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Understanding the use of the MEPP 2.0 website in facial rehabilitation

Submission date
22/12/2022

Recruitment status
No longer recruiting

Registration date
12/01/2023

Overall study status
Completed

Last Edited
21/10/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
Facial paralysis is a condition that greatly affects those who have it. When there is no spontaneous recovery, we see facial sequelae set in which hinder speech, facial expressions and swallowing in patients who suffer from it. This has a considerable impact on their quality of life and self-esteem. In some countries, such as France or the United States, facial rehabilitation is then often proposed, with the aim of minimizing the onset of the facial sequelae named above. In Quebec, recent research initiatives have brought together researchers, clinicians, health science students and patients, in order to provide the health network with an innovative techno-social tool for facial rehabilitation: the MEPP 2.0 tool. However, the factors modulating the use of this tool in the clinic are still relatively unknown and must be studied empirically.

The current research project aims to carry out a prospective cross-design and intra-subject study, with the general objective of studying the implementation and appropriation of the MEPP 2.0 tool by clinicians and patients. This project will make it possible to understand the variables facilitating and hindering the use of the MEPP 2.0 tool, which will then make it possible to find and implement solutions to better use this rehabilitation tool. Ultimately, this project will improve the accessibility of clinicians and patients to an innovative facial rehabilitation tool, which uses augmented reality, and is based on evidence.

To achieve this objective, various partners in the health network and academia will work together to collect data on the use of MEPP 2.0. The effects of MEPP 2.0 will be measured in patients who use the tool, in an objective and standardized way, in terms of adherence to treatment, user experience and body identification (embodiment). In addition, the use of the MEPP in the clinic will be studied by measuring among clinicians certain factors influencing their practice and their user experience.

The teams' interest in studying MEPP 2.0 stems from the fact that it is a fully Quebec tool, which uses augmented reality developed in open code, is completely free for its users, and aims to provide the greatest number of users (clinicians and patients) with effective telehealth tools to improve facial function following peripheral facial paralysis. Our project was conceived and designed to work in concert with clinical settings and aims to measure the potential added value of the tool in the Quebec health system, with the double perspective of patients and caregivers.

This ensures that the project is fully aligned with the institutional strategic priorities of the University of Montreal, and the realities of the host communities. In addition, the funding obtained from Partnership for the current project will make it possible to ensure its feasibility, to hire students wishing to develop experience in research and innovation, and will allow our team to contribute to the institutional "Bio-innovation and digital health" while building bridges with the Digital Health Consortium and the Innovation Lab, which we will consult for mentorship.

Who can participate?
Patients with facial paralysis and clinicians working with customers with facial paralysis

What does the study involve?
Together with our main partners, the general objective of this project will be to study the implementation and appropriation of the techno-social tool for facial rehabilitation MEPP 2.0, both for patients and for clinicians. The specific objectives are as follows:
1. In patients, compare the MEPP 1.0 tool with version 2.0, by measuring in an objective and standardized way the effects on adherence to treatment, on the user experience and on body identification (embodiment)
2. Among clinicians, evaluate the integration of MEPP 1.0 versus MEPP 2.0 tools in the clinic, by measuring factors modulating this integration in practice and user experience.

What are the possible benefits and risks of participating?
Participants have or will have free access to the MEPP 2.0 therapeutic tool allowing specialized rehabilitation for patients with facial paralysis. They will also have privileged moments to discuss with a speech therapist who is an expert in the field of facial paralysis, either to highlight their experience as a patient or as a clinician, which promotes a reflective practice. Participants will also be able to maintain their access and continue to use the MEPP 2.0 tool beyond the duration of the study, as long as the use is clinically justified.

For patients, the study is about their facial rehabilitation which may be distressing. For all participants, this project will require a time commitment to attend interviews and complete questionnaires. Meetings may cause fatigue. Clinicians benefit from an agreement with their managers that allows them to take time to carry out the research project. However, patients will need to take personal time to complete questionnaires and interview questions.

