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Evaluating the effect of a simple cooling cap in heat-sensitive people with multiple sclerosis

Submission date
06/12/2022

Recruitment status
No longer recruiting

Registration date
03/02/2023

Overall study status
Completed

Last Edited
03/02/2023

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a condition that can affect the brain and spinal cord, causing a wide range of potential symptoms, including problems with vision, arm or leg movement, sensation or balance.
Heat sensitivity is a common symptom in MS. Symptom deterioration usually appears after 8 minutes of heating, when the body temperature has increased by 0.8°C, and is reduced approximately after 15 minutes after heating is ended. Especially during the hot summer months, an increase in body temperature can cause difficulties in normal daily functioning in people with multiple sclerosis. In previous studies, different techniques and equipment have been used to provide cooling. Active cooling techniques (usually a vest or other liquid condition garment) achieve a greater effect than passive ones. The main limitations of these garments are the lack of transportability and large power source. Other options represent cooling techniques based on the principle of evaporation. In most cases, cooling the centre of the body, i.e. the torso area, is achieved with various types of vests. In clinical practice, we sometimes meet patients who have had a positive experience with simple cooling devices based on the principle of evaporation (manufactured, for example, for athletes or motorcyclists).
The aim of this study was therefore to verify whether these simple and cheap cooling aids can really affect functional performance in thermosensitive people with MS.

Who can participate?
People with multiple sclerosis who are thermosensitive (they feel worsening of their symptoms during hot days).

What does the study involve?
It is necessary to visit the rehabilitation centre on 2 different days to receive a cooling cap and undergo functional assessment (walking tests, fine motoric skills and questionnaire).

What are the possible benefits and risks of participating?
The benefit of participating in the study is receiving a cooling cap. There are no risks associated with participation in the study.

Where is the study run from?
Department of Neurology First Faculty of Medicine and General University Hospital (Czechia)

When is the study starting and how long is it expected to run for?
September 2016 to December 2020

Who is funding the study?
MS rehab z.s. (Czechia)

Who is the main contact?
Klara Novotna, klara.novotna@vfn.cz

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
116/16 GA UK 1.LF

Study information

Scientific Title

Evaluating the effect of a simple cooling cap on functional performance in thermosensitive people with multiple sclerosis

Study objectives
The aim of this study is to verify whether a simple cooling cap can really affect functional performance in thermosensitive people with multiple sclerosis (MS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2016, Ethical Committee of General University Hospital in Prague (Na Bojišti 1, 3. patro, 128 08 Praha 2, Czech Republic; +420 (0)224 964 131; eticka.komise@vfn.cz), ref: 116 /16 GA UK 1.LF

Study design
Interventional randomized cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Thermosensitive people with multiple sclerosis

Interventions
Participants will be examined during warm summer days (with a temperature ≥20°C) using functional tests commonly used in clinical practice. To evaluate the effect of local cooling, the participants will be randomly divided into experimental and control groups with sealed envelopes. The experimental group will undergo an assessment first with local cooling and then with sham cooling. The control group (with sham cooling) will complete the same in reverse order.

To evaluate the effect of local negative thermotherapy, the following tests commonly used in clinical trials with MS were chosen: the Timed 25-foot walk test (T25FW) and the endurance walking test for 2 minutes (2MWT) to evaluate functional mobility. The nine-hole peg test (9HPT) was selected to assess fine motor function. Cognitive functions were assessed using the Symbol Digit Modalities test (SDMT)

Local negative thermotherapy will be implemented through a cooling cap. During the true negative thermotherapy, the cooling cap is soaked in cold water according to the manufacturer's instructions. In the sham cooling group, the cap is only placed into the freezer for a few seconds. This only gave to the participants in the control group a short-term cooling sensation, but there is no cooling effect by the gradual slow evaporation of water from the fabric. The effect of both real and sham negative thermotherapy will last for 15 minutes each time; during that time, the participants will be at rest. Then the participants will complete functional tests of walking, fine motoric and cognition.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Measured after each experimental period:
1. Functional mobility measured using the timed 25 foot walk test
2. Functional mobility measured using the 2 minute walking test
3. Fine motoric function measured using the nine hole peg test

Secondary outcome measures
Measured after each experimental period:
1. Cognitive function measured using the symbol digit modality test
2. Fatigue measured using the Fatigue Severity Scale

Overall study start date
01/09/2016

Completion date
12/12/2020

Eligibility

Key inclusion criteria
1. Patients treated in MS centre of the Department of Neurology, First Faculty of Medicine Charles University and General University Hospital in Prague, who suffered from subjectively perceived thermosensitivity
2. Clinically stable MS (at least 60 days since the last attack)
3. Stable medication (no changes in treatment in last 90 days)
4. Without the presence of another serious disease (disease of musculoskeletal system, internal disease etc)
5. Without significant limitation of cognitive function

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
A minimum of 10 in each group

Total final enrolment
21

Key exclusion criteria
1. Any other condition that limit walking and fine motoric skills
2. Non thermosensitive patients

Date of first enrolment
01/06/2020

Date of final enrolment
30/07/2020

Locations

Countries of recruitment
Czech Republic

Study participating centre
Department of Neurology First Faculty of Medicine and General University Hospital
Katerinska 30
Prague
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Sponsor information

Organisation
MS rehab z.s.

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Sponsor type

Charity

Website
https://www.msrehab.cz

Funder(s)

Funder type
Charity

Funder Name
MS rehab z.s.

Results and Publications

Publication and dissemination plan
The publication of study results are planned for 2021 (conference) and 2022 (published publication).

Intention to publish date
01/05/2022

Individual participant data (IPD) sharing plan
Dataset available on request to principal investigator Klara Novotna (klara.novotna@vfn.cz).

IPD sharing plan summary
Available on request