Patient Partner Education Program 4 All after Resuscitation

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The main goal of the study is to measure the effectiveness of the Patient and Partner Education program 4 all (PPEP4ALL) in patients with hypoxic brain injury and/or their spouse/caregiver.

Ethical review	Approved WMO
Status	Suspended
Health condition type	Cognitive and attention disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON41058

Source
ToetsingOnline

Brief title
PPEP4All-R

Condition

- Cognitive and attention disorders and disturbances

Synonym
hypoxic brain injury, postanoxic encephalopathy

Research involving
Human

Sponsors and support

Primary sponsor: Rijnlands RevalidatieCentrum
Source(s) of monetary or material Support: eigen gelden Stichting vrienden Rijnlands Revalidatie Centrum

Intervention

Keyword: Education Program, Hypoxic Brain Injury, Rehabilitation, Resuscitation

Outcome measures

Primary outcome

Primary study parameter is the quality of life (SF-36) of the patients and the experienced strain of the caregiver (Caregiver Strain Index).

Secondary outcome

Clinical outcomes are:

• Experienced cognitive complaints(Cognitive Failure Questionnaire),

• Experienced cognitive changes by the spouse/care giver (Informant Questionnaire on Cognitive Decline in the Elderly),

• Effects towards autonomy and partipation (Impact on Participation and Autonomy)

• Severity of fear and derpession (Hospital Anxiety and Depression Scale)

• Amount of care of patients and caregiver/spuse (focus group)

• Cognitive functioning (Montreal Cognitive Assessment)

outcomes process:

• Satisfaction of patient, partner and trainer towards the followed/given intervention (Visual Analoge Scale)

• Any necessary modifications made in the existing PPEP4All workbooks and meetings.

Study description

Background summary

The main goal of a rehabilitation centre is to help patients and their spouse to return back as good as possible to society after an event.
To optimize the care for patients after a cardiac arrest patients who start rehabilitation in the RRC are being screened for possible cognitive deficits or complaints due to hypoxic brain injury.
Patients with cognitive complaints are offered a cognitive rehabiliation program after the regular cardiac rehab program. At the moment the RRC wants to provide a selfmanagement program for patients and spouse who experience difficulties due to persisting cognitive damage. By introducing a patient and partner education program the RRC can provide a structured therapy for patients with cognitive problems. The program can also provide in adjusted counseling for the spouse which at the moment is experienced as insufficient.

Study objective

The main goal of the study is to measure the effectiveness of the Patient and Partner Education program 4 all (PPEP4ALL) in patients with hypoxic brain injury and/or their spouse/caregiver.

Study design

This randomised controled prospective study includes patients with stbale cognitive complaints (>= * year after OHCA) and/or their partner. Patients are recruited in the region Leiden by the Rijnlands Rehabilitation Centre, local hospitals (LUMC, Diaconessen en Rijnland Ziekenhuis) and local news papers. If necessary patients will also be recuited at the Sophia Rehabilitation Den Haag or the Spaarne Hospital at Nieuw Vennep who have a collaborating link with the RRC.
Patients and/or partners will take part in the PPEP4All during 8 weeks which will be held at the RRC, Leiden.

To achieve the aim of this project the following five fases will be carried out:

Fase 1: a deepening literature study and write roadmap/script.

Fase 2: recruit subjects

Fase 3: introduce intervention to subjects.

Fase 4: Analyses and report

Fase 5: Write standard module and implement

Planning schedual
The controled part of the study will take two years. The intervention will be given in a group during eight weeks. A group exists of 4 to 7 patients and their spouse/care giver (in total 8 to 10 groups). The period of the controled part of the study will cover 95 weeks and 125 weeks including the final measurements of the not controlled part of the study.

Intended date to start: 1st of April 2014.

Study burden and risks

to fill in the questionnaires takes extra time for the patient and partner/care giver which can be experienced as cumbersome. Also the intervention can be experienced as fysically or metally cumbersome.

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

minimum 1/2 year after cardiac arrest; survival after cardiac arrest; cognitive complaints objectified with MoCA, CFQ and IQCODE; age >=18 years; <5 years after cardiac arrest; patients and partners can join individually or together.

Exclusion criteria

patients: bad physical state; braindamage not due cardiac arrest; insufficient use of dutch language; restrictive behavioural problems;affecting psychiatric comorbidity;partners: restrictive behavioural problems; insufficient use of Dutch langauge; bad physical state

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-04-2014
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO Date:	02-07-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-10-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL47704.058.14