Appraising CFX Treatment for Concussion

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON25096

Source
Nationaal Trial Register

Brief title
ACTC

Condition

- Structural brain disorders

Health condition

Concussion; Mild traumatic brain injury

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC, Emma Children's Hospital, location AMC
Source(s) of monetary or material Support: Hersenstichting

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

- Quantitative change in functioning on questionnaires and multidisciplinary assessment

Secondary outcome

- Qualitative change in functioning of patients (questionnaires and in-depth interview) - Identification of treatment aspects important for patient experience (in-depth interview) - Aetiology of potential change in recovery effects (re-analysis of existing clinical brain scans that will be requested at CFX)

Study description

Background summary

Worldwide, an estimated 54-60 million individuals sustain traumatic brain injury (TBI) annually. Mild TBI (or concussion) represents 90% of TBIs. Concussion can cause a wide range of symptoms that typically recover within weeks. However, approximately 10-30% of cases develop persistent symptoms beyond three months post-injury (~7,000 – 21,000 Dutch individuals), causing severe reduction in societal participation. Currently, there are no evidence-based treatments under the Dutch Health Care Insurance that aim to cure persistent symptoms. Recently, there has been a surge in attention from Dutch patients for a specific concussion clinic, Cognitive FX (CFX, Utah, USA). Thanks to promising patient experiences that circulate on social media, 200-300 Dutch patients travel to Utah yearly for ‘Enhanced Performance in Cognition’ (EPIC) treatment. However, effectiveness remains unclear from an evidence-based point of view. This pilot study will investigate the value of EPIC treatment in two work packages. The exploratory work package will systematically explore the content of the treatment, justification by CFX experts and patient experience. In addition, an inventory of potential working mechanisms will be made by a panel of independent experts. The quantitative work package will objectively determine short-term and longer-term functional change in relevant domains and statistically explore factors in recovery. Thereby, this study will provide better understanding for clinicians, facilitate patients in better informed decisions and indicate the need for follow-up research to researchers, policy makers and health care insurance providers.

Study objective

This study will investigate the potential value of CFX treatment, by prospective monitoring of functioning in patients that undergo this treatment. Likewise, aspects of the treatment that are important for patient experience will be systematically explored. Furthermore, this study aims to provide better understanding of the aetiology of potential recovery effects (with re-use of existing clinical brain scans). The results of this study will be reported in open-access summaries and published in peer-reviewed journals. Thereby, this study will provide better understanding for clinicians, facilitate patients in better informed decisions and indicate the need for follow-up research to researchers, policy makers and health care insurance providers.

Study design

This study has a quantitative approach with a prospective longitudinal observational design. In addition, a qualitative approach will be applied for a subsample of patients (n = 15) using in-depth interviews.

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)

Inclusion criteria

- Aged between 18 and 60 years - Sustained a concussion, defined as mild TBI (Glasgow Coma Scale score 15-13, loss of consciousness duration < 30 minutes, post-traumatic

amnesia duration < 24 hours) without known intracranial pathology on neuroimaging (if available). - Persistent symptoms of concussion - At least 12 months post-injury - Scheduled for CFX treatment in the (near) future

Exclusion criteria

- History of psychiatric or neurological condition (other than concussion)

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2022
Enrollment:	64
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	17-05-2021

Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 52204
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9786
CCMO	NL76945.018.21
OMON	NL-OMON52204

Study results