The effect of therapeutic horseback riding on balance, spasticity and general well being on patients after stroke / non-congenital brain injuries

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This project has been defined to investigate the effect of therapeutic horse riding on balance, spasticity and general wellbeing in 30 adults in the age of 18-80 with physical impairments following a stroke or non-congenital brain injury.

Ethical review	Approved WMO
Status	Pending
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON31177

Source
ToetsingOnline

Brief title
The effect of therapeutic horseback riding

Condition

- Structural brain disorders

Synonym
cerebrovasculair accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh

Source(s) of monetary or material Support: Stichting Manege het Roessingh

Intervention

Keyword: balance, horseback riding, stroke, therapeutic

Outcome measures

Primary outcome

Various parameters will be compared between baseline and time of measurement after intervention. The interventiongroup will also be compared with the controlgroup.

The most important parameters are Berg Balance Scale, EMG-pattern and the Ashworth Scale. Furthermore, the VAS-scale, Borg-scale, Clonus score, Spasme Frequency Scale,

SF-36, Falls Efficacy Scale and the Timed Up & Go test will be measured and compared.

Secondary outcome

nvt

Study description

Background summary

Therapeutic horseback-riding is used as a form of physical therapy. During the therapy a patient is positioned astride a horse and passively interacts with and responds to the three-dimensional movements of the horse. The dynamic gait of the horse stimulates vestibular, motor, proprioceptive and tactile systems (Meregillano, 2004; McGibbon et al., 1998). The position of the subject, in hipflexion, -abduction and external rotation, and the three-dimensional movements are assumed to contribute to an unique therapeutic effect on balance, posture and spasticity (Bertoti, 1991; Sterba et al., 2002; Meregillano, 2004; Lechner et al., 2004). Interaction with a horse may also have positive effects on cognition, social behavior and emotion (Meregillano, 2004; Hammer et al.,

2005).
The literature on the effect of therapeutic horse-riding is scarce and besides that limited in its methodological quality. The quality of the studies is moderate because of a number of factors. Firstly, the studies describe mainly subjective outcome measures to quantify the effects of therapeutic horse riding (see e.g. Lechner et al., 2004) without covering the relevant aspects of the ICF domains. Secondly, the studies are usually performed with a small population which hinders the interpretation and generalisation of the findings (Sterba, 2007). Finally, the effect of therapeutic horse riding is only evaluated by comparing simply pre- and post measurements, wthout controlgroups. Understanding the mechanism of the therapy is therefore difficult and the lasting effects of the therapy remain unknown.

Study objective

This project has been defined to investigate the effect of therapeutic horse riding on balance, spasticity and general wellbeing in 30 adults in the age of 18-80 with physical impairments following a stroke or non-congenital brain injury.

Study design

The study is designed as an interrupted time series trial with an additional untreated control group.
The population is divided in 3 groups, of which 2 receive the intervention. All 3 groups undergo a general observation in week 1 (baseline), 6, 11 and 16. The intervention is applied to the first group in week 2, 3, 4 and 5. Before and after the intervention a short measurement is done. The second group recieves the intervention and measurements at week 7, 8, 9 and 10. The controlgroup will only be measured in the general observation. This traject will be repeated after 16 weeks with a entirely new group of patients.

Intervention

Four therapeutic horseback riding sessions of at least 20 minutes and maximal 30 minutes each are provided.
Prior to the intervention, subjects will be shown a video of the therapy to reduce adverse effects. After the laboratory tests, the subject is placed on the back of the horse using a lift. The horse steps in one direction in a quit pace and is guided by a qualified worker, who ensures a good position of the subject and takes care of the safety of the patient. A therapist will be in the vicinity for help when needed. The area will be reserved only for the study during the sessions.

Study burden and risks

Subject load is estimated acceptable since:
- Required measurement time is limited and rest is possible
- Measurement is restricted physically and mentally demanding
- There is limited health risk involved in participating in the study compared to other
daily activities

Subject risk is estimated acceptable since professional workers of the riding school are involved in the intervention with years of experience with therapeutic horse back riding

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- at least 3 months post stroke or brain injury
- report spasticity in knee extensors, - flexors or hip adductor group
- sufficient balance to sit on a horse independently
- stable medical condition

Exclusion criteria

- allergy to latex or horses
- insufficient cognitive capabilities to understand instructions
- problems with communication for understanding instructions and feedback
- severe contractures

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-10-2007

Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18297.080.07