

APPENDIX

Ethics Committee approvals



CHARLES UNIVERSITY IN PRAGUE
FACULTY OF PHYSICAL EDUCATION AND SPORT
José Martího 31, 162 52 Praha 6 -Velešlavín
tel. +420 2 2017 1111
<http://www.ftvs.cuni.cz/>

Application for Ethics Board Review

Postgraduate research

Project title: Applied neurobiomechanical principles in robotic assisted gait training in pediatric neurorehabilitation

Nature of the research project: postgraduate research study for dissertation thesis

Author (chief investigator): Dragana Žarković, M.Sc.

Supervisor (in case of student research): assoc. prof. Monika Šorfová (doc. Ing. Monika Šorfová, PhD.)

Research project description: This research serves as a main part of the student's dissertation thesis. The aim of the research is to investigate therapeutic effect of the Lokomat device on the selective voluntary movement control in the lower extremities in pediatric patients with bilateral spastic cerebral palsy.

Guaranteed safety to be judged by experts:

Chief investigator guarantees that all methods used in the research are non-invasive and will not cause any harm to the patient nor to the expert.

Ethical aspects of the research:

Chief investigator guarantees that all personal data, ID and face of the subject will certainly not be presented in the public.

Informed consent (attached)

All subjects (and their parents or guardians) have read and signed the informed consent.

Date: July 31, 2015

Author's signature: Dragana Žarković, M.Sc.

Faculty of Physical Education and Sport, Charles University in Prague
ETHICS BOARD REVIEW

Ethics Board members: Prof. Ing. Václav Bunc, CSc.
Prof. PhDr. Pavel Slepíčka, DrSc.
Doc. MUDr. Jan Heller, CSc.

The Ethics Board at the Faculty of Physical Education and Sport, Charles University, approved the research project. aa

Approval number: 120/2015

Date: 12. 8. 2015

The Ethics Board at the Faculty of Physical Education and Sport, Charles University, reviewed the submitted research project and found no contradictions with valid principles, regulations and international guidelines for biomedical research involving human subjects.

The chief investigator of the project met the necessary requirements for receiving the Ethics Board approval.

UNIVERZITA KARLOVA v Praze
Fakulta tělesné výchovy a sportu
Official school stamp 252 Praha 6


Signature. RFB Chairman



**Univerzitetni
rehabilitacijski
inštitut**
*Republike Slovenije -
Soča*

Linhartova cesta 51
SI-1000 Ljubljana, Slovenija
Tel.: +386 (0)1 47 58 100
Faks: +386 (0)1 43 72 070
www.ir-rs.si

id.št. za DDV SI73541346
TRR: SI56 0110 0603 0278 088

Mag. Katja Groleger Sršen, dr. med..
- tu;

Datum: 5. oktober 2015

Spoštovani!

Komisija za medicinsko etiko je na seji dne 5. oktobra 2015 obravnavala vlogo za mnenje o etični ustreznosti raziskovalnega projekta »Applied neurobiomechanical principles in robotic assisted gait training in pediatric neurorehabilitation« mag. Dragane Žarković pod mentorstvom prof. Monike Šorfove in somentorstvom mag. Katje Groleger Sršen, dr. med., in odgovorne zdravnice mag. Katje Groleger Sršen, dr. med..

Člani komisije za medicinsko etiko so menili, da je raziskovalni projekt »Applied neurobiomechanical principles in robotic assisted gait training in pediatric neurorehabilitation« mag. Dragane Žarković pod mentorstvom prof. Monike Šorfove in somentorstvom mag. Katje Groleger Sršen, dr. med. in odgovorne zdravnice mag. Katje Groleger Sršen, dr. med., etično ustrezen ob sodelovanju strokovnih sodelavcev teama za kineziološko analizo.

Predsednica komisije za medicinsko etiko URI-Soča:
prim. Tatjana Erjavec, dr. med.



Nalozba je naša priložnost!
EVROPSKI SKLAD FINANČNA EVROPSKA UNIJA
hranite vaša tla!



Evropski odbor za fizikalno in rehabilitacijsko medicino je URI-Soča podelil Evropsko akreditacijo in naziv evropskega učnega centra

WRITTEN INFORMED CONSENT FORMS

**Informed Consent form for subjects and their parents taking part in the research
study**

**Dragana Žarković, M.Sc., a physical therapist a student of a PhD. program
Biomechanics at Charles University, Faculty of Sport and Physical Education,
Prague, Czech republic**

in cooperation with

**University Rehabilitation Institute of Republic Slovenia, Children's Department of
Rehabilitation**

POSTGRADUATE DOCTORAL RESEARCH STUDY

on

**“Applied neurobiomechanical principles in robotic assisted gait training in
pediatric neurorehabilitation”**

This Informed Consent Form is for children's subjects (signed by their parents or guardians) who attend University Rehabilitation Institute of Republic Slovenia, and who are invited to participate in the postgraduate doctoral research study on children with cerebral palsy.

