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An exploratory randomised controlled trial of a DEPression Recognition and Treatment package for families living with STROKE

Submission date 04/03/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/03/2011	**Overall study status** Completed	
Last Edited 29/05/2020	**Condition category** Circulatory System	

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
8188

Study information

Scientific Title
An exploratory randomised controlled trial of a DEPression Recognition and Treatment package for families living with STROKE

Acronym
DEPRET-STROKE

Study objectives
Evaluate whether families after stroke who are treated with the Depression Recognition and Treatment package in Stroke (DepReT-Stroke) in addition to treatment as usual (TAU) show improved mental well being compared to those families who receive only TAU.

On 28/04/2014 the anticipated end date was changed from 01/08/2013 to 02/01/2015.
On 12/02/2015 the overall trial date was changed from 03/01/2011 to 03/01/2014. Recruitment start and end dates were also added.

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H0310/23; First MREC approval date 20/04/2010

Study design
Randomised interventional treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Topic: Mental Health Research Network; Subtopic: Depression; Disease: Depression

Interventions
DepReT-Stroke, Six session with a trained study nurse delivered at fortnightly intrvals plus two booster sessions.; Follow Up Length: 6 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Mental Component Summary of the SF-36v2; Timepoint(s): Six months

Secondary outcome measures
Beliefs about Medicines Questionniare (BMQ); Timepoint(s): 6 months; Hospital Anxiety and Depression Scale (HADS); Timepoint(s): 6 months; Knowledge of Depression Multiple Choice Question Test; Timepoint(s): 6 months

Overall study start date
03/01/2012

Completion date
02/01/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/04/2014:
1. Patient diagnosed with ischaemic or haemorrhagic stroke
2. Stroke type confirmed
3. Patient identified by a participating NHS Trust
4. Patient diagnosed with a stroke between 1 month and 5 years ago.
5. Patient has been living at home for not less than 2 weeks
6. Patient has a self-defined primary carer
7. Patient and/or carer scores as depressed on any clinical tool used to identify depression in clinical practice
8. Patient and carer over 18 years of age (no upper age limit)

Previous inclusion criteria:
1. Patient diagnosed with ischaemic or haemorrhagic stroke
2. Stroke type confirmed by computerised tomography scan
3. Patient listed in the NNUH Stroke Register
4. Patient diagnosed with a stroke for at least three months.
5. Patient has been living at home for not less than two weeks
6. Patient has a self defined primary carer.
7. Patient and/or carer scores =8 on the Hospital Anxiety and Depression Scale (HADS)
8. Patient and carer aged between 18-110 years of age
We have stipulated the widest possible age range for eligibility as the DepReTStroke package will be designed to be as inclusive as possible and accommodate the needs of persons with stroke and their carers irrespective of age.

Target Gender: Male & Female; Upper Age Limit 110 years ; Lower Age Limit 18 years

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 126; UK Sample Size: 126

Key exclusion criteria
1. Serious or unstable medical conditions (e.g. advanced/incurable cancer; severe comorbidity or severe unpredictable pain)
2. Psychosis or other severe mental illness
3. Suicidal thoughts or ideation
4. Dementia
5. Institutionalised (e.g. care home resident)
6. Participating in any other research concerning stroke or depression

Added 28/04/2014:
7. Current treatment for depression (anti-depressant medication or talking therapies)

Date of first enrolment
10/12/2012

Date of final enrolment
02/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Nursing Science
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
Norfolk and Norwich University Hospital NHS Trust (UK)

Sponsor details
Colney Lane
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United Kingdom
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rdoffice@nnuh.nhs.uk

Sponsor type
University/education

Website
http://www.nnuh.nhs.uk/

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/04/2011		Yes	No