Investigation of the Effectiveness of Visual Feedback Training on Upper Extremity Functions in Cerebral Palsy

Study Protocol with Statistical Analysis Plan (SAP) and Informed Consent Form (ICF)

January 1, 2018

Investigation of the Effectiveness of Visual Feedback Training on Upper Extremity Functions in Cerebral Palsy

Study Protocol

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January 1, 2018

Study Protocol

Study titled 'Investigation of the Effectiveness of Visual Feedback Training on Upper Extremity Functions in Cerebral Palsy was approved by Marmara University Faculty of Medicine Clinical Researches Ethics Committee meeting on 05.01.2018 with approval number: 09.2018.007 (Annex-1).

The legal representatives of the children who participated in the study were informed about the aim, duration and the programs to be applied throughout the study. Volunteer Information Form has been signed and approved in accordance with the standards deemed appropriate by the Clinical Researches Ethics Committee of Marmara University Faculty of Medicine (This form can be seen on Informed Consent Form (ICF) section). The study was conducted in accordance with the Declaration of Helsinki.

Hypothesis of the Study

H_0: Addition of the exercises performed with Cogniboard® Light Trainer device to the neurodevelopmental (NDT) based rehabilitation program in patients with cerebral palsy does not contribute positively in improving the efficiency of upper extremity functions.

H_1: Addition of the exercises performed with Cogniboard® Light Trainer device to the neurodevelopmental (NDT) based rehabilitation program in patients with cerebral palsy contributes positively to improve the efficiency of upper extremity functions.

Randomization of the Study Groups

Children with Cerebral Palsy who applied to the Dilbade Education and Rehabilitation Center for rehabilitation were invited to participate to the study. Children who volunteered to participate and whom met the criteria for participation were randomized with simple random sampling method and divided into two groups. Individual Neurodevelopmental (NDT) based rehabilitation programs were applied to the participants in both groups. The Cogniboard® Light Trainer education system was added to the rehabilitation program of the Group II (the study group).

Inclusion Criteria

• Volunteered to participte,
• The child and the family have agreed to participate in the study,
• Having a diagnosis of Cerebral Palsy,
• Children aged between 4 - 18 years,
• Having upper extremity spasticity (0), (1), (1+) according to the modified Ashworth Scale (MAS)
• To be able to cooperate to the exercises

Exclusion Criteria

• Botulinum Toxin (BOTOX) injection applied to the upper extremity within the last 6 months,
• Congenital deformity in upper extremity
• Epileptic attack history,
• Any cardiac or orthopedic problem,
• Visual or hearing impairement

Applied Evaluations

Evaluations are applied twice: before and after the study. All evaluation data are noted to ‘Participants Tracking Form’ (Annex-2). Spasticity was defined with 'Modified Ashworth Scale'; upper extremity joint range of motion (ROM) with ‘goniometer'; grip and pinch strength with ‘dynamometer'; hand skills with 'Minnesota Hand Skill Test'; functional abilities with 'Childhood Health Assessment Questionnaire (CHAQ) and functional level with ‘Gross Motor Function Classification System (GMFCS)’

Treatment Program

The participants in our study were all rehabilitated in Dilbade Education and Rehabilitation Center twice a week for 8 weeks, a total of 16 sessions (Duration of one session is 45 minutes).

Group I (Control Group) received individual Neurodevelopmental (NDT) based rehabilitation program.

Group II (Study Group) received individual NDT based rehabilitation program (35 minutes) + Cogniboard® Light Trainer education (10 minutes).

Cogniboard® Light Trainer Education Protocol

Upper limb exercises were applied to the study group with the device which is a training program with visual feedback for 10 minutes in addition to individual 35 minutes neurodevelopmental treatment program. Devices were placed in the mirror so that the participants could see their own reflection. The distances of the participants to the mirror were proportional to their height. For children between 100-149 cm, the distance of the child with the mirror was set as 40 cm and for the children between 149-175 cm, 50 cm. Eight devices were placed in the mirror within the reach of the participant. While the shoulder and wrist were flexed, the shoulder was placed in the lateral distances that the shoulder could reach while the shoulder was in 90°, while the shoulder was in extension and the other devices were placed between these points (Picture 1).

(Picture 1. Application of Cogniboard® Light Trainer Education Device)

Neurodevelopmental Therapy (NDT) Based Upper Extremity Rehabilitation

In accordance with the needs of the patients for their gross motor functions, the children in both groups were included in the NDT program, which was determined according to the age, sex, mental status and preferences of the individual. NDT program included; rehabilitation of muscle tonus disorders, sensory-perception-motor integrity enhancement, exercises to increase upper extremity functions, stretching and strengthening exercises due to muscular shortness and weakness, exercises to accommodate movements in daily life, and training of activities such as standing up, eating, walking, body care.

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Statistical Analysis Plan (SAP)

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Statistical Analysis Plan (SAP)

The statistical program Statistical Package for Social Sciences (SPSS) Version 11.5 (SPSS Inc., Chicago, IL, USA) was used in the data analysis of the study. The p value of $p<0.05$ was considered to be statistically significant in the data analysis. Shaphiro-Wilks test was used to investigate the appropriateness of the variables to normal distribution.

In the comparison of the nominal characteristics of the participants in both groups, such as gender, CP type, GMFCS and dominant side, Fisher Precise Chi-Square Test was used.

The initial demographic characteristics such as age, height, weight, body mass index (BMI) of the participants in both groups and the changes before and after the treatment were compared with Independent Samples t-Test and Paired Samples t-Test.

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Informed Consent Form (ICF)

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Informed Consent Form (ICF)

Description of the Physiotherapist

This study, if you accept your child to be participated, is a scientific research and it is titled as 'Investigation of the Effectiveness of Visual Feedback Training on Upper Extremity Functions in Cerebral Palsy'. In this study, individuals with Cerabral Palsy will be evaluated in terms of upper extremity (arm) functions, upper extremities' joint range of motion with universal goniometer, gripping force with dynamometer, pinching force with pinchmeter, spasticity will be defined with Modified Ashworth Scale (MAS), hand skills with 'Minnesota Hand Skill Test'; functional abilities with 'Childhood Health Assessment Questionnaire (CHAQ) and functional level with 'Gross Motor Function Classification System (GMFCS)'. The study, which is planned to last in 8 weeks, requires participants to attend the study regularly for 2 days a week and each day for one session which is 45 minutes. There will be no disruption of the body during the process.

This research will be carried out by Physiotherapist Dilara Merve SARI (Tel: 0533 344 46 01) and will be under the supervision of Assoc. Prof. Dr. Tuğba KURU ÇOLAK at Marmara University, Institute of Health Sciences, Department of Physiotherapy and Rehabilitation.

Your child is being invited to a research project. It is very important you to understand why and how this research will be done before making a decision. Please take some time and read the following informations carefully, discuss it with others if you wish. If you have an unclear section or need more detailed information, you can get information from us. You are invited to our research because we think your child matches the criterias to be included. We would like to note that participation is voluntary and that refusal to participate does not lead to any penalty or loss of any benefit. In the same way, you can withdraw from the research at any time.

After getting the demographic information of the participants, the upper extremity functions will be measured by the above physiotherapist and with the mentioned tests. The evaluation tests will be repeated 2 times throughout the treatment. The data obtained from the assessments will be recorded in the computer and the changes during pre- and post-treatment will be analyzed.

The assessments applied to the participants in our research do not have any known harm. In the event of any unexpected damage in the evaluation process or during the rehabilitation process, the information will be given immediately to you. In case of any damage to the participants, the necessary applications shall be covered by the researchers without any recourse. For this, you will not be charged any fees, neither you nor your social security insurance.

While participation in the research does not help you immediately, it is hoped that our research results will have benefits for the organization, society or science in the future. You will not be charged any fees for the purposes of the research or for the social security institution to which you are affiliated.

Consent of the Participant

I have read the entire information form clearly and understood or because I do not know how to read/not able to or do not understand the language it was read or translated to me. I was given the opportunity to ask, evaluate and decide on my health status both during and after my application and when filling this form in. All kinds of treatment and diagnostic alternatives, including the possibility of not getting the treatment, their risks and dangers are explained.

Name and the Surname of the Participant and Legal Representative:

Date: **Signature:**

Name and Surname of the Withness:
Date: **Signature:**

Declaration of the Physiotherapist

I gave the patient the necessary information about the study and the procedures to be performed. I believe that the patient understood this information, asked me the questions that she/he wanted to ask, and accepted the process with her/his free will.

Researcher: Physiotherapist Dilara Merve Sarı
Address: Dilbade Education and Rehabilitation Center – Silahtaraga, 129 34050 Eyup / Istanbul / Turkey
Mobile Phone: +90 533 344 46 01 **E-mail:** dilaramervesari@gmail.com
Date: **Signature:**

Declaration of the Participant / Legal Representative

Ms. Dilara Merve SARI stated that a medical research will be carried out and the above information about this research was explained to me. I know my child is invited to this research as a participant. If I participate in this research, I believe that the confidentiality of the information of my child during research will be treated with great care and respect. I was given enough information that my child's personal information would be protected with care during the use of the research and the results will only used for educational and scientific purposes. During the research I can withdraw my child from the study at any time without any cause (But in that case I am aware of the difficult situation it would cause to the reaseachers if I do not give any notice). I don't take any financial responsibility for the research expenses. There will be no payment for me. Whether directly, indirectly arised any health problem that may occur during the research, I will not undergo any monetary burden. When we encounter any health problem during the research; at any hour, I know I can call physiotherapist Dilara Merve SARI from +90 533 344 46 01 (mobile).

My child does not have to be participated in this research or may not participate. We have not experienced any compelling behavior to participate in the research. If we refuse to participate, I know that this will not bring any harm to our medical care and our relationship with my physiotherapist.

I have understood all the explanations made to me in detail. At the end of a certain period of thinking on my own, I decided that my child could take part in this research project as a participant. On behalf of my child, I accept this invitation voluntarily.

Voluntary Approval Form

I have read the text above which shows the information that should be given to the volunteer before investigating. These were written and was explained verbally. With these conditions, I agree to participate in this research without any pressure or compulsion on me and my child. A signed 2 copies of this form, which consists of 4 pages, a copy of the documents will be given to me.

Name and the Surname of the Participant and Legal Representative:

Date: **Signature:**

Name and Surname of the Withness (who have witnessed the process of receipt until the end**):**
Date: **Signature:**

The researcher who made the explanations,
Researcher: Physiotherapist Dilara Merve Sarı
Address: Dilbade Education and Rehabilitation Center – Silahtaraga, 129 34050 Eyup / Istanbul / Turkey
Mobile Phone: +90 533 344 46 01 **E-mail:** dilaramervesari@gmail.com
Date: **Signature:**

Annex 1. Marmara University Faculty of Medicine Clinical Researches Ethics Committee Approval (Approval made at the meeting on 05.01.2018 with number: 09.2018.007)

Marmara Üniversitesi Tıp Fakültesi
Klinik Araştırmalar Etik Kurulu

BAŞVURU BİLGİLERİ	**PROTOKOL KODU**	**09.2018.007**
	PROJE ADI	Serebral Palsili Olgularda Görsel Geri Bildirimli Eğitimin Üst Ekstremite Fonksiyonlarına Etkinliğinin Araştırılması
	SORUMLU ARAŞTIRICI ÜNVANI/ADI	Doç. Dr. Tuğba KURU ÇOLAK

KARAR BİLGİLERİ	**Tarih 05.01.2018** **Yukarıda başvuru bilgileri verilen araştırma başvuru dosyası ve ilgili belgeler araştırmanın gerekçe, amaç, yaklaşım ve yöntemleri dikkate alınarak incelenmiş ve gerçekleştirilmesinde sakınca bulunmadığı için Kurulumuzca onaylanmasına oy birliği ile karar verilmiştir. Onay sonrasında yapılacak her türlü proje değişiklikleri (katılımcılar, başlık vb.) veya protokol değişikliklerinin Etik Kurula bildirilerek proje onayının yenilenmesi gerekmektedir.**

ÜYELER

Unvanı / Adı / Soyadı	Uzmanlık Dalı	Kurumu / EK Üyeliği	Onaylanan Proje ile İlişkisi	Toplantıya katılım	İmza
Prof.Dr. Haner DİRESKENELİ	Romatoloji	M.Ü Tıp Fakültesi/ Başkan	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Prof.Dr. Tülin ERGUN	Dermatoloji	M.Ü Tıp Fakültesi/Başkan Yrd.	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Prof. Dr. Şefik GÖRKEY	Tıp Tarihi ve Etik	M.Ü Tıp Fakültesi/Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Prof.Dr. Handan KAYA	Patoloji	M.Ü Tıp Fakültesi/Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Prof.Dr. M.Bahadır GÜLLÜOĞLU	Genel Cerrahi	M.Ü Tıp Fakültesi/Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Prof.Dr. Atila KARAALP	Farmakoloji	M.Ü Tıp Fakültesi/Üye	▪ Var ▪ Yok	□ EVET ▪ HAYIR	
Prof.Dr. Semra SARDAŞ	Eczacı	M.Ü Eczacılık Fak./Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Prof.Dr. Başak DOĞAN	Diş Hekimi	M.Ü Diş Hekimliği Fak./Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Prof. Dr. Beste Melek ATASOY	Radyasyon Onkolojisi	M.Ü Tıp Fakültesi/Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Doç. Dr. Elif KARAKOÇ AYDINER	Çocuk Sağlığı ve Hastalıkları	M.Ü Tıp Fakültesi/Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Doç.Dr. Meltem KORAY	Diş Hekimi	İstanbul Üniv. Diş Hekimliği Fak./Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Doç. Dr. Gürkan SERT	Hukukçu	M.Ü Tıp Fakültesi/Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Doç.Dr: Figen DEMİR	Halk Sağlığı	Acıbadem Üniv. Tıp Fak.	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Doç.Dr. Pınar Mega TİBER	Biyofizik	M.Ü Tıp Fakültesi/Üye	▪ Var ▪ Yok	□ Evet ▪ Hayır	
Gözde Aynur MİRZA	Sağlık Mensubu olmayan kişi	Serbest	▪ Var ▪ Yok	□ Evet ▪ Hayır	

Annex 2. Participants Tracking Form

Participant's Name - Surname:

Legal Representative Name - Surname:

Phone number:

Age / Gender: **Height:** **Weight:**

Date of birth:

Type of Cerebral Palsy (CP) (Mark X): **Spastic** **Diskinetic** **Ataxic**

Which side of the arm is effected mostly?

Which side is your dominant side?

How did the problem occur? (Preterm birth, after birth etc. Please explain.)

How many years have you been going to a rehabilitation center?

Did you have any operations? Please write if you did:

Are you using any device? If so, what are theyt?

<u>Evaluations:</u>

Muscle Tone: (According to the Modified Ashworth Scale 0/1/1+/2/3/4)

Right or Left Arm (Please mark)

Hand Wrist Function:

Elbow Flexion:

Supination:

Do you have any additional medical problems?

Yes / What is it?:

No:

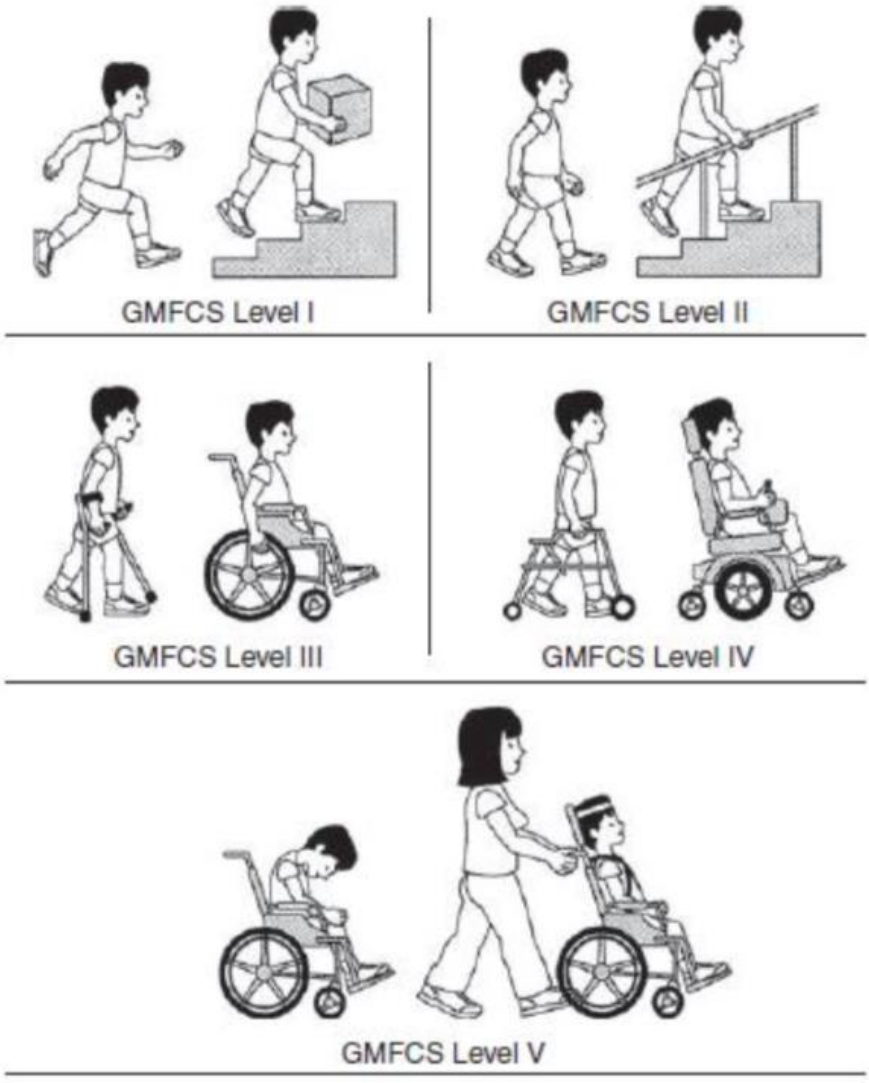
Range of Motion:		Before Treatment	After Treatment
Shoulder	**Flexion**		
	Abduction		
Elbow	**Flexion**		
Front Arm	**Extension**		
	Supination		
	Pronation		
Hand Wrist	**Flexion**		
	Extension		

Muscle Strength	Before Treatment	After Treatment
Grasping		
Tip Pinch		
Lateral Pinch		
Triple Pinch		

Minnesota Hand Skill Test	Before Treatment	After Treatment
Placement with the affected hand (sn)		
Placement bilaterally (sn)		

Gross Motor Functional Classification System (GMFCS)

Level of the participant:



CHILDHOOD HEALTH ASSESSMENT QUESTIONNAIRE

In this section we are interested in learning how your child's illness affects his/her ability to function in daily life. Please feel free to add any comments on the back of this page. In the following questions, please check the one response which best describes your child's usual activities (averaged over an entire day) **OVER THE PAST WEEK. ONLY NOTE THOSE DIFFICULTIES OR LIMITATIONS WHICH ARE DUE TO ILLNESS**. If most children at your child's age are not expected to do a certain activity, please mark it as "Not Applicable". **For example, if your child has difficulty in doing a certain activity or is unable to do it because he/she is too young but not because he/she is RESTRICTED BY ILLNESS, please mark it as "NOT Applicable".**