Introduction

Dear children, parents and guardians,

my name is Dragana Žarković. I am a physical therapist and a PhD. student of Biomechanics at Charles University, Faculty of Sport and Physical Education in Prague, Czech republic. In cooperation with University Rehabilitation Institute of Republic Slovenia, Children's Department of Rehabilitation, I have created the postgraduate doctoral research study on children with cerebral palsy and robotic assisted gait training. I am going to give you information and invite you to be part of this research. You do not have to decide today whether you will participate in the research. Before you decide, you can talk to anyone you feel comfortable 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, please, feel free to ask.

Purpose of the research

Children with cerebral palsy (CP) have problem with production of selective voluntary movements. They have reduced ability to develop the skilled movements - such as

walking. It has been suggested that ability to move selectively especially in the lower extremities (legs) is an important predictor of improvement in therapeutic interventions. Current research confirms that repetitive task-specific practice can significantly improve motor function in pediatric patients. The reason we are doing this research is to find out if there is a possibility to influence the selective voluntary movements in the lower extremities (legs) in children with CP after an intensive rehabilitation program with device called Lokomat.

Type of Research Intervention

This research will involve attendance in intensive rehabilitation program that would take 1 month as well as 1 follow-up visit to the University Rehabilitation Institute of Republic Slovenia, Children's Department of Rehabilitation.

Participant selection

We have invited all children participants from 5 to 15 years old with bilateral spastic cerebral palsy to attend our research study.

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. You may change your mind later and stop participating even if you agreed earlier.

Duration

The research takes place in Children's Rehabilitation Department in University Rehabilitation Institute of Republic Slovenia. The research takes over 1 month. During that time, it will be necessary for you to come with a child to the clinic for 5x per week (20 times) for 1 hour of therapy. We would like to meet with you after few months for a final check-up. We call this "follow-up".

In total, you will be asked to come 23 times (3 pre and after measurements including follow-up, 20 therapy sessions).

Procedures and Protocol

During the research :

- In the first visit functional physiotherapy tests and clinical gait analysis will be assessed. The results will be scored in the core-sheets or in the computer. We call this as "pre-assessment".
- At the next visit, the rehabilitation program with Lokomat device will start.
- You attend rehabilitation program with Lokomat device daily for 4 weeks (20 sessions)
- After 4 weeks, your last session will be completed with all assessments made in the first visit. We call this as "after-assessment".

Side Effects and risks

The Ethics Committee has approved the research study. Chief investigator guarantees that all methods used in the research are non-invasive and will not cause any harm to the patient nor expert.

Benefits

In this research, nor the patient nor the chief investigator will require any money ward, nor anyone will charge you.

Reimbursements

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

Confidentiality

The information that we collect from this research project will be kept confidential. Chief investigator guarantees that all personal data, ID and face of the subject will certainly not be presented in the public.

Sharing the results

Confidential information will not be shared. We will publish the results in order that other interested people may learn from our research. On your personal request you may see the results and be fully informed about the results.

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 the chief investigator via email : draganazarkovic.physiotherapy@seznam.cz.

Certificate of Consent

I state that I have read 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 in this research. In the case of children's participants (under 18 years old participant), their parents or guardians are signed in this certificate of consent.

Print Name of Participant _____

Date of birth _____

Signature of Participant (parents or guardian) _____

Date _____

Day/month/year

Print Name of Researcher/person taking the consent : Dragana Žarković, M.Sc.

Signature of Researcher /person taking the
consent _____

Date _____

Day/month/year

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



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Republike Slovenije - Soča

Strinjam se z uporabo fotografij in video posnetkov v raziskovalne namene. Vodja raziskave- Dragana Žarković, M. Sc., zagotavlja varnost osebnih podatkov ter zakrit obraz sodelujočih (le ta bo viden samo v zasebni uporabi).

V Ljubljani _____

Podpis staršev _____

Podpis vodje raziskave _____



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Predlog obrazca za sodelujoče

Podpisani

izjavljam, da sem seznanjen z namenom in potekom raziskave, z možnimi koristmi in tveganji.

Seznanjen sem, da lahko na svojo željo brez posledic kadarkoli prekinem sodelovanje. V primeru nujnosti v zvezi z raziskavo lahko pokličem odgovornega nosilca na tel. številko _____ ali dežurnega zdravnika URI-Soča na tel. št. 031 514 076.

Na podlagi danih informacij zavestno pristopam k raziskavi in se zavežujem, da bom vestno upošteval navodila.

Datum: _____

Podpis: _____