



Protocols

The effectiveness of low-level laser therapy combined with facial expression exercises in patients with moderate-to-severe Bell's palsy: A study protocol for a randomised controlled trial



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ABSTRACT

Background: Even though corticosteroid therapy and facial expression exercises were found to be effective, still 30% of participants with bell's palsy achieve incomplete recovery from the facial paralysis. The study objective was to evaluate the effectiveness of low-level laser therapy (LLLT) combined with progressive facial expression exercises in participants with moderate to severe bell's palsy.

Methodology: A total of 120 participants with idiopathic bell's palsy to be equally allocated in three groups. LLLT, electrical stimulation and corticosteroid/antiviral therapy will be performed respectively in the group I, group II and Group III and facial expression exercises as a common intervention. First two groups to be treated with respective interventions weekly 3 days for 6 consecutive weeks and third group will receive prescribed doses of medications and facial expression exercise for 6 weeks. The functional recovery will be assessed at baseline, 3 weeks, 6 weeks, and 12 weeks using the Facial Disability Index and House-Brackmann Scale. The overall within and between group differences in the clinical outcomes to be reported based on the Friedman Repeated Measures ANOVA and Kruskal-Wallis test. Whereas Wilcoxon Signed Rank and Mann-Whitney-U tests will be performed to report the within and between groups timeline differences.

Discussion: Based on the dearth of evidence for the effective treatment of moderate to severe bell's palsy, we framed a most appropriate LLLT dosage along with facial expression exercises. Our study's intervention protocol designed with equal duration and number of interventions for all three groups. Even the comparator groups such as electrical muscle stimulation and Corticosteroids therapy will be receiving similar facial expression exercises. We believe that this intervention protocol would benefit by promoting the complete facial function recovery in patients with moderate to severe bell's palsy.

Dissemination: We plan to publish this review in a peer-reviewed journal. We may also present this review at local and/or national conferences.

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1. Introduction

Bell's palsy is a lower motor neuron disorder of the facial nerve, in which the patients develop ipsilateral hemifacial paralysis and

loss of taste sensation in the anterior $\frac{2}{3}$ of the tongue. The incidence rate of bell's palsy is estimated to be 15–30 per 100,000 population and most prevalent in the age of group of 15–40 years irrespective of gender [1]. Still, etiology is not well known, but it is believed to be associated with acute exposure to the cold atmosphere, herpes viral infection, nerve ischemia, and inflammation [2]. Importantly, herpes infection may develop severe pain, degeneration of facial nerve and residual weakness of the facial muscles [2].

Abbreviations: IBP, Idiopathic Bell's palsy; LLLT, Low-level laser therapy.

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The collective clinical features of bell's palsy include muscle weakness, sensitivity to sound, dry eyes, drooling of saliva, and difficulty in speaking, eating, drinking, swallowing, and altered facial expressions interfere with social interaction and communication of the patients [3]. Fortunately, mild symptoms of idiopathic bell's palsy (IBP) resolve within a few weeks even without any treatment, but 20–30% of patients attain only incomplete recovery even after a several months, especially in case of moderate to severe paralysis [4]. Thus, it is important for the clinicians to closely monitor disease progress and treat appropriately to prevent residual weakness and improve the functional recovery sooner than usual recovery period.

According to the evidence, corticosteroids therapy with or without antiviral drugs, physiotherapy, acupuncture, massage, and neuromuscular facilitation are commonly used to treat bell's palsy [5,6]. However, a systematic review with meta-analysis reports that corticosteroid injection in acute inflammatory idiopathic facial palsy only achieve incomplete motor recovery at six months with minimum to moderate clinical efficacy [7]. Even though corticosteroid plus antiviral drug therapy is recommended for inflammation, some high-quality studies show incomplete recovery and a higher rate of adverse effects among the patients of severe paralysis [8,9].

Physiotherapy interventions such as electrical muscle stimulation, massage, exercise training were found to be the useful methods to improve the facial muscle function irrespective of the severity of the conditions [5,6] particularly, exercise training is employed to improve the facial neuromuscular conduction [5]. Facial expression exercises combined with other medical or physiotherapy interventions were employed as a multimodal treatment approach in the routine clinical practice. However, there is no strong evidence to support the existing physiotherapy or pharmacological therapies for the improvement of functional outcomes [10]. On the other hand, low power laser irradiation has been widely used to treat acute pain, inflammation, and soft tissue injuries [11]. Literature review shows that the rate of absorption of low-level laser energy by the nervous tissues is high compared to the other soft tissues.

