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Annex 1: Ethical Committee approval



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FACULTY OF PHYSICAL EDUCATION AND SPORT
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**Request for approval of the research project by Ethical Committee at
Faculty of Physical Education and Sport at Charles University**
research project for PhD, Master's Thesis concerning the evaluation of the human participants

Title: Presence and influencing factors of motor fatigue during 6MWT in Multiple Sclerosis

Form of the project: ~~basic research / applied (for staff)*~~
~~doctoral / rigorous thesis*~~
Master's thesis / ~~bachelor thesis*~~

Author: Vendula Doležalová

Promoter: PhDr. Kamila Řasová, Ph.D.

Project description:

The purpose of the study is to describe and identify the Motor Fatigue and its relation to patient characteristics, walking measures and subjective evaluation the impact of the fatigue on physical, cognitive and psychosocial functioning. Another goal is to describe the differences in pacing strategy during 6MWT in groups with and without motor fatigue.

Design of the study: Cross-sectional multicentre study

Investigation methods and investigators expertise:

(age, gender, Body Mass Index, Expanded Disability Status Scale, type of Multiple Sclerosis, disease duration), walking measures (Six Minute Walking Test, Timed Up and Go test, Timed 25 Foot Walk Test, Multiple Sclerosis Walking Scale-12) and subjective evaluation the impact of the fatigue on physical, cognitive and psychosocial functioning (evaluated by Modified Fatigue Impact Scale).

Ethical aspects of the research:

In this study was not used any invasive will not expose the participants to the

Informed consent: (attached)

Prague, day: 20.3.2014

Authors signature:

Ethical Committee conclusion

Committee members: Doc. MUDr. Staša Bartůňková, CSc.
Prof. Ing. Václav Bunc, CSc.
Prof. PhDr. Pavel Šlepička, DrSc.
Doc. MUDr. Jan Heller, CSc.

Project was approved by the Ethical Committee Faculty of Physical Education and Sport at Charles

University under reference number: 113 / 2014

Date: 25.3.2014

Ethical Committee Faculty of Physical Education and Sport at Charles University concluded that the content of the project is fully in accordance with the applicable conventions, rules and international directives for the biomedical research which involves the human participants.

Investigator fulfilled the conditions needed to acquire Ethical Committee approval.

Stamp
UNIVERZITA KARLOVA v Praze
Fakulta tělesné výchovy a sportu
Josef Martího 31, 162 52, Praha 6

Ethical Committee president's signature

Annex 2: Informed consent form

INFORMED CONSENT

Dear Sir or Madam,

You have been asked by your neurologist to participate in the multicentre study investigating the motor fatigue in persons with Multiple Sclerosis.

The aim of this research is to investigate presence and influencing factors of the motor fatigue in persons with the Multiple Sclerosis.

The investigation will take a place at multiple research centres in Europe. In the Czech Republic it will be specifically at the 3rd Faculty of Medicine at Neurology department of Faculty Hospital Královské Vinohrady, Prague.

The testing protocol contains in total 6 non-invasive clinical tests investigating the walking abilities and the influence of the fatigue in daily life. The clinical tests are 3 short walking tests, 1 endurance walking test (= walking for 6 minutes) and 2 questionnaires. The examination will be performed by experienced examiner and by your neurologist. One day examination will last approximately 45 minutes.

Your personal data recorded during the investigation will be anonymously used for the data analysis and further anonymously published in the research article. The participation in this research is fully voluntary. You have the right to terminate your participation any time during the examination.

Annex 3: Scoring sheets – Patient Characteristics and Walking Tests

GENERAL DATA

Name:

Surname:

Date of birth:

Gender: Male / Female

Height: (cm)

Weight: (kg)

EDSS:

Type of MS: PP / SP / RR

Drug use:

WALKING TESTS

Timed Up and Go Test (usual speed):
TIME: _____ (sec.)

Timed 25 Foot Walk Test (fast speed):
TIME: _____ (sec.)

Timed 10 Meter Walk Test (usual speed):
TIME: _____ (sec.)

Six-Minute Walk test (as far as possible):					
1. min.	2. min.	3. min.	4. min.	5. min.	6. min.
(m)	(m)	(m)	(m)	(m)	(m)
TOTAL DISTANCE: _____ (m)					

Annex 4: Scoring sheets – Multiple Sclerosis Walking Scale-12

Multiple Sclerosis Walking Scale-12 (MSWS-12)

In the past 2 weeks, how much has your MS ...

	<u>Not at all</u>	<u>A little</u>	<u>Moderately</u>	<u>Quite a bit</u>	<u>Extremely</u>
1. Limited your ability to walk?	1	2	3	4	5
2. Limited your ability to run?	1	2	3	4	5
3. Limited your ability to climb up and down stairs?	1	2	3	4	5
4. Made standing when doing things more difficult?	1	2	3	4	5
5. Limited your balance when standing or walking?	1	2	3	4	5
6. Limited how far you are able to walk?	1	2	3	4	5
7. Increased the effort needed for you to walk?	1	2	3	4	5
8. Made it necessary for you to use support when walking indoors (e.g., holding on to furniture, using a stick, etc.)?	1	2	3	4	5
9. Made it necessary for you to use support when walking outdoors (e.g., using a stick, a frame, etc.)?	1	2	3	4	5
10. Slowed down your walking?	1	2	3	4	5
11. Affected how smoothly you walk?	1	2	3	4	5
12. Made you concentrate on your walking?	1	2	3	4	5

Annex 5: Scoring sheets – Modified Fatigue Impact Scale

Modified Fatigue Impact Scale (MFIS)

Because of my fatigue during the past 4 weeks...

	<u>Never</u>	<u>Rarely</u>	<u>Sometimes</u>	<u>Often</u>	<u>Almost Always</u>
1. I have been less alert.	0	1	2	3	4
2. I have had difficulty paying attention for long periods of time.	0	1	2	3	4
3. I have been unable to think clearly.	0	1	2	3	4
4. I have been clumsy and uncoordinated.	0	1	2	3	4
5. I have been forgetful.	0	1	2	3	4
6. I have had to pace myself in my physical activities.	0	1	2	3	4
7. I have been less motivated to do anything that requires physical effort.	0	1	2	3	4
8. I have been less motivated to participate in social activities.	0	1	2	3	4
9. I have been limited in my ability to do things away from home.	0	1	2	3	4
10. I have had trouble maintaining physical effort for long periods.	0	1	2	3	4
11. I have had difficulty making decisions.	0	1	2	3	4
12. I have been less motivated to do anything that requires thinking.	0	1	2	3	4
13. My muscles have felt weak.	0	1	2	3	4
14. I have been physically uncomfortable.	0	1	2	3	4
15. I have had trouble finishing tasks that require thinking.	0	1	2	3	4

16. I have had difficulty organizing my thoughts when doing things at home or at work.	0	1	2	3	4
17. I have been less able to complete tasks that require physical effort.	0	1	2	3	4
18. My thinking has been slowed down.	0	1	2	3	4
19. I have had trouble concentrating.	0	1	2	3	4
20. I have limited my physical activities.	0	1	2	3	4
21. I have needed to rest more often or for longer periods.	0	1	2	3	4