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-OMON52204

Source
ToetsingOnline

Brief title
The ACTC Study

Condition

- Structural brain disorders

Synonym
Concussion; Mild traumatic brain injury

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: Cognitive FX treatment, concussion, mild traumatic brain injury

Outcome measures

Primary outcome

- Quantitative change in functioning on questionnaires and multidisciplinary assessment

The primary study parameters will be obtained based on dimensionality reduction methods (e.g. principal component analysis) to select a limited number of dependent variables from a broad range of measurements.

The measurements in questionnaires relate to:

- Global outcome (Glasgow Outcome Scale-Extended)
- Symptoms of concussion (SCAT-5 symptom scale)
- Participation (USER-Participation)
- Anxiety and depression (Hospital Anxiety and Depression Scale)
- Sleep Quality (Pittsburg Sleep Quality Index)
- Quality of Life, partner relation, system support (custom questionnaire)

Multidisciplinary assessment consists of:

- Neurocognitive functioning (Emma Toolbox for Neurocognitive Functioning)
- Eye-tracking (Sensomotoric Instruments RED 250)
- Postural Control and Balance (Motek Dynstable)

- Vestibular and Ocular functioning (Vestibular/OculoMotor Screening)

Secondary outcome

Secundary parameters relate to:

- Qualitative change in functioning of patients (questionnaires and in-depth interview)

- Identification of treatment aspects important for patient experience (in-depth interview)

- Etiology of potential change in recovery effects (re-analysis of existing clinical brain scans that will be requested at CFX)

The in-depth interview will cover the following apsects

- Perceived importance of personal characteristics (e.g., motivation, willpower, hope)

- Role of contextual characteristics (e.g., commitment of health professionals, being away from home, social contacts with peers during treatment)

- Planned follow-up trajectory after treatment (e.g. interventions or guidance)

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 CFX treatment. This situation is problematic from a societal point of view, since (1) very little is known about the content and potential working mechanisms of the treatment, (2) the treatment is costly (11-15 k¤) and therefore only available to a small part of the population; and (3) effectiveness remains unclear from an evidence-based point of view.

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.

Study burden and risks

Burden
Patients (N = 66) will:
(1) Fill out an online intake questionnaire (once, after inclusion) with an expected total duration of 60 minutes);
(2) Fill out online monitoring questionnaires (four time points, at T0 = before treatment, T1 = directly after treatment, T2 = in the month after treatment and T3 = at follow-up) with an expected total duration of 185 minutes all together;
(3) Visit the research location to undergo multidisciplinary assessment (at T0, T2 and T3). The multidisciplinary assessment will have a maximum duration of 3 hours per visit, with a total duration of 9 hours for all assessments.
(4) In-depth interview (60 minutes) will be performed (once, at T1) with a subsample of patients (n = 15).

Thereby, total duration of study participation is (60 minutes + 185 minutes + 9 hours ~) 13 hours (excluding travel time) spread over a time frame of 7 months. For the subgroup of 15 patients that also participate in the interview,

total duration of study participation is (13 + 1 =) 14 hours.

Risks
The risks of participating in this observational study are considered negligible.

Benefit
Patients do not have direct benefit of participation.

Group-relatedness
Patients in the study sample are adults with persisting symptoms of concussion. These patients may have limitations in their tolerance for physical and/or cognitive strain. This is inherent to the target population. Patients have the possibility to complete the online questionnaires at own pace (e.g. in parts spread over several days) and the assessment scheme during visits will be customized in continuous consultation with the participant (e.g. with regard to planning of breaks).

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Aged between 18 and 65 years, in order to confine the population to the adult range
- 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, as defined by self-report
- At least 12 months post-injury, in order to minimize the potential contribution of spontaneous recovery and other interventions in the observation period
- Scheduled for CFX treatment in the (near) future, in order to allow monitoring of functioning before, directly after treatment and at follow-up

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- History of psychiatric or neurological condition (other than concussion)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2022
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	17-05-2021
Application type:	First submission
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

ID: 25096
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL76945.018.21