	Without ANY Difficulty	With SOME Difficulty	With MUCH Difficulty	UNABLE To do	Not Applicable
DRESSING & GROOMING					
Is your child able to:					
- Dress, including tying shoelaces and doing buttons?	☐	☐	☐	☐	☐
- Shampoo his/her hair?	☐	☐	☐	☐	☐
- Remove socks?	☐	☐	☐	☐	☐
- Cut fingernails?	☐	☐	☐	☐	☐
ARISING					
Is your child able to:					
- Stand up from a low chair or floor?	☐	☐	☐	☐	☐
- Get in and out of bed or stand up in a crib?	☐	☐	☐	☐	☐
EATING					
Is your child able to:					
- Cut his/her own meat?	☐	☐	☐	☐	☐
- Lift up a cup or glass to mouth?	☐	☐	☐	☐	☐
- Open a new cereal box?	☐	☐	☐	☐	☐
WALKING					
Is your child able to:					
- Walk outdoors on flat ground?	☐	☐	☐	☐	☐
- Climb up five steps?	☐	☐	☐	☐	☐

*** Please check any AIDS or DEVICES that your child usually uses for any of the above activities:**

- Cane	☐	- Devices used for dressing (button hook, zipper pull, long-handled shoe horn, etc.)	☐
- Walker	☐	- Built up pencil or special utensils	☐
- Crutches	☐	- Special or built up chair	☐
- Wheelchair	☐	- Other (Specify:_____)	☐

*** Please check any categories for which your child usually needs help from another person BECAUSE OF ILLNESS:**

- Dressing and Grooming	☐	- Eating	☐
- Arising	☐	- Walking	☐

	Without ANY Difficulty	With SOME Difficulty	With MUCH Difficulty	UNABLE To do	Not Applicable
HYGIENE					
Is your child able to:					
- Wash and dry entire body?	☐	☐	☐	☐	☐
- Take a tub bath (get in and out of tub)?	☐	☐	☐	☐	☐
- Get on and off the toilet or potty chair?	☐	☐	☐	☐	☐
- Brush teeth?	☐	☐	☐	☐	☐
- Comb/brush hair?	☐	☐	☐	☐	☐
REACH					
Is your child able to:					
- Reach and get down a heavy object such as a large game or books from just above his/her head?	☐	☐	☐	☐	☐
- Bend down to pick up clothing or a piece of paper from the floor?	☐	☐	☐	☐	☐
- Pull on a sweater over his/her head?	☐	☐	☐	☐	☐
- Turn neck to look back over shoulder?	☐	☐	☐	☐	☐
GRIP					
Is your child able to:					
- Write or scribble with pen or pencil?	☐	☐	☐	☐	☐
- Open car doors?	☐	☐	☐	☐	☐
- Open jars which have been previously opened?	☐	☐	☐	☐	☐
- Turn faucets on and off?	☐	☐	☐	☐	☐
- Push open a door when he/she has to turn a door knob?	☐	☐	☐	☐	☐
ACTIVITIES					
Is your child able to:					
- Run errands and shop?	☐	☐	☐	☐	☐
- Get in and out of a car or toy car or school bus?	☐	☐	☐	☐	☐
- Ride bike or tricycle?	☐	☐	☐	☐	☐
- Do household chores (e.g. wash dishes, take out trash, vacuuming, yardwork, make bed, clean room)?	☐	☐	☐	☐	☐
- Run and play?	☐	☐	☐	☐	☐

*** Please check any AIDS or DEVICES that your child usually uses for any of the above activities:**

- Raised toilet seat	☐	- Bathtub bar	☐
- Bathtub seat	☐	- Long-handled appliances for reach	☐
- Jar opener (for jars previously opened)	☐	- Long-handled appliances in bathroom	☐

*** Please check any categories for which your child usually needs help from another person BECAUSE OF ILLNESS:**

- Hygiene	☐	- Gripping and opening things	☐
- Reach	☐	- Errands and chores	☐

PAIN: We are also interested in learning whether or not your child has been affected by pain because of his or her illness. How much pain do you think your child has had because of his/her illness IN THE PAST WEEK? Place a mark on the line below, to indicate the severity of the pain

No pain 0 ——————————————— 100 Very severe pain

GLOBAL EVALUATION: Considering all the ways that arthritis affects your child, rate how he/she is doing by placing a single mark on the line below.

Very well 0 ——————————————— 100 Very poor