Study Protocol and Statistical Analysis Plan

Title:
The Effect of Music Therapy on Cognition in Neurorehabilitation – A Feasibility Randomized Controlled Trial

Date:
12 Nov. 23

Expected Risks and Benefits

The investigators1 do not foresee any additional risks to subjects who participate in the study, compared to the day-to-day standard therapy protocol, as the interventions will be implemented in the same physical environments, with the same equipment and personnel. There could also be a potential risk of breach of confidentiality and anonymity. See Safety Measurement on how the investigators aim to minimize the risk and protect the confidentiality of subjects. On the other hand, potential benefits may include but are not limited to, improved cognitive functions after the music therapy interventions.

Safety Measurements

In the event of any adverse event, the standard protocol will be implemented. Subjects' confidentiality will be guarded by assigning IDs, which link to their names in a separate password-protected document accessible via a password-protected user account in a laptop or desktop, only accessed by the investigator. All physical documents will be locked in a designated file cabinet in a locked office where only the investigator has the key. All documents will be kept for two years before they are shredded. All subjects may raise any concerns about the research to the music therapist directly, or the music therapist's supervisor at the facility. A phone number and an email address will be given to all subjects in the consent form. They may also report to the person in charge of the ethics committee team, whose contact information will be provided on the consent form as well.

Data Collection and Analysis

Data will be analyzed using descriptive and inferential statistics. As this is a feasibility/exploratory study, the number of subjects is set at a minimum of 30, given the capacity of the music therapist. It is intended for the data collection phase to not exceed 1 year. After data collection is complete for a minimum of 30 subjects, data analysis will begin. The pre-and post-intervention scores, across each condition, for each subject, as well as for subjects undergoing the same condition, will be compared, to show the effect size, with 95% Confidence Interval.