can be taken for study.The patients who are already undergoing treatment in our IPD and diagnosed with facial palsy will be assessed for the eligibility in the study as per the inclusion and exclusion criteria.Informed patient consent will be taken before allocation and after elaborating the purpose ,nature,procedure, benefits and effects of the intervention.

Implementation:

Selection of the participants will be supervised by the research coordinator and principal investigators.

Blinding:

Tester(s) will be blinded to assign the subjects to the group .To ensure blinding ,subjects will be mandated not to reveal any details of their treatment to the tester.

Study procedure:

The participants will be categorized into 2 groups:

Group A:(Conventional physiotherapy):The participants in this group will undergo 1 hour of conventional physiotherapy program daily,5 days per week for 2 weeks.It will be performed by a physiotherapist in IPD.It will comprise of electrical muscle stimulator,visual feedback,facial exercises.

Group B:(Video self modelling combined with conventional physiotherapy):The participants in this group will undergo 30 minutes of conventional physiotherapy and 30 min of video self modelling based physiotherapy daily for 5 days per week for 2 weeks provided by physiotherapist in IPD. Each participant would be presented with their own videotape of video self-modeling, which included the best attempts at their evenest acts (smiles). In the following way we will make a videotape. A mobile video camera will be at a constant distance from the subject matter and set to run at session start. Subjects would be asked to complete a series of 5 smiles that included both their normal "everyday" (nonlinear) smile and their best (linear) "adapted" smile. The entire tape will be reviewed after a session, and 2 or 3 of the best smiles will be recorded using video editing software. Following 2 weeks of tape viewing the actions will be assessed.

The outcome of the treatment will be assessed by Kinect Azure from first day and after 2 weeks of intervention.

OUTCOMES

Primary outcome measures:

1)House-Brackmann Scale- For assessment of degree of facial paralysis.

2)Facial Disability Index used as an initial assessment tool and as an monitoring instrument to view

the outcome of intervention.

Secondary outcome measure:

Kinect Azure

DATA COLLECTION AND MANAGEMENT

Data collection

The assessment data will be collected from a pre-established spreadsheet with the baseline characteristics variable. Testing data will be put into a secure REDCap database. The nonelectronic data ,such as hard copies of assessment forms ,signed consent forms,etc. will be stored securely in the study setting. The employment of regular feedback concerning adherence and reminder phone calls(for attending the treatment)will be done.

Data management:

Data collection and documentation will be done under the guidance of the principal investigators. The study documentation will be evaluated thoroughly for accuracy. The Excel spreadsheet will be released at the end of the study to an allocation blinded statistician for conducting the necessary analysis,following which unblinding of the groups will be done.Checklists are used to prevent missing data due to the improper staff procedure.

Statistical Analysis Plan

Therapy induced changes in the primary outcome measures will be analysed via mixed-effects linear models across 'time'(pre-intervention vs post-intervention) and 'group'(Experimental vs control).The comparison will be done between the two groups using t-tests for the demographic measures and initial scores on outcome measures. For the interpretation of the results ,we will significant differences. Significance will be set at P less than 0.05.The results will be accounted for as per the CONSORT guidelines.

BIAS

Our study will have a low degree of selection bias(Oculus Quest).Measures will be taken to prevent attrition bias by giving reminder calls before each intervention and by giving transportation aids to those who require it. Thus we anticipate a low percentage of dropouts.

Discussion

Our study aims to estimate efficacy of video self modelling compared to conventional physiotherapy in individuals with Bell's palsy. Physical therapy has played a significant part in Bell's palsy management. Rehabilitation appeared effective in recovering facial symmetry, reducing paresis severity by 0.6 grades on the HB scale, and controlling synkinesis.[9] Physiotherapy rehabilitation of an adapted (more symmetrical) smile was investigated by Dr Susan E in FNP subjects 1 year after the start, using video self-modeling (video replay of only the best adapted smiles) and implementing intentions (preplanning adapted smiles for specific situations and concluding that reaction time (RT) for the initiation of adapted smiles was 224 ms faster, adapted smiles were completed 544 ms faster, adapted smiles had higher overall quality, movement control and symmetry ratings , and Facial Disability Index scores also improved .. His study supports these techniques of rehabilitation to maximize the quality of the smiles following facial nerve palsy.[5] Kinect platform can be used to develop low cost approaches to measure the movement aspects objectively.[10]

Research and development prospects and future therapeutic applications work with the Kinect are comprehensive. This will help to make diagnostic and prognostic evaluations.[11] .

Ethical Approval and Dissemination

Ethical approval will be taken from institutional ethical committee. The DMIMS which will fund research and the subjects which will participate in the study will be able to access the research's main findings. For the enrolled subjects, data held safely for a minimum of five years. Once data collection is complete, a completion report will be produced for statistical analysis and sent for publication after review by institutional research cell.

Patient Consent

Principal Investigators will obtain the informed consent from the patient and one of the relatives on a printed form with signatures and give the proof of confidentiality.

Confidentiality

The study program will be explained to the participant and one of his/her relative, and the principal investigator will take personal information. The consent

form will include the comfidentiality statement and signatures of the principal investigator, patient and 2 witnesses. If required to disclose some information for the study, consent will be taken from the patient with complete assurance of his confidentiality.

Author's contribution

DJ suggested the design of the study.MD and DJ led to the creation and design of the study.MD wrote the manuscript of this article.MD and DJ read and approved the final manuscript fpr publication.

Declaration of interests: The authors declare no conflicting interest .

Funding: No direct support will be taken for funding this research from any public and private organizations. The Department of Physiotherapy under Datta Meghe Institute Of Medical Sciences,Deemed to be University,will provide the necessary material for the research.

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