Where is the study run from?
Hôpital Maisonneuve Rosemont (Canada)

When is the study starting and how long is it expected to run for?
May 2022 to February 2025

Who is funding the study?
University of Montreal (Canada)

Who is the main contact?
Dr Sarah Martineau, sarah.martineau.sm@gmail.com

Study website
https://mirroreffectplus.org/#/login

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
Nil known

Study information

Scientific Title
Implantation and development of the technosocial webtool MEPP 2.0 for facial rehabilitation

Acronym
MEPP

Study objectives
The general objective of this research project is to ensure that MEPP 2.0 really improves facial rehabilitation practices compared to version 1.0, both for patients and professionals. To do this, the specific objectives aim to measure the 2 tools in a comparative manner according to various variables.

For the first objective of the comparative measures taken in patients, we hypothesize that the user experience and the body identification of the face should be better with the MEPP 2.0 site than with the MEPP 1.0 site, but that adherence to treatment will potentially be mixed, regardless of the type of tool, but could be improved by MEPP 2.0.

Regarding the second objective of the comparative measurements taken among clinicians, we hypothesize that the user experience should be better with the MEPP 2.0 site than with the MEPP 1.0 site. Moreover, we believe that internal self-reported clinical factors and processes will not necessarily affect the use of the 2 websites in a differentiated way, except for the perception of helping the patient, which should be greater with the MEPP 2.0 site. External clinical factors should generally favor the use of MEPP 2.0 because of the existing resources that accompany this tool. In general, we do not hypothesize the factors influencing practice in facial rehabilitation beyond the MEPP 1.0 versus 2.0 tools, but it will be interesting to validate this aspect in a descriptive and exploratory way, in order to support this practice in the network.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/12/2022, Research Ethics Committee of the Integrated University Health Center and social services of the East-of-the-Island-of-Montreal (5415 Assomption Boulevard Montreal, Quebec, H1T 2M4, Canada; +1 514-252-3400 5708; cer.cemtl@ssss.gouv.qc.ca), ref: MP-12-2023-3218

Study design
Intra-subject crossover prospective randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Facial rehabilitation in patients with facial palsy

Interventions
The MEPP for rehabilitation of peripheral facial palsy
The MEPP is based on relevant components from two existing facial rehabilitation protocols: The Mirror Effect Protocol and the Neuromuscular Retraining protocol, and allows the combined advantages of both interventions. It first includes the use of a modified visual-feedback mechanism to help decrease cortical sensory-motor disturbances that occur in peripheral facial palsies. Interestingly, the MEPP has been shown to be effective. Also, components of the Neuromuscular Retraining protocol were included in the MEPP. For chronic Bell's palsy, Neuromuscular Retraining is the gold standard for facial rehabilitation. It mostly consists of re-learning adequate facial movements through individualized, slow, and specific facial exercises. However, many authors consider that the use of modified visual feedback during NMR could further improve facial function and increase patients' compliance.

To provide the MEPP and its modified visual feedback, an open-source and free website was developed. In its first version, the MEPP website used the central axis of the image to duplicate the patients' faces, and users reported difficulties in maintaining facial stability while performing facial exercises. Therefore, we developed a second version of the MEPP website, called MEPP 2.0, that incorporates augmented reality techniques, and that could potentially improve user experience and concentration on facial tasks. Since augmented reality technology provides a more organic and realistic face rendition, it could also have positive impacts on embodiment and motor learning, which are core principles in MEPP therapy.

Assessing patients' and clinicians' perceptions is crucial when developing rehabilitation tools because their willingness to use the tools strongly affects engagement in the rehabilitation process. Thus, this study compared clinicians' and patients' user experience with both versions of the MEPP website to analyse factors modulating their clinical use.
Materials:
Website MEPP 1.0 : https://mepp.marcottelab.ca/
Website MEPP 2.0: https://mirroreffectplus.org/#/login

Procedures for Clinicians: For MEPP 1.0: Training material at https://drive.google.com/drive/folders/1NBMzjstO7KX10ugtPzHKhH1skvEMPTZH?usp=share_link

Procedures for Patients: Mirror Effect Plus Protocol
Exercises with both MEPP-websites
Nature (examples will be specified following patients' needs)
1. Think about something surprising and rise gently the eyebrows. Release.
2. Think about something frustrating and gently frown the eyebrows. Release.
3. Close and open the eyes very SLOWLY while feeling progressively the opening and closing of the eyelid.
4. Think about something disgusting and wrinkle your nose GENTLY and briefly. Release.
5. Think about something funny and smile with a closed mouth. Release.
6. Think about something funny and smile with an open mouth. (The index finger should follow the movement on the cheeks). Release.
7. Think about someone you love and send him/her a kiss. Release.
8. Think about something disgusting and make an inverted smile. Release.
Repetitions: 5 times each

Randomization: Each exercise sequence should be done in a random order, from session to session.
Contraction/Rest time ratio: Hold the contraction for 7-10 seconds, rest for 10 seconds.

