Head in the Game - a study on long-term effects of playing elite football on brain structure and function

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Primary Objective: The aim of the proposed project is to assess (a) neurocognitive performance and (b) structure and function of brain networks in retired female football players compared to a matched control group of retired female elite athletes...

Ethical review	Approved WMO
Status	Pending
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON46652

Source
ToetsingOnline

Brief title
Head in the Game

Condition

- Neurological disorders NEC

Synonym
brain damage

Research involving
Human

Sponsors and support

Primary sponsor: Fédération Internationale de Fotoball Association (FIFA)
Source(s) of monetary or material Support: Fédération Internationale de Football Association (FIFA)

Intervention

Keyword: brain function, brain structure, elite atheletes, football

Outcome measures

Primary outcome

* Neurocognitive performance including the following domains: sustained, simple and complex attention, verbal and visual memory, executive function, verbal fluency, visuospatial skills, psychomotor speed, reaction time, reasoning, motor speed, working memory, processing speed and cognitive flexibility

* Functional/structural connectivity within the DMN and SN

Secondary outcome

* Previous head injuries

* Mental and neurologic health, e.g. Depression, ADHD, Anxiety, Migraine

* QOL

* Personal and sports career related variables, e.g. age, heading frequency, career length, playing position

Study description

Background summary

In recent years, sports-related concussions have been the topic of numerous studies, consensus statements, position papers and media reports 1-4. The most common acute symptoms of concussion are headache and dizziness, which usually resolve within 7-10 days 5. However, in 10-15% of concussions persistent symptoms are reported 6. Further, several pathological case-studies and case-series have suggested a potential for long-term neurological health problems in football players and other professional contact sport athletes 7 8. These may include the development of neurodegenerative diseases (such as chronic traumatic encephalopathy 9, Alzheimer*s dementia 10 or mild cognitive impairment 11) and affective disorders (such as depression 12). However, the

proposed association is far from established, mainly due to inappropriate study designs 13.

Equally controversial is the debate whether repetitive subconcussive blows to the head (i.e. purposeful heading) have an effect on neurocognitive performance in football players 14. While some authors suggest heading related deficits of attention and memory 15 16, others did not find such an association 17 18. A most recent systematic review 19 found repeat head impacts to play a merely putative role in the development of neurocognitive deficits and identified low-quality assessment of heading frequency as a major confounder. With regards to short- and medium-term consequences, Matser et al. 20-22 found a negative association between neurocognitive performance and number of previously incurred concussions in football players. Several subsequent studies were conducted in active football players yielding inconclusive results 23-34. An investigation with female university level players suggested that functions related to cognitive processing speed are most vulnerable and may still be impaired 6 month after concussion 31. However, in a prospective five-year follow-up study with a sample of young elite male footballers no significant neurological, structural brain imaging or neuropsychological changes were found 34.

To date, only four studies evaluated long-term neurocognitive changes in retired football players, and none included female players 35-38. In the most recent investigation Vann Jones et al. 38 screened 92 male former professional footballers for mild cognitive impairment (MCI) or dementia and reported that the risk of disease falls in line with the general population. Yet, Koerte et al. 36 39 found an association between repetitive subconcussive head impacts (RSHI) and neuroinflammation as well as cortical thinning in a small sample of former professional male football players. Both markers may precede long-term neurocognitive changes. Therefore, the aim of this study is to assess (a) neurocognitive performance and (b) structural/functional abnormalities in brain networks in former elite female football players compared to a matched control group of former elite female athletes from noncontact sports.

