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A randomised