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Dialectical behaviour therapy in patients with borderline personality disorder who self-harm: a pragmatic exploratory trial

Submission date
30/07/2008

Recruitment status
No longer recruiting

Registration date
25/09/2008

Overall study status
Completed

Last Edited
23/07/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PB-PG-0906-10540

Study information

Scientific Title

Acronym
DIALECT

Study objectives
Self-harming patients receiving a one-year course of dialectical behaviour therapy (DBT) will self-harm less over the 12 months than patients receiving one year of treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Camden and Islington Community Local Research Ethics Committee, 18/02/2008, ref: 07/H0722/98

Study design
Pilot randomised controlled pragmatic exploratory trial

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
Borderline personality disorder, self-harm

Interventions
DBT and care co-ordination versus waiting list control group with standard NHS care, over 12 months. DBT consists of 3 hours of therapy a week: this comprises 1 hour of individual therapy and 2 hours of group skills classes.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Days with self-harm during the 12-month period.

Secondary outcome measures
1. Pre-post changes in self-harming during the 12-month period
2. Number of accident and emergency (A&E) attendances during the 12-month period
3. Inpatient admissions during the 12-month period
4. Use of other services in primary and secondary care during the 12-month period
5. Service costs during the 12-month period
6. Use of medication during the 12-month period
7. Pre-post changes in self-rated and observer-rated symptom level and quality of life at the end of the 12 month period
8. Quality of the therapeutic relationship at the end of the 12-month period
9. Treatment satisfaction at the end of the 12-month period

Overall study start date
01/02/2008

Completion date
01/07/2011

Eligibility

Key inclusion criteria
1. Frequent self-harm (more than 5 days with self-harm over 12 months)
2. Aged 16 years and older, either sex
3. Sufficient command of English
4. At least one personality disorder

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
60

Key exclusion criteria

Learning disabilities

Date of first enrolment
01/02/2008

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Unit for Community and Social Psychiatry
London
United Kingdom
E13 8SP

Sponsor information

Organisation
East London NHS Foundation Trust (UK)

Sponsor details
Trust Headquarters
EastONE
22 Commercial Street
London
England
United Kingdom
E1 6LP
+44 (0)20 7655 4000
webadmin@eastlondon.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/01q0vs094

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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?
Results article	results	01/01/2012		Yes	No