

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/02/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 03/02/2023	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Thermosensitive people with multiple sclerosis

Interventions

Participants will be examined during warm summer days (with a temperature $\geq 20^{\circ}\text{C}$) 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(s)

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

Key secondary outcome(s)

Measured after each experimental period:

1. Cognitive function measured using the symbol digit modality test
2. Fatigue measured using the Fatigue Severity Scale

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Czech Republic

12000

Sponsor information

Organisation

MS rehab z.s.

Funder(s)

Funder type

Charity

Funder Name

MS rehab z.s.

Results and Publications

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