e-COGRAT: The development, efficacy and implementation of *blended care* treatment in acquired brain injury-induced fatigue. First step: feasibility of e-COGRAT, a pilot study.

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1) Is e-COGRAT usable within the ABI population?2) What are the patients* experiences with e-COGRAT?3) What are the therapists* experiences with e-COGRAT?4) What changes in the e-COGRAT are necessary?5) Does this pilot with e-COGRAT show a decline...

Ethical review	Approved WMO
Status	Pending
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON43913

Source
ToetsingOnline

Brief title
e-COGRAT, pilot

Condition

- Structural brain disorders
- Lifestyle issues

Synonym
Fatigue after acquired brain injury, post ABI fatigue

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Revalidatiefonds;Johanna KinderFonds en Stichting Rotterdamse Kinderrevalidatie Fonds Adriaanstichting.

Intervention

Keyword: Acquired Brain Injury (ABI), Blended Care, e-Health, Fatigue

Outcome measures

Primary outcome

Patients:

- Questionnaire concerning user experience of the e-COGRAT

- Fatigue: Checklist Individuele Spankracht (CIS-20R, J. H. Vercoulen et al.,

1994; J. H. H. M. Vercoulen et al., 1999) & Dutch Multifactor Fatigue Scale

(DMFS, Visser-Keizer, A.C. et al., 2015).

- During the treatment period patients will be asked weekly about physical and

mental change (scale 1-10) and physical and mental fatigue (scale 1-10).

- Quality of life: RAND36 (van der Zee & Sanderman, 2012).

Therapists:

- Demographics (age, profession, number of working years)

- Semi-structured interview about using the internet and applications and

experiences with eHealth.

- Questionnaire concerning user experience of the e-COGRAT

- Semi-structured interview concerning user experiences

Secondary outcome

Patients:

- Anxiety and depression: Hospital Anxiety and Depression Scale (HADS) (Zigmond

& Snaith, 1983).

- Psychosocial distress: Brief Symptom Inventory (BSI) (Derogatisa &

Melisaratosa, 1983).

- Executive problems: Dysexecutive Questionnaire (DEX) (Alderman, Evans,

Burgess, & Wilson, 1993).

- Happiness-question (7-point Likert scale).

- Information about work sick leave and use of health care: questionnaire

User-P.

Study description

Background summary

Fatigue is a common and often very restricting complaint following acquired brain injury (ABI). To better cope with this fatigue, an effective protocol has been developed: the COGRAT (Cognitive and Graded Activity training Zedlitz AMEE, Fasotti L & Geurts ACH, Clinical Rehabilitation, 2011).

The current study is a pilot / feasibility study, aiming to develop a blended care / e-health variant, the e-COGRAT.
Using focus groups (both patients and therapists) the COGRAT will be converted into a (partially) digital module, the e-COGRAT.

Subsequently this module will be tested - with small groups of patients - for feasibility (pilot).
In the future (beyond the scope of the current study) effectiveness and cost-effectiveness will be further investigated.

Study objective

1) Is e-COGRAT usable within the ABI population?
2) What are the patients* experiences with e-COGRAT?
3) What are the therapists* experiences with e-COGRAT?
4) What changes in the e-COGRAT are necessary?
5) Does this pilot with e-COGRAT show a decline in (subjective) fatigue compared to former research concerning COGRAT in rehabilitation setting?
6) Is the e-COGRAT more efficient than the COGRAT in terms of time investment

of therapists and travel time of patients?
7) Is the for adolscents developed treatment usable for these adolescents?

Study design

A. Using focus groups, COGRAT will be converted to e-COGRAT
B. This first version of e-COGRAT will be evaluated on feasibility with a small group of patients and therapists.

Intervention

Focus Groups:
Per group, 4 meetings will be planned on well accessible locations

Treatment Groups:
Originally, COGRAT consisted of 12 cognitive therapy group sessions and 24 Graded Activity Training sessions in a 12-week period. In e-COGRAT this will be reduced (exact numbers are partially dependent of the results obtained from the focus groups) to 4 life-sessions of cognitive therapy and 12 sessions of Graded Activity Training. All other sessions will be presented digitally.

Study burden and risks

The burden for the patients is equal to or less than when participating in regular treatment for fatigue.
The extra burden consists of participating in the focus groups (if applicable) and filling out questionnaires and evaluation forms.
The risk is estimated to be nil.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- age 15-24 (group 1)
- age > 24 (group 2)
- acquired brain injury (ABI) at least 3 months prior to inclusion
- suffering from (severe) chronic fatigue
- being able to walk at least 30 feet independently
- have access to a computer with internet connection and know the basics to use it.

Exclusion criteria

- severe comorbid heart and/or long-disease
- comorbid psychiatric disorder (depression or personality disorder)
- IQ below 80
- severe cognitive disorders (neglect, aphasia, memory-disorders or disinhibition).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	32
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-11-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL54404.058.16