Low-level laser therapy (LLLT) is a non-invasive, non-thermal phototherapy, where the laser light transmitted into the body tissues to prevent cell death, reduce inflammation, and promote cell regeneration by activating the intracellular signalling pathways of nucleic acid synthesis, protein synthesis, enzyme activation and cell cycle progression [11–13]. Numerous studies on low-level laser therapy have shown its efficacy in wound healing and nerve regeneration. However, its efficacy was not evidenced with a significant difference on the clinical outcomes in favour of low-level laser therapy compared to other routine care treatments in patients severe facial weakness [14]. Thus, our current study was designed to find-out the effectiveness of low-level laser therapy combined with facial exercises in participants with moderate to severe Bell's palsy.

1.1. Study hypothesis and objectives

This study hypothesizes that low-level laser therapy combined with facial exercises may fasten the functional recovery by activating the cellular healing mechanisms, nerve conduction in participants with moderate to severe bell's palsy.

1. Firstly, to compare clinical outcomes of facial functions on Facial Disability Index and House-Brackmann Scale between the participants received low-level laser therapy, electrical muscle stimulation and pharmacological therapies, all combined with facial exercises
2. Secondly, to compare the number of participants with incomplete recovery from functional disabilities of face at 6th-week post-intervention and 12th-week follow-up between the

participants received low-level laser therapy, electrical muscle stimulation and pharmacological therapies, all combined with facial exercises

2. Methods and materials

2.1. Ethics approval and consent to participate

Ethical approval was obtained from the institutional ethics committee. In this study ethics of human research according to the declaration of Helsinki to be followed and the written informed consent will be obtained from all participants before the randomization and allocation of treatment. The allocated interventions will be performed according to the group identification number in the random number block.

2.2. Study design

A randomized controlled trial was designed according to the recommendations for interventional trials guidelines, and the consolidated standards of reporting trials guidelines for randomized controlled trial was adopted to report the results after the trial. The participants diagnosed with moderate to severe level Bell's palsy by the physicians will be treated by licensed physiotherapists. The low-level laser therapy, electrical muscle stimulation and pharmacological therapies are the independent variables in this study. The dependent variables are facial disability index and house-brackmann scale. The data collection will be carried out in the Department of Physiotherapy, between December 2020 to May 2022.

2.3. Participants

Both male and female participants who visit with the complaints of unilateral idiopathic Bell's palsy will be recruited after the preliminary examinations and investigations by the physician after taking due consent. Bell's palsy participants without contraindications for low level laser therapy and electrical muscle stimulation are to be referred to physiotherapy department where further screening of participants will be done using the selection criteria by the therapist.

2.4. Inclusion and exclusion criteria

Participants diagnosed with idiopathic Bell's palsy by the Physicians, moderate to severe facial muscle weakness i.e. grade III–VI on the House-Brackmann scale and duration of the condition less than 2 weeks are the inclusion criteria. Participants with a middle ear infection, parotid gland tumor, malignant otitis externa, tumors in the base of the lateral skull, upper motor neuron facial palsy, segmental muscle weakness, recurrent episodes of facial paralysis, polyneuropathies and Ramsay Hunt Syndrome will be excluded from the study.

2.5. Sample size

To obtain the clinically meaningful difference between the groups on the primary outcomes, we planned for a priori larger sample size for this repeated measure randomized controlled trial. Hence, the F-test statistic in the G*Power 3.0.10 statistical software was employed to calculate the sample size using 0.05 alpha error, 0.80 power, 0.5 effect size, and the number of treatment groups as 3. According to the calculation, the required sample size was 107, assuming 10% of anticipated dropout ($n = 10.7$) approximately 120 participants, 40 in each group will be recruited.

2.6. Randomization

A total of 120 computer-generated random numbers in the sequential order to be equally allocated into the three groups using a block randomization and concealment method with the allocation ratio of 1:1:1. Randomization procedures were carried out by the independent researcher who is not involved in the study, outcome assessors will be blinded to the treatment allocation throughout the trial. Physiotherapists who are involved with the delivery of treatments will be informed about the allocated intervention via office assistant according to the group identification number from Group-I, Group-II or Group-III. The outcome assessors and participants will be instructed not to disclose the treatment given to the participants throughout the trial.