The training is for speech-language pathologists who intervene with facial palsy patients, who already have access to MEPP 2.0 for their clinical work and who underwent specific training to use the websites.

For patients, face-to-face explanations will be given during patient clinical follow-ups and then home trials with both websites.

For clinicians, zoom calls will be undertaken for explanations and then website trials during the clinical time.

Will be given in 10 institutions pertaining to the public health network of Quebec's province

Therapy session by a clinician: 45 minutes, once to twice a week for 2 weeks. Education on facial anatomy and function
1. Description of the facial exercises and adjustments made if needed
2. Progressive diminution of commentaries/feedback during therapy. This should help motor learning even if it decreases spontaneous motor performance

Home exercises:
1. 10 minutes of facial massages (twice a day) for 2 weeks
2. 15 minutes of daily facial exercises with a specialised website using the mirror effect. (see below)
3. Motor imagery sessions for total facial palsy and to help integrate the facial anatomy as well as kinaesthetic cueing
4. In the case of synkinesis: make target movement without eliciting the synkinesis by reducing the amplitude and force of the target movement.
5. Education on facial anatomy and function

As described earlier, the nature of the exercises will be tailored to each patient's needs, which will depend on the assessment done by the responsible clinician, prior to the study.

Compliance with therapy will be measured for both MEPP websites through intrinsic functionality. Specifically, a history of logins and completed sessions for each patient will be recorded on the websites.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MEPP 2.0

Primary outcome measure
User experience of clinicians and patients with website MEPP 2.0 and with MEPP 1.0 (crossover) measured using the standardized MeCUE questionnaire after 2 to 4 weeks of use for each website

Secondary outcome measures
1. Adherence to treatment for patients measured using the number of completed sessions recorded by the websites after 2 to 4 weeks of use for each website
2. Embodiment for patients measured using the standardized Virtual Embodiment Questionnaire (VEQ) after 2 to 4 weeks of use for each website
3. Modulating factors of clinical practice for clinicians measured using standardized interviews after 2 to 4 weeks of use for each website

Overall study start date
01/05/2022

Completion date
01/02/2025

Eligibility

Key inclusion criteria
Patients with facial paralysis:
1. Aged 18 years old and over
2. Suffer from peripheral facial paralysis
3. Have used or agreed to use the MEPP 1.0 and the MEPP 2.0 in the clinic or during a standardized trial to obtain enlightened comparative impressions of the two tools
4. Speak and read enough French and/or English to be able to answer an interview and standardized questionnaire.

Clinicians working with customers with facial paralysis:
1. Aged 18 years and over
2. Having used the MEPP 1.0 and the MEPP 2.0 in the clinic or during a standardized trial allowing to obtain comparative impressions enlightened on the two tools
3. Speak and read French and/or English enough to be able to answer an interview and standardized questionnaire

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
56 comprising forty (40) patients and sixteen (16) clinicians

Total final enrolment
60

Key exclusion criteria
Patients:
Not have a major cognitive impairment that interferes with the ability to answer the questionnaires and interview questions of this project, as assessed by a score higher than 27 on the Montreal Cognitive Assessment (MoCA)

Date of first enrolment
16/01/2023

Date of final enrolment
01/10/2023

Locations

Countries of recruitment
Canada

Study participating centre
Hôpital Maisonneuve-Rosemont (Centre intégré universitaire de santé et de services sociaux de l'Est-de-l'Île-de-Montréal (CIUSSS))
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Sponsor type
Research organisation

Website
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ROR
https://ror.org/03rdc4968

Funder(s)

Funder type
University/education

Funder Name
Université de Montréal

Alternative Name(s)
University of Montreal, UDEM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/05/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/10/2024	21/10/2024	Yes	No