Study objective

Primary Objective: The aim of the proposed project is to assess (a) neurocognitive performance and (b) structure and function of brain networks in retired female football players compared to a matched control group of retired female elite athletes from noncontact sports. Further we are interested in an exploratory analysis of correlates between neurocognitive performance and potential abnormalities in the connectivity of brain networks. Specific primary research questions are:

(1) Is there a difference between female retired non-contact sports athletes and female retired football players in (a) neurocognitive performance and/or

(b) structure/function of brain networks?
(2) Is there a difference between female retired non-contact sports athletes and female retired football players reporting previous concussions in (a) neurocognitive performance and/or (b) structure/function of brain networks?
(3) Is there a difference between female retired non-contact sports athletes and female retired football players reporting frequent heading exposure in (a) neurocognitive performance and/or (b) structure/function of brain networks?
(4) What is the individual and cumulative effect of (1) previous concussions and (2) frequent heading exposure on (a) neurocognitive performance and (b) structure/ function of brain networks in football players?
(5) Are there correlates between neurocognitive performance and potential abnormalities in structure or function of brain networks?

Secondary Objective(s): If the data allows, we will evaluate the effect of playing elite football, previous concussions and frequent heading exposure on the prevalence of neurological and mental health issues and quality of life (QOL). Specific secondary research questions are:
(6) Is there a difference between female retired non-contact sports athletes and female retired football players in (a) the prevalence of mental/neurological health issues and/or
(b) QOL?
(7) Is there a difference between female retired non-contact sports athletes and female retired football players reporting previous concussions in (a) the prevalence of mental/ neurological health issues and/or (b) QOL?
(8) Is there a difference between female retired non-contact sports athletes and female retired football players reporting frequent heading exposure in (a) the prevalence of mental/neurological health issues and/or (b) QOL?

Study design

We will conduct a case-control study design to evaluate the research questions. One of the main short-comings in previous case-control studies on the topic is the inclusion of inadequate control groups. To account for potential effects of elite level exposure to exercise on brain structure and/or function, we will compare retired female football players to a group of retired elite athletes from non-contact sports. Further we will apply a mixed methods approach, combining neurocognitive testing and neuroimaging modalities. This will enable us to evaluate if subclinical abnormalities in brain networks are functionally relevant. Additionally, a mixed methods approach will improve both the validity and reliability of potential findings.

Study burden and risks

No known risks are associated with participation in the proposed investigation. However, psychological discomfort may be associated with the MRI scan due to space limitations in the scanner. Further, the NSP test battery may be

cognitively exhausting. There are several contra-indications for participation in an MRI examination (specified above) and participants who meet these criteria will be excluded from the study.

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

two groups of atheltes will be included in this study:;50 football players
- female, aged 30-50 years
- played at least 5 mathces in a first league club team or the national team
- retired from elite football over 2 years ago (no first league or international matches);30 elite athletes from non-contact sports
- age, gender and handedness matched
- former elite athlete (over 5 competitions at national or international level) in a non-contact

sport or anthoer sport with a low risk of head injury
- Retired from elite sports over 2 years ago (no competition on national or international level)

Exclusion criteria

Football players
* Previous non-football-related severe head injury diagnosed or treated by a physician
* Symptomatic mental disorder (e.g. depression or schizophrenia).
* Symptomatic chronic disease (i.e. cancer, diabetes, cardiovascular disease) except osteoarthrosis/-arthritis and medically controlled hypertension.
* MRI contra-indications (specified below).;Elite athletes
* Previous or current regular participation (* once a week for *1 year) in football, or other sports with high risk of head injury.
* Previous severe head injury diagnosed or treated by a physician.
* Symptomatic mental disorder (e.g. depression, schizophrenia).
* Symptomatic chronic disease (i.e. cancer, diabetes, cardiovascular disease, dementia), except osteoarthrosis/-arthritis and medically controlled hypertension.
* MRI contra-indications (specified below).;MRI Contraindication
* Pregnancy (even though there is no evidence of adverse effects).
* Metal and/or recently implanted joint replacements.
* Implanted electric and electronic devices are a strict contraindication to magnetic resonance imaging, and in particular: heart pacemakers (especially older types), insulin pumps, implanted hearing aids, neuro-stimulators, intracranial metal clips, metallic bodies in the eye.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-10-2017
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	21-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL62276.029.17