2.7. Interventions

2.7.1. Low-level laser therapy in group I

Calibration of laser therapy equipment was performed by the manufacturing company using a thermal power meter. Before the application of a laser probe, the affected side face of the patient will be cleaned with alcohol liquid to remove the blockades to the laser beam transmission. To deliver the low-level laser, a LP-1000 gallium-arsenide diode (GaAlAs) laser with 795 nm (± 5 nm) wavelengths, 1 W power output, 1 cm² irradiation spot size will be used. The average energy density of 1 J/cm² in 1 second for 4 seconds (total of 4 J) will be delivered in each one of the 8 points over the superficial nerve courses of the facial nerve (i.e. $8 \times 4 = 24$ seconds per session). We will continue to apply LLLT three days in a week for 6 consecutive weeks (i.e. 18 sessions) using the direct contact method [15]. Both patient and physiotherapist will wear protective glasses to avoid exposure to the eyes.

2.7.2. Interrupted galvanic current stimulation in group II

Prior to the application of electrical stimulation, the participants will be instructed about the possible experience of pinpricking and muscle twitch sensation. Also, the physiotherapist will inform the participants to report immediately if they experience any uncomfortable sensation during the treatment in order to modify or stop the treatment [16]. The interrupted galvanic electrical impulses with the duration of 3–30 milliseconds, the tolerable intensity will be applied over the motor points of each facial muscle. A total of 30–60 electrical twitch induced muscle contractions will be maintained for each muscle and repeated for 2–3 times per session, 3 days in a week for 6 consecutive weeks [17]. After every session of electrical stimulation, areas of the skin over the motor points and nerve trunk will be examined to find out the possible adverse effects of interrupted galvanic current stimulation.

2.7.3. Drug intervention in group III

As per the direction of general physicians or neurologists, the participants will be receiving the corticosteroid with or without antiviral drugs. Treatment dosage of corticosteroids and/or antiviral drugs to be decided by the consulting physician according to the severity of the condition and treatment protocol followed in this study [18].

2.7.4. Facial exercises as a common intervention for all three groups

The facial muscles exercise training with mirror-visual feedback will be progressed to resisted exercises by self and/or therapist assistance. All exercises are going to be demonstrated to participants by the therapist's efforts and instructed the participants to continue the exercises twice a day for 10–15 minutes for 6 consecutive weeks [19]. A pictorial leaflet of facial expressions exercises

with appropriate instructions to perform exercises in English and Arabic languages will be given to each patient.

2.8. Outcome measures

2.8.1. Facial disability index (FDI)

The physical and social wellbeing functions associated with bell's palsy is to be assessed using the facial disability index which has good internal consistency (theta reliability: 0.88 for physical and 0.83 for social wellbeing functions) to assess both functions in participants with neuromuscular facial muscle weakness [20]. FDI has 5 items (each item scoring range 0–5) to assess the physical function and another 5 items (each item scoring range 0–6) for the social function, and the total score for each division ranges from 0–100 where a 100 indicates maximum disability and 0 indicate no disability.

2.8.2. House-Brackmann scale (HBS)

Similarly, to grade the facial muscle weakness and movement impairments associated with Bell's palsy we will employ the House-Brackmann scale which is also identified as a reliable tool to assess the overall and segmental muscle weakness in the face [21]. The facial movement impairment grade ranges between I to VI, where grade I indicates normal facial muscle contraction and grade VI indicates no possible movement.

2.8.3. General health-related quality of life assessment

The health-related quality of life of the bell's palsy participants to measure the impact of health-related issues on the general wellbeing by widely used short form 36 health survey questionnaire (SF-36). It is an validated generic instrument that measures health-related QOL in diverse patient populations [22].

All the outcome measures will be assessed at baseline, 3rd-week, 6th-week post-intervention and 12th-week follow-up.

2.9. Statistical methods

2.9.1. Data entry

The collected data will be periodically verified and transferred into the excel spreadsheet by the office assistant, and co-authors will be instructed to check the accuracy of data recorded. Intervention groups are coded as 1, 2 or 3 to prevent unmasking of datasets during analysis as the statistician will remain blind to the group of assignments. Data from individual participants are recorded by research numbers. The spreadsheet containing the research data is stored on a portable drive and locked in the same room as the research folders.

