ISRCTN97280643 https://doi.org/10.1186/ISRCTN97280643

Cognitive behavioural therapy (CBT) for the treatment of post-traumatic stress disorder (PTSD) in intensive care unit (ICU) survivors

Submission date
21/05/2010

Recruitment status
No longer recruiting

Registration date
21/05/2010

Overall study status
Completed

Last Edited
11/04/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7987

Study information

Scientific Title
A randomised controlled pilot study of the effectiveness of recreating a coherent narrative of events using novel developments in cognitive and behaviour therapy for the treatment of post-traumatic stress disorder in survivors of intensive care treatment

Study objectives
A single-centre randomised single-blind controlled pilot study evaluating the efficacy of a brief psychological intervention for the treatment of intensive care unit (ICU) survivors with post-traumatic stress disorder (PTSD), based on novel developments in cognitive behavioural therapy (CBT) and narrative exposure therapy (NET). The study will create and implement a psychotherapeutic intervention to address the problem of fragmented and delusional memories, by creating a coherent narrative of events, which would allow the ICU survivor to process their ICU experience. The different components of the intervention proposed have been validated as an effective intervention in studies on PTSD (CBT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Essex 2 Research Ethics Committee, 05/07/2007, ref: 07/Q0302/20

Study design
Single-centre observational treatment case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact jacobus.preller@addenbrookes.nhs.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Critical Care

Interventions

We plan to screen all patients discharged from ICU for symptoms of PTSD using questionnaires and to follow them up four weeks after discharge. After screening, patients with symptoms of PTSD would be randomly allocated to receive a brief specialised CBT-based intervention or normal aftercare.

The non-intervention arm ceases at the 4-week follow-up stage. The intervention arm using cognitive behavioural therapy has the treatment occurring at between 3 and 6 months and final follow-up to measure outcome of treatment occurring at 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
PTSD measurement questionnaires, measured at 3, 6, and 12 months after discharge

Secondary outcome measures
Assessed and analysed at the conclusion of the study:
1. Determine the incidence of PTSD
2. Develop a prediction score that can be used to identify the patients at risk of PTSD

Overall study start date
01/01/2010

Completion date
01/01/2012

Eligibility

Key inclusion criteria
1. Patients must be admitted to ICU for more than 24 hours
2. Patients must be older than 16 years
3. Patient must have physical and mental capacity to comprehend questions
4. The patient must be able to understand and communicate adequately in English

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 200

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment
01/01/2010

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Addenbrooke's Hospital (UK)

Sponsor details
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

ROR
https://ror.org/055vbxf86

Funder(s)

Funder type
Research council

Funder Name
Addenbrooke's Charitable Trust, Cambridge University Hospitals

Alternative Name(s)
Addenbrooke's Charitable Trust, Cambridge University Hospitals NHS Foundation Trust, ACT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration