Version 1
March 13, 2020

INFORMED CONSENT FORM

1. Name and Quality of the Study:

The effect of virtual reality treatment on upper extremity functions in patients with hemiplegic cerebral palsy.

Single blind, randomized, controlled, prospective clinical trial

Cerebral Palsy is a permanent but altered movement, sensory, perception and posture disorder that occurs in the central nervous system as a result of the brain's inability to complete its anatomical development from the early stages of life or any non-progressive disease or trauma in the development process. In "Unilateral Cerebral Palsy", which is one of the classification types, the arm and leg on one side of the body are more affected. This group constitutes 28% of all Cerebral Palsy patients. In unilateral Cerebral Palsy patients, the impairment of arm and hand functions on the one hand affects daily life activities to a great extent. Effective use of the hand and arm is generally impaired in activities such as reaching forward, holding, releasing, and directing objects. Weakness, spasm, movement and sensory disturbances and not using the hand are common.

Exercises performed with the visual biofeedback method are actively used in children and adult stroke patients with unilateral cerebral palsy by improving the movements of hand fingers, wrist, elbow and shoulder. The main features of this treatment are repetitions of the movement, teaching the movement from easy to difficult, and being fun and motivating thanks to the treatment applied in the form of a game. Considering that this treatment, which was previously applied to adults with a stroke (stroke), would be more effective due to the ongoing development of nerve cells and brain in children, many studies have been conducted to investigate visual biofeedback therapy in children.

Volunteer patients who meet the inclusion criteria will be randomized into two groups with the computer program after being numbered according to the order of application. Classical physiotherapy will be applied to the first group. The name of the treatment to be applied to the second group in addition to the classical physiotherapy application is virtual reality mediated rehabilitation methods. In addition to the classical physiotherapy application, exercise therapy will be applied by the physician (Dr. Ahmet Kıvanç Menekşeoğlu) using visual biofeedback methods through virtual reality glasses, which will last for 6 weeks, 3 sessions per week for 45 minutes. Within the scope of the study you will participate in as a volunteer, an hour-long seminar will be organized individually or in groups for the parents who take care of the child before the sessions begin. Measurements will be made before the study begins, after the intervention, and after 12 weeks, evaluating the effects of the treatment in both groups. These measurements will take approximately 1-1.5 hours.

All reviews Dr. It will be carried out by Ahmet Kıvanç Menekşeoğlu and Physiotherapist (Physiotherapist) Elçim Yılmaz. AHA evaluator Fzt. Elçim Yılmaz (Physiotherapist with AssistingHandAssesment certificate) will not know which group the children are in until the last measurements are completed in the 3rd month. It is important that the families show the necessary

sensitivity to keep this information confidential and not to share it with the evaluator in any way, in order not to affect the results of the study.

If this study is evaluated in terms of its contribution to science, it is expected that important data will be obtained about which intervention can be more effective in improving hand and arm functions in children with unilateral CerebralPalysis. These data are important for planning future treatments.

The envisaged total duration of this study is 4 months. A total of 40 participants will be included in the study.

2. Providing Information on the Rights of the Volunteer

Volunteers have the right to refuse to participate in this research. Volunteers may withdraw from the study by notifying the researcher at any time or they may be excluded from the study when deemed necessary by the researcher. The treatment of the volunteers excluded from the study, which is deemed appropriate for their current situation, or a different treatment will continue. In case the volunteer does not accept the research or is removed from the study program for any reason, there will be no disruption in the treatment of his disease. Volunteers will not bear any monetary responsibility for expenses for research. In addition, no payment will be made to the volunteer or his family.

The identity information of the volunteers and their families will be kept confidential.

Participant's / Patient's Statement

Dear Prof. Dr. Ayşe Resa Aydın and Dr. Ahmet Kıvanç Menekşeoğlu stated that a medical research will be conducted in the Department of Physical Medicine and Rehabilitation at Istanbul Faculty of Medicine, and the above information about this research was transferred to me. After this information, I was invited as a "participant" (subject) to such a study.

If I participate in this research, I believe that the confidentiality of my information, which should remain between me and the physician, will be approached with great care and respect during this research. I have been given sufficient confidence that my personal information will be protected with care when using research results for educational and scientific purposes.

I can withdraw from the research without giving any reason during the execution of the project. (However, I am aware that it would be appropriate if I declare in advance that I will withdraw from the study in order not to put researchers in a difficult situation). I can also be excluded from research by the researcher, provided that my medical condition is not harmed.

I do not take any financial responsibility for the expenses for research. No payment will be made to me either.

I have been assured that any medical intervention will be provided in the event of any health problem that may arise due to direct or indirect reasons arising from the research practice. (I will not be burdened with money for these medical interventions either).

When I encounter a health problem during research; at any hour, Prof. Dr. Ayşe Resa Aydın or Dr. I know that I can call Ahmet Kıvanç Menekşeoğlu at 0212 4142000-12850 / 31732 and Istanbul

Medical Faculty Physical Medicine and Rehabilitation Department Şehremini / Fatih / İstanbul or again responsible and / or assistant researchers.

Professor Dr. Resa Aydin, Mobile phone: 0532 446 2804; E-mail address: raydin@istanbul.edu.tr

Dr. Ahmet Kıvanç Menekşeoğlu, Mobile phone: 0537 819 2424; E-mail address kivancmenekseoglu@gmail.com

I do not have to and may not participate in this research. I have not encountered any compelling behavior in my participation in the research. I also know that if I refuse to participate, it will not harm my medical care and my relationship with the doctor.

I understand all the explanations given to me in detail. I made the decision to take part in this research project as a "participant" (subject) after a certain period of reflection on my own. I accept the invitation on this subject with great satisfaction and willingness. A copy of this signed form sheet will be given to me.

Informed Consent Signature Page

I have read the text above, which shows the information to be given to the volunteer before research. I have been given written and verbal explanations about these. Under these circumstances, I agree to participate in this clinical trial with my own consent, without any pressure or coercion.

Date:

Volunteer;

Name and surname:

Signature:

The researcher who made the explanations; Name and surname:

Signature:

The institution officer who witnessed the consent process from the beginning to the end; Name and surname:

Role:

Signature:

Preflight Results

Document Overview

Title:
Author: asus
Creator: Microsoft® Word 2016
Producer: www.ilovepdf.com

Preflight Information

Profile: Convert to PDF/A-2b
Version: Qoppa jPDFPreflight v2020R1.03
Date: Aug 20, 2020 10:25:27 AM

Legend: (X) - Can NOT be fixed by PDF/A-2b conversion.
(!X) - Could be fixed by PDF/A-2b conversion. User chose to be warned in PDF/A settings.

Page 1 Results
(X) Font Arial,Bold is not embedded.

Page 2 Results
(X) Font Arial,Bold is not embedded.

Page 3 Results
(X) Font Times New Roman,Bold is not embedded.