The effect of head cooling on cognitive functioning in kickboxing; a pilot study.

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42855

Source
ToetsingOnline

Brief title
Head cooling in kickboxing.

Condition

- Other condition

Synonym
cognitive disfunctioning, concussion

Health condition

neurologische aandoeningen, d.w.z. traumatisch hersenletsel waaronder hersenschuddingen

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuis Amstelland
Source(s) of monetary or material Support: Game Ready (CoolSystems: Alameda, California),Ziekenhuis Amstelland; onderzoek valt binnen mijn werkzaamheden.

Intervention

Keyword: Cognition, Headcooling, Kickboxing

Outcome measures

Primary outcome

The main parameter will be the difference in scores on the Impacttest, a computerized test battery that measures cognitive function, between the experimental group and the control group. This will be measured after the possible intervention of a cooling helmet has been applied. This measurement will take place 2-3 days after the fight.

Secondary outcome

Cognitive function

Cognitive function, tested by the Impacttest, will also me measured at two other measurement moments. The first measurement will take place before the fight and serves as a baseline measurement. The second measurement will take place directly after the fight.

Symptoms

Directly after the fight there will be checked for a number of symptoms using a symptom check list. During the fight, the jury will note the total amount of kicks and punches to the head each fighter received.

Fight exposure

To measure the possible influence of fight exposure on cognitive function, the total years of fighting and total number of fights will be noted.

Mood

Mood, i.e. anxiety and depression, has a possble influence on cognitive function. Therefore mood will be measured by a questionnaire. Also the influence of the fight exposure score on mood will be measured.

Return to play

It will be interesting to see how quickly an athlete recovers after a possible consussion and measure the possible difference between the experimental group and the control group. Return to play will be measured by how many days cognitive function will recover and return to the same level of baseline measurement.

Study description

Background summary

Kickboxing is a combat sport, which consists mainly of kicking and punching. It is accompanied by a high rate of injuries (390.1 per 1000 athlete-exposures (AEs)), of which the head (57.8%) and lower limb (26.1%) are most frequently affected (Lystad, 2015). That study also reported that 29.6% of all contests were ended by technical knock-out (TKO), which means that a fight is stopped by the referee or the ringside doctor. Knock-out (KO) occurred in 10.7% of the cases (Lystad, 2015). Another study reported that of the fights ended by TKO in an other combat sport, i.e. mixed martial arts (MMA), 90% was ended because of head trauma due to repetitive striking in which the athlete was not able to defend himself anymore (Hutchison et al., 2014). A study from Zazryn and

colleagues reported similar numbers regarding injury site. In that study, 51.6% of all injuries that occurred during kickboxing were caused by injuries to the head, neck and face, followed by injuries to the lower extremity (39.8%) (Zazryn et al., 2003). These data emphasize that the head is an important target in kickboxing. This could result in a concussion and subsequently to traumatic brain injury (TBI) (Tanriverdi et al., 2007). One study investigated the type of injuries leading to the end of a match amongst amateur kickboxers, who where working in the U.S. military. Their results show that 65.2% of the injuries that forced the referee to end match was due to TBI (20.3% of a total of 74 matches) (Buse and Wood, 2006).
In sum, the high rate of head injuries in kickboxing due to repetitive head trauma is clinical relevant, as it may lead to, among others, a decline in cognitive functioning. Various brain areas that play a crucial role in cognitive functioning, i.e. the thalamus, basal ganglia and hippocampus, can be damaged (Lystad, 2015). A decline in volume of brain structures, such as the thalamus and caudate nucleus has been reported as a consequence of repetitive head trauma in boxers and MMA fighters (Bernick et al., 2015). They also showed that the more an athlete has experienced head trauma, the greater the risk of developing cognitive impairment, especially a decline in processing speed (Bernick et al., 2015).
The question arises whether an intervention applied directly after the injury, may limit its neuronal consequences. For example, a possible beneficial effect on the neurological outcome after TBI has been seen after head cooling (Rupich, 2009). Head cooling took place by introducing a mild hypothermia, resulting in an intracranial temperature of 32-35°C (Rupich, 2009). The rationale underlying this application is that after TBI, inflammation, apoptosis and excitotoxicity causes brain damage and that the temperature of the brain increases (Harris et al., 2012). This may worsen neurological outcome. Selective brain cooling, i.e. by a cooling helmet, could be beneficial. It might reduce further damage to the brain by lowering the intracranial pressure (ICP) and brain temperature, increase cerebral perfusing pressure (CPP) and reduce brain oedema, inflammatory response and metabolic rate (Rupich, 2009; Harris et al., 2012).

Study objective

The goal of the present study is to investigate the effect of head cooling after kickboxing matches on cognitive functioning amongst both amateur and professional kickboxers. Based on the above mentioned studies, it is hypothesized that head cooling, applied directly after the match, may limit the negative consequences of TBI on cognitive functioning.

Study design

A prospective, single-blind, randomized, controlled, clinical trial.

Intervention

A cooling helmet from The Game Ready System will be used. It will be applied directly after a kickboxing match for 45 minutes. A study reports that within 30-40 minutes after applying a cooling helmet, like the cooling helmet of the Game Ready System, the intracranial temperature will have been reduced to 35°C (Gladen et al., 2014).
The Game Ready System (CoolSystems: Alameda, California) simultaneously delivers both adjustable continuous-flow cold therapy and intermittent compression through a portable control unit filled with ice and with water and anatomically designed wraps.
The GRS has four pressure settings; no pressure, low pressure (5-15 mmHg), medium pressure (5-50 mmHg) and high pressure (5-75 mmHg). Temperature can also be adjusted and is indicated by one, two or three snowflakes. If tolerated, we will use the coldest setting which is 3 snowflakes corresponding with a minimal temperature of 4.0°C. We will start with the lowest pressure setting and increase the setting stepwise. Cold or pressure settings are reduced if requested by the patient.

Study burden and risks

The experimental group will be treated with a cooling helmet of the GRS. There is a small risk of complications associated with this cooling helmet (0.00225%). These are minor complications, i.e. small skin lacerations.
The potential benefits, when applying the cooling helmet, could be a less decline in or preservation of cognitive function by reducing brain temperature and therefore brain oedema and other negative consequences of repetitive head striking. A quicker recovery of concussion and other brain injuries and therefore a less recovery time to *return to play* is expected.

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

Kickboxers 18 years or older, both male and female, who are in contest will be included. Both amateur and professional athletes will be recruited.

Exclusion criteria

Participants will be excluded when they have a history of psychiatric disorders (e.g. depression), alcoholism, disorders of the central nervous system (e.g. epilepsy).

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	Cooling helmet
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	14-11-2017
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL58232.094.16