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Early intervention aimed at preventing persistent complaints after mild traumatic brain injury: a comparison between cognitive behavioral therapy and telephone counselling

Submission date
14/07/2016

Recruitment status
No longer recruiting

Registration date
16/07/2016

Overall study status
Completed

Last Edited
30/08/2023

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Every year, 100-300 of every 100,000 people suffer from a concussion due to a fall or blow to the head. After this, the person often experiences a short period of unconsciousness or confusion, known as mild traumatic brain injury (mTBI). In the early stage of recovery, patients can experience a range of related problems, such as headache, fatigue (extreme tiredness), dizziness, difficulty concentrating and irritability. Although these complaints go away in the majority of patients within days to weeks, in some patients (around 20-25% of the total) these problems are long-term. It is thought that patients that suffer a lot of these complaints very early after injury have a higher chance of developing long-lasting complaints, for months or even years. This can prevent people from being able to return to work and other daily activities. The treatment of these problems is very difficult when it is done too long after the injury. It is therefore important to develop a treatment program that can be used very soon after the injury to prevent short-term problems from becoming long-term. Recent research has shown that a form of talking therapy called cognitive behavioral therapy (CBT) might be an effective strategy. CBT is used as a treatment in many mental health conditions, as it helps patients to manage problems by changing the way they think and behave. The aim of this study is to find out whether a program of CBT delivered soon after a head injury is effective at preventing long-term complaints and assisting return to work.

Who can participate?
Adults with mTBI admitted to the emergency department, who are in paid work or studying at the time of the injury.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive five sessions of CBT over a course of four weeks in small groups of 2-4 people. The treatment starts 4-6 weeks after the head injury has happened and is run by an experienced therapist. In the sessions, participants are given information of what symptoms to expect and how best to deal

with them and manage stress so that they can return to work and normal activities sooner. Those in the second group receive an information sheet when they leave hospital, followed by five follow up telephone calls over the same four weeks which offer information and reassurance without counseling. After 12 months, participants in both groups are followed up in order to assess whether they are experiencing any long-lasting problems and if they have returned to work.

What are the possible benefits and risks of participating?
Participants benefit from receiving more in-depth and accurate information about mTBI and the recovery process, as well a receiving very short line of communication with diverse health care practitioners. There are no notable risks involved with participating.

Where is the study run from?
1. University Medical Center Groningen (Netherlands)
2. St. Elisabeth Ziekenhuis Tilburg (Netherlands)
3. Medisch Spectrum Twente (Netherlands)

When is the study starting and how long is it expected to run for?
January 2013 to January 2016

Who is funding the study?
Dutch Brain Foundation (Netherlands)

Who is the main contact?
1. Ms Myrthe Scheenen (public)
m.e.scheenen@rug.nl
2. Professsor Jacoba Spikman (scientific)

Contact information

Type(s)
Scientific

Contact name
Ms Myrthe Scheenen

ORCID ID
http://orcid.org/0000-0002-4596-4618

Contact details
University Medical Center Groningen
Afdeling Neuropsychology (AB60)
Hanzeplein 1
Groningen
Netherlands
9700RB
+31 503617503
m.e.scheenen@rug.nl

Type(s)
Scientific

Contact name
Prof Jacoba Spikman

Contact details
University Medical Center Groningen
Afdeling Neuropsychology (AB60)
Hanzeplein 1
Groningen
Netherlands
9700RB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Ps2012-06

Study information

Scientific Title
The effect of early CBT-based intervention compared to telephone counselling on return to work and complaints after mild traumatic brain injury: a randomized trial

Acronym
UPFRONT study

Study objectives
The aim of this study is to investigate whether an intervention based on cognitive behavioral therapy (CBT) early after mild traumatic brain injury (mTBI) for patients at-risk of suffering from persistent cognitive complaints result in better vocational reintegration, expressed in a significantly earlier resumption of work and a significantly better work status at one year post-injury (compared to a control telephone counselling).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethical Committee of the University Medical Center Groningen, 20/11/2012, ref: METc 2012/285

Study design
Multi-center single-blind randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Persistent post-concussive complaints following mild traumatic brain injury.

Interventions
Patients who have given consent to participate are randomly assigned the early intervention or control treatment. by drawing a lot from an envelope containing 20 lots are put (10 CBT, 10 control) by an independent person.