2.9.2. Descriptive statistics

The data such as gender, side-affected, number of participants with moderate and severe Bell's palsy, and other co-morbid conditions will be described as frequency (N) and percentage (%). Further, we will describe the patient's age, duration of the condition and vital signs as mean and standard deviation (SD), the scores of FDI, HBS and SF-36 as median and inter-quartile range (IQR).

2.9.3. Inferential statistics

An appropriate parametric or non-parametric statistical test will be employed to compare the distribution of baseline data among the three groups. The overall within- and between-group functional recovery on the primary outcome measures to be reported based on the results of Friedman repeated measures ANOVA and Kruskal Wallis test, respectively. The Wilcoxon signed-rank test and Mann-Whitney-U tests will be used respectively to analyse the within and between groups differences at the different timeline periods if there is a significant statistical

difference identified in the Friedman repeated measures ANOVA and Kruskal Wallis test. Furthermore, the significant between-group differences in the number of participants with complete and incomplete recovery to be reported based on the chi-square test results. The severity of Bell's palsy may be a potential covariate in predicting the clinical outcomes; therefore, we will perform the subgroups analysis between the moderate and severe Bell's palsy participants by using pairwise comparisons.

2.9.4. Statistical analysis tool

Both descriptive and inferential statistics will be performed using the IBM SPSS Statistics V21. All the statistical tests to be performed at 5% alpha level (95% confidence interval), 80% power, and p-value less than 0.05 will be considered as statistical significance.

2.10. Trial monitoring and reporting policies

2.10.1. Trial monitoring

Since this trial involves the non-invasive treatment, there is no trial monitoring committee formed. All researchers are responsible for sharing their information and feedback related to the trial progress details and at least monthly once the researchers will meet via google-meet to discuss the issues encountered during the trial and modify accordingly. The investigative team consists of the authors listed in this protocol, physicians involving with preliminary examination and investigation, physical therapists who measure the dependant variables and administrative research staff who will assist with appointment scheduling and data entry. The principal investigator will manage data flow and perform audits of the procedures, enrolment, and treatment throughout the entire process of the study. The associate investigators will monitor data collection processes and data integrity with periodic evaluation performed continually during the data collection phase.

2.10.2. Risk and burdens

Even though this trial uses the non-invasive treatments, still there are possibilities for the development of certain adverse effects during or after the application of electrical stimulation, low-level laser therapy, and medication therapies. Appropriate precautions will be taken before, during, and after the respective group interventions. If any participants develop adverse reactions, they will receive medical attention and appropriate interventions immediately. All the investigators involved in this study are educated about the risk, harms, and benefits of the interventions before the commencement of the trial. The patient satisfaction rating and adverse event chart will be provided to each patient after the first session of the treatment for the easy documentation of the harms and risk of each trial intervention.

2.10.3. Modifications and enquiry

The modifications in the trial protocol will be addressed to the Dean and institutional research unit. All trial-related information can be obtained from the principal investigator.

2.10.4. Confidentiality

The information about the participants such as personal details, assessment forms, consent forms and images taken during the or after the treatment will be stored separately in the principal investigator's room with confidentiality.

2.10.5. Dissemination policy

After the trial completion, the results will be shared with the clinicians, academic institutions to perform the appropriate intervention selection based on the participants' expectations and willingness. Further, the data will be sent to the peer-reviewed

journals for publication and make available for the researchers and clinicians around the world.

2.10.6. Declaration of competing interest:

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

3. Discussion

To the best of our knowledge, there is a dearth of evidence for complete facial function recovery has been reported in patients with moderate to severe facial weakness. Thus, this study proposed a hypothesis that the low-level laser therapy combined with facial exercises may be superior to electrical stimulation or corticosteroid therapy combined with facial expression exercises in participants with moderate to severe Bell's palsy.

Recently published randomised control study (2017) indicated that LLLT, 3 days in a week for 6 weeks combined facial exercises was achieved greater improvement on facial muscle function compared to standalone facial exercises in very early stage of bell's palsy. However, the duration of intervention differed between groups and no clear information on the selection of severity of bell's palsy in this study [19].

The findings of case report (2018) suggest that laser therapy was a safe and effective modality to reduce the facial myalgia and improve the facial functions in a 13-year-old girl presented absence of facial movement and difficulty in chewing and talking. This report also indicates that even three sessions of infrared laser (100 mW output power, 100 J/cm² of energy density, 28 s per point) applied at the origin and insertion of the right superficial masseter muscle produced a complete recovery from pain and muscle weakness [23].

