ISRCTN93896690 https://doi.org/10.1186/ISRCTN93896690

The effect of the Mirror Effect Plus protocol in acute Bell's palsy

Submission date
16/10/2020

Recruitment status
No longer recruiting

Registration date
25/11/2020

Overall study status
Completed

Last Edited
18/07/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Bell's palsy is a weakness or lack of movement affecting one side of the face. The aim of this study is to assess the feasibility of a future larger study on the Mirror Effect therapy for patients with Bell’s palsy. Most patients with Bell’s palsy recover completely. However, symptoms might persist over time, which often result in facial deformity and reduced mouth mobility. Therefore, people with such symptoms might experience changes in swallowing and speaking, which could impact their quality of life and self-esteem. In the present study, the researchers are assessing the impacts of early speech therapy on overall recovery and prevention of complications, called facial synkinesis. Synkinesis is defined as involuntary facial movements that occur while attempting to move another part of the face. This study is recruiting a small number of patients to be able to obtain an estimate of the effectiveness of the new therapy called the Mirror Effect Plus Protocol (MEPP). The MEPP will be combined with general recommendations given by the speech therapist and pharmaceutical treatment currently provided in Quebec. The researchers will compare this treatment to the usual course of treatment in Quebec, which is general recommendations given by the speech therapist and traditional pharmaceutical treatment. A positive outcome will lead to a larger study to assess the efficacy of the MEPP.

Who can participate?
Patients aged 18 and over with acute and severe Bell's palsy

What does the study involve?
Participants are randomly allocated to one of the two treatment groups to receive either the “mirror effect” treatment and the current pharmaceutical treatment recommended in Quebec, or the current pharmaceutical therapy recommended in Quebec at the moment plus counselling and a personalized exercise program 1 year after the onset of their Bell’s palsy, if needed. The severity of facial palsy is assessed at the initial assessment (10 to 14 days after onset) as well as 1, 2, 3, 4, 5, 6 and 12 months after onset

What are the possible benefits and risks of participating?
According to current knowledge, participation in this study does not involve any medical risk.

Participants may get a personal benefit from their participation, but the researchers cannot guarantee it. By participating, they will be able to benefit from support and a meeting with a speech therapist experienced in the field, who will answer their questions.

Where is the study run from?
Hôpital du Sacré-Coeur de Montréal and Hôpital Maisonneuve-Rosemont (Canada)

When is the study starting and how long is it expected to run for?
September 2015 to October 2021

Who is funding the study?
1. Réseau Provincial en Adaptation – Réadaptation and the Ordre des Orthophonistes et Audiologistes du Québec (Canada)
2. Fonds de recherche du Québec- Santé (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Efficacy of the Mirror Effect rehabilitation in acute Bell’s Palsy: a pilot study

Acronym
MEPP

Study objectives
The goal of this research study is to assess the feasibility of a future larger study on the Mirror Effect therapy for patients with Bell’s Palsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/11/2016, research ethics board of CIUSSS du Nord-de-l'Île-de-Montréal (5400 Gouin Ouest, Montréal, H4J 1C5, Canada; +1 (0)514 338 2222 ext. 3581; julie.hammamji.cnmtl@ssss.gouv.qc.ca), ref: MP-32-2017-1365

Study design
Multicenter longitudinal randomized feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied
Acute Bell's palsy

Interventions
In the present study, the researchers are recruiting a small number of patients to be able to obtain an estimate of the effectiveness of the new therapy called “Mirror Effect”. The Mirror Effect therapy will be combined with general recommendations given by the speech therapist and pharmaceutical treatment currently provided in Quebec. The researchers will compare this treatment to the usual course of treatment in Quebec, which is general recommendations given by the speech therapist and traditional pharmaceutical treatment. A positive outcome of this process will lead to a larger study to assess the efficacy of the Mirror Effect Therapy.

40 participants suffering from acute and severe Bell's palsy will be recruited and randomly attributed to one of the two treatment conditions. Assignation to the control group or MEPP group is performed by an external researcher who was not in direct contact with the patients, through computerized balanced block randomization. Thus, the 20 participants attributed to the experimental condition will receive the “mirror effect” treatment and the current pharmaceutical therapy recommended in Quebec, while the 20 other participants will be assigned to the control condition, which is the current pharmaceutical therapy recommended in Quebec at the moment plus counselling.