Early intervention group: Participants receive five sessions of Cognitive Behavioural Therapy in small groups of 2-4 people, led by an experienced neuropsychologist. The treatment period will start at 4-6 weeks post injury and end at 8-10 weeks post injury. The five sessions will be done within a time period of 4 weeks, with preferably session 1 and 2 within one week. The treatment aims to:
1. Provide psycho-education on mTBI
2. Identify and replace dysfunctional beliefs about mTBI with functional beliefs
3. Enhance effective coping and sense of self-control
Patients will receive information on expected symptoms and strategies to cope with these symptoms and manage stress in order to support a gradual increase of activities towards a previous level of participation.

Control group: Participants receive five sessions of telephonic conversations comprising information and reassurance without counselling. The first session contains of psycho-education based on the written information sheet that is given at discharge, in the form of verbal information on common cognitive complaints and its usual course of recovery. At regular intervals after randomization, between 4 and 8 weeks after discharge, the patient will be contacted by phone weekly by a professional (either a psychologist or physician) to monitor the course of eventual complaints or to answer questions regarding the information sheet. The content of provided information will be restricted to explanation/reassurance of the nature of complaints without giving instructions to the patient concerning modification of behavior or exercise in the home situation.

Participants are followed up 2 weeks, 3, 6, and 12 months after injury.

Intervention Type
Behavioural

Primary outcome measure
Level of resumption of work is measured using the RTW scale at 6 and 12 months.

Secondary outcome measures
1. Working status, defined as total days off work at 12 months, is measured by a questionnaire at 12 months
2. Functional outcome is measured using the Extended Glasgow Outcome Scale (GOS-E), determined at 6 and 12 months
3. Trauma related complaints are measured using the Head Injury Symptom Checklist (HISC), Dutch version of the Rivermead Postconcussion Questionnaire at 2 weeks, 3, 6, and 12 months
4. Physical and mental complaints are measured using the Symptoms Checklist (SCL-90 revised) at 6 and 12 months
5. Mood is measured using the Hospital Anxiety and Depression scale (HADS) at 2 weeks, 3, 6, and 12 months
6. Impact of Event is measured using the DSM criteria PTSS-List and Centrality of Event List-short at 2 weeks, 6 and 12 months
7. Coping is measured using the Utrechtse Copinglist (UCL) at 2 weeks, 3, 6 and 12 months
8. Fatigue is measured using the Dutch Multidimensional Fatigue Scale at 12 months
9. Self-efficacy is measured using the Dutch General Self-Efficacy Scale (DGSES) at 6 and 12 months
10. Executive dysfunction is measured using the Dysexecutive Questionnaire (DEX) at 6 and 12 months

Overall study start date
01/01/2013

Completion date
01/01/2016

Eligibility

Key inclusion criteria
1. Mild traumatic brain injury (mTBI) patients admitted to the emergency departments (ED's) of the participating centers
2. Age between 18 and 65 years
3. Normal admission CT scan
4. In paid work or studying at the time of injury
5. Patients at-risk for persistent post-concussive complaints are selected for enrollment in the intervention, starting within 4-6 weeks post-trauma. At-risk status was based on the score on the Head Injury Symptom Checklist (HISC), which comprises of 16 complaints commonly described after TBI with premorbid levels, using values from 0 to 2 (0= never, 1= sometimes, 2= often). Eligible patients must report three or more complaints of which at least one should be in the cognitive or in the emotional domain.

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
88

Total final enrolment
84

Key exclusion criteria
1. Chronic alcohol and/or drug abuse
2. Major psychiatric or neurological disorders
3. Without comprehension of Dutch language
4. Without a permanent home address

Date of first enrolment
01/02/2013

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen (UMCG)
Hanzeplein 1
Groningen
Netherlands
9700RB

Study participating centre
St. Elisabeth Ziekenhuis Tilburg (EZT)
Hilvarenbeekseweg 60
Tilburg
Netherlands
5022GC

Study participating centre
Medisch Spectrum Twente (MST)
Koningsplein 1

Enschede
Netherlands
7512KZ

Sponsor information

Organisation
Hersenstichting Nederland (Dutch Brain Foundation)

Sponsor details
Pr. Catharina-Amaliastraat 16
Den Haag
Netherlands
2496XD
+31 703604816
infolijn@hersenstichting.nl

Sponsor type
Charity

Website
https://www.hersenstichting.nl/

ROR
https://ror.org/04y8met08

Funder(s)

Funder type
Charity

Funder Name
Hersenstichting Nederland (Dutch Brain Foundation)

Results and Publications

Publication and dissemination plan
Planned publication of study results in a high-impact peer reviewed journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017	09/08/2019	Yes	No
Other publications	Two case examples are presented to demonstrate the application of the intervention	24/01/2017	30/08/2023	Yes	No