A pre-post-test experimental study (2020) on the effect of standalone LLLT in 30 diabetic patients with bell's palsy have demonstrated a complete recovery only on 18 patients after the 12 sessions of treatment. Remaining 12 patients has achieved partial recovery even after 3 months, this may attribute to the non-inclusion of facial expression exercises or other supporting intervention in addition to the LLLT [24]. Another randomised control study (2014) which compared the effects of high- and low-level laser therapy over controlled intervention on the forty-eight bell's palsy study participants reveals that 6 weeks of laser treatment significantly improved the facial function recovery [15].

A recent systematic review (2020) also recommended for 6 weeks of LLLT interventions using an 830 nm wavelength laser with 100mW power to produce a significant improvement in facial functions. Further, this study also report that the evidence was inconclusive on the functional improvements for the standalone LLLT in patients with bell's palsy duration less than 1 week [14].

We critically reviewed current literature evidence to find out the research gaps and framed a most appropriate LLLT dosage along with facial expression exercises in patients of moderate to severe bell's palsy with less than 2 weeks duration. Our study's intervention protocol designed with equal duration and number of interventions among the three groups to produce significant clinical outcomes. Even the comparator groups i.e. 1) electrical muscle stimulation with facial expression exercises, and 2) Corticosteroids therapy with facial expression exercises were given similar duration of interventions in this study which may show the significant difference between the groups post trial. To reduce the number of incomplete recovery cases, our current study proposed 18 sessions of LLLT combined with facial expression exercises.

Overall, we feel that the post study results would significantly benefit patients with moderate to severe bell's palsy, and the clinician can provide efficient treatment options to avail by patients based on their individual preferences.

4. International journal of surgery protocols

The following information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned. If you have nothing to declare in any of these categories then this should be stated.

5. Please state any conflicts of interest

All authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

NIL.

6. Please state any sources of funding for your research

All sources of funding should be declared as an acknowledgement at the end of the text. Authors should declare the role of study sponsors, if any, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. If the study sponsors had no such involvement, the authors should so state.

NIL.

7. Consent

Studies on patients or volunteers require ethics committee approval and fully informed written consent which should be documented in the paper.

Authors must obtain written and signed consent to publish a case report from the patient (or, where applicable, the patient's guardian or next of kin) prior to submission. We ask Authors to confirm as part of the submission process that such consent has been obtained, and the manuscript must include a statement to this effect in a consent section at the end of the manuscript, as follows: "Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request".

Patients have a right to privacy. Patients' and volunteers' names, initials, or hospital numbers should not be used. Images of patients or volunteers should not be used unless the information is essential for scientific purposes and explicit permission has been given as part of the consent. If such consent is made subject to any conditions, the Editor in Chief must be made aware of all such conditions.

Even where consent has been given, identifying details should be omitted if they are not essential. If identifying characteristics are altered to protect anonymity, such as in genetic pedigrees, authors should provide assurance that alterations do not distort scientific meaning and editors should so note.

Written informed consent will be obtained from the patient.

8. Registration of research studies

In accordance with the Declaration of Helsinki 2013, all research involving human participants has to be registered in a

publicly accessible database. Please enter the name of the registry and the unique identifying number (UIN) of your study.

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Dr. Praveen Kumar and Dr. Sukumar Shanmugam

Ethical approval

Research studies involving patients require ethical approval. Please state whether approval has been given, name the relevant ethics committee and the state the reference number for their judgement.

"The effectiveness of low-level laser therapy combined with facial expression exercises in patients with moderate-to-severe Bell's palsy: a study protocol for a randomised controlled trial"

Author contribution

Please specify the contribution of each author to the paper, e.g. study concept or design, data collection, data analysis or interpretation, writing the paper, others, who have contributed in other ways, should be listed as contributors.

Praveen Kumar, Sukumar Shanmugam, Sampath Kumar Amaravadi, Prathap Suganthirababu, and Shaikh Altaf Basha involved with study design and intervention protocol. Statistical power and sample size calculation were performed by Sukumar Shanmugam, and Praveen Kumar will perform the trial interventions except for the prescription of medication therapy in the control group. Sukumar Shanmugam and Praveen Kumar prepared the first draft of the manuscript and later it was revised by Sampath Kumar Amaravadi. The final version of this manuscript was approved by all researchers of this trial. Geovinson George Stephen will be involved with collection of outcome measures.

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