Treatment group: All participants receive the MEPP, a facial rehabilitation consisting of facial counselling and retraining during four in-clinic sessions during the first 2 weeks following the initial assessment. Each patient first receives information about facial function and anatomy. They then practise motor imagery (see Eaves et al., 2016) and receive passive soft tissue manipulation (Diels & Beurskens, 2014). Subsequently, specific facial exercises are explained and executed with the help of a free webpage (https://www.webcamtoy.com or MEPP web site https://mepp.marcottelab.ca/auth/signin) that provides modified visual biofeedback and a symmetrical image of the patient’s face generated by duplicating the healthy side. Instructions for facial exercises are provided to promote facial motor learning using small specific movements, emotional cueing, exercise randomization, and proper pacing. Exercises are continued at home twice daily until recovery was achieved.

Control group: The control group receive basic counselling such as instructions for avoiding excessive facial movements; however, participants did not attend therapy sessions. The control group will also receive a personalized exercise program 1 year after the onset of their Bell’s Palsy if needed.

For both groups: The first assessment is performed 10-14 days after BP onset and prior to any intervention or therapy. Reassessments are performed 1, 2, 3, 4, 5, 6 and 12 months after onset.

Intervention Type
Behavioural

Primary outcome measure
Severity of facial palsy assessed using the Facial Nerve Grading System 2.0 (FNGS 2.0; also known as the House-Brackmann 2.0 score and the Sunnybrook Facial Grading System at the initial assessment (10 to 14 days after onset) as well as 1, 2, 3, 4, 5, 6 and 12 months after onset

Secondary outcome measures
Speech intelligibility measured using a visual analog scale at the initial assessment (10 to 14 days after onset) as well as 1, 2, 3, 4, 5, 6 and 12 months after onset

Overall study start date
03/09/2015

Completion date
07/10/2021

Eligibility

Key inclusion criteria
1. Aged 18 years and older
2. First episode of Bell's Palsy
3. Having persistent severe Bell's palsy 10 days post-onset
4. Received the recommended drug regimen for severe and total BP (1000 mg valacyclovir three times daily for 7 days and 50 mg prednisone once daily for 10 days) began within 72 hours of onset
5. Normal cognitive status based on the Montreal Cognitive Assessment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. History of trauma to the 7th cranial nerve
2. Having suffered from Bell's palsy previously or any other facial palsy of another origin (e.g. secondary to surgery or a syndrome
3. History of neurological disorders (e.g. stroke, neurodegenerative diseases)
4. Psychiatric illness on active treatment (e.g. schizophrenia, severe depression)
5. History of neoplastic diseases

Date of first enrolment
27/02/2017

Date of final enrolment
07/10/2020

Locations

Countries of recruitment
Canada

Study participating centre
CIUSSS Nord-de-l'île-de-Montréal (Hôpital du Sacré-Coeur de Montréal)
5400 Gouin Ouest
Montréal
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Study participating centre
CIUSSS Est-de-l'île-de-Montréal (Hôpital Maisonneuve-Rosemont)
5415, boulevard de l'Assomption
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Sponsor information

Organisation
Centres Intégré Universitaires de Santé et de Services Sociaux

Sponsor details
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Sponsor type
University/education

Website
https://rechercheciusssnim.ca

ROR
https://ror.org/041c8tt83

Funder(s)

Funder type
Research organisation

Funder Name
Réseau provincial en adaptation-réadaptation and Ordre des orthophonistes et audiologistes du Québec

Funder Name
Fonds de recherche Québec-Santé

Results and Publications

Publication and dissemination plan
The longitudinal data of all participants will be submitted for publication in a peer-reviewed journal by the end of 2021 or the beginning of 2022.

2020 preliminary results in https://www.cjslpa.ca/detail.php?ID=1260&lang=en

Intention to publish date
01/01/2022

Individual participant data (IPD) sharing plan
According to the informed consent, data will only be accessed by researchers and team members (which is standard procedure in Quebec). Research data will be stored at the Hôpital du Sacré-Coeur de Montréal in a safe location by researchers responsible for the research project for a period of 5 years, after which the research files will be destroyed and can be consulted only by the participants in the research project.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/06/2022	18/07/2022	Yes	No