MARMARA UNIVERSITY SCHOOL OF MEDICINE

This Informed Consent Form is for parents of children who attend Pediatric Rehabilitation Clinic of Department of Physical Medicine and Rehabilitation, Marmara University School of Medicine *and who we are inviting to participate in research on the effect of vest type dynamic elastomeric fabric orthosis (DEFO) on sitting balance and gross manual dexterity. The title of our research project is "* The effect of vest type dynamic elastomeric fabric orthosis (DEFO) on sitting balance and gross manual dexterity in children with bilateral cerebral palsy: A feasibility and randomized, single-blinded, pilot study.

Name of Principal Investigator: Esra Giray

Name of Organization: *Pediatric Rehabilitation Clinic of Department of Physical Medicine and Rehabilitation,* Marmara University School of Medicine

Name of Sponsor: None

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Esra Giray, working at the *Pediatric Rehabilitation Clinic of Department of Physical Medicine and Rehabilitation,* Marmara University School of Medicine ***as Physiatrist (Physical medicine and Rehabilitation Specialist). We are doing research on cerebral palsy disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.***

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose of the research

Cerebral palsy (CP) is a disorder of development of movement and posture due to non-progressive lesion in fetal or infant brain. Postural control in children with cerebral palsy (CP) is deteriorated due to inappropriate muscle force and lack of sensory integration. The trunk which is found in the centre of the body plays a crucial role in postural control. Research and treatments in CP have focused on extremities rather than trunk control. Both evaluation and treatment of trunk impairment have not been adequately addressed in previously published studies. Improved proximal stability obtained by a better trunk control may lead to improvements in upper extremity function.

Dynamic elastomeric fabric orthosis (DEFO) which are lycra based compression garments provide extra proprioceptive information which enhances body awareness. The more correct proprioceptive input result in the more proper alignment. Vest type dynamic elastomeric fabric orthosis (DEFO) is composed of a front part which is compromised of double-or triple-layer of lycra fabric attached to velcro sensitive neoprene back panel. Thus, it provides adjustable compression around the shoulder, trunk, pelvis, and hips. It is proposed that these orthotic garments provides stabilization of the trunk, shoulder and pelvis girdle and thus improve proximal stability and upper extremity function. Children with sensory deficits and poor muscle strength including children with neuromotor developmental disorders and hypotonia can benefit from the use of vest type dynamic elastomeric fabric orthosis. Severe restricted pulmonary function and refractory cyanosis are absolute contraindications for lycra based orthosis use while having severe reflux symptoms, uncontrolled epilepsy, cardiovascular circulatory disorders and being diagnosed with diabetes are relative contraindications. The adverse events pertaining to the use of these orthoses are difficulty in donning/doffing, toileting problems such as constipation and urinary leakage, decrease in respiratory function, heat and skin discomfort. Due to those unwanted effects, it can be assumed that longer wear time of the orthosis may lower compliance. However, the optimal wear time for vest type dynamic elastomeric fabric orthosis has not been established so far. The reported wear time of suit therapies range from 2 to12 hours a day during 2-12 weeks. The aim of this study was to investigate if the use of a vest type dynamic elastomeric fabric orthosis (DEFO) *vest type dynamic elastomeric fabric orthosis* is feasible or not and will lead to improvement in sitting balance, sitting as a gross motor function and gross manuel dexterity. The secondary purposes of the present study are to evaluate parent satisfaction with the orthosis and to compare 2 hours vs 6 hours of daily wear time.

Type of Research Intervention

Your child will be hospitalized for 2 weeks and will receive conventional exercise therapy including range of motion, strengthening, trunk control and strengthening exercises and exercises to improve fine and gross motor skills during hospital inpatient stay throughout 2 weeks 2 hours a day (SG). Control group will receive conventional exercise therapy only. SPIO 2 hours group will receive conventional exercise therapy with the garment on for 2 hours. SPIO 6 hours group will wear the SPIO 4 hours more in addition to 2 hours during therapy.

Participant selection

We are inviting all children with cerebral palsy who had impaired sitting balance to participate in the research on the effects of vest type dynamic elastomeric fabric orthosis (DEFO) on sitting balance and gross manual dexterity.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital for cerebral palsy, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?

B. Description of the Process, Duration

Your child will receive the treatment of cerebral palsy according to national guidelines. This means that the child will receive conventional exercise therapy.

Your child will be hospitalized for 2 weeks and will receive conventional exercise therapy including range of motion, strengthening, trunk control and strengthening exercises and exercises to improve fine and gross motor skills during hospital inpatient stay throughout 2 weeks 2 hours a day (SG). Control group will receive conventional exercise therapy only. SPIO 2 hours group will receive conventional exercise therapy with the garment on for 2 hours. SPIO 6 hours group will wear the SPIO 4 hours more in addition to 2 hours during therapy.

Benefit from the use of orthosis will be measured via sitting domain of Gross Motor Function Measure (GMFM), Sitting Assessment Scale (SAS), Box and Block Test (BBT) and Parent satisfaction questionnaire.

Sitting Assessment Scale (SAS) was used to evaluate posture and balance during sitting while sitting dimension of Gross Motor Function Measure (GMFM) were used for assessing sitting as a gross motor function. Box and Block Test was used to evaluate gross manuel dextrity.

Sitting Assessment Scale (SAS)

Sitting Assessment Scale was devoloped for observational assessment of posture and balance during sitting after seating interventions. The scale consists of 5 items including head control, trunk control, foot control, arm function and hand function which are assessed as follows: 1= none; 2= poor; 3= fair; 4= good). The minimum and maximum possible scores are 5 to 20 respectively.

Gross Motor Function Measure-B, sitting dimension

Gross Motor Function Measure shows gross motor functional status and changes in functional status of children ages between 15 months and 13 years after interventions. It is composed of 88 items which are catagorized into 5 dimensions including lying and rolling (17); sitting (20); crawling and kneeling (14); standing (13); and walking, running, and jumping (24). It assesses degree of achievement of gross motor functions rather than quality of them. Each item is scored according to special instructions on GMFM Manuel with a 4-point Likert scale including 0 = does not initiate, 1 = initiates, 2 = partially completes, 3 = completes. If it is not possible to test an item, it should be noted as not tested (NT).

In this study sitting dimension of GMFM was used to evaluate degree of achievement of sitting as a gross motor function. Evaluations were done according to GMFM User's Manuel 20.

Box and Block Test

Box and Block Test which consists of a box divided into two compartments by a partition and blocks with standardized dimensions is used to assess unilateral gross manual dexterity. The object is instructed to transport boxes one by one from one compartment of the box to other in 60 seconds. The score is the number of boxes transferred from one compartment to other in 60 seconds. The object should sit on a chair with a standard height and face the box. He/she should practice for a 15 second trial period before testing. If two blocks are carried at the same time, it is counted as one. And also, if the block falls on the floor after it has been carried across, it is still counted.

Parent Satisfaction Survey

A non-standardized 5-point Likert type scale was invented by the investigators to assess compliance and satisfaction with wearing orthosis. Parents were completed the questionnaire PT, 1 MPT and 3 MPT. The items numbered 3, 5 and 7 were questioning about treatment efficacy while the other items were questioning the ease and utilization of the use of orthosis. That's why to compare all groups only 3.,5. and 7. items were used when all of them were completed for the comparison of SPIO groups.

Assessments for measuring benefit from therapies will be conducted before treatment (BT) (TO), at posttreatment (PT), 1 month posttreatment (1 MPT) and 3 months posttreatment (3 MPT). In total, you will be asked to come 2 times to the clinic in 3 months. At the end of three months, the research will be finished.

Side Effects

The adverse events pertaining to the use of these orthoses are difficulty in donning/doffing, toilleting problems such as constipation and urinary leakage, decrease in respiratory function, heat and skin discomfort.

Risks

By participating in this research it is possible that you will not be at greater risk.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you immediate care.

Benefits

If you participate in this research, you will have the following benefits:

Your child will be trained in order to improve sitting balance and upper extremity skills.

Reimbursements

You will not be given any other money or gifts to take part in this research.

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)

Right to Refuse or Withdraw

(Example: You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.)

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Contact: Esra Giray, MD ,

Marmara University School of Medicine Department of Physical Medicine and Rehabilitation

İstanbul, Turkey, 34899

Telephone:+90 2166570606 Ext:6515 email: girayesra@hotmail.com

This proposal has been reviewed and approved by local ethics comitte of Marmara university School of medicine which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [etikkurul@marmara.edu.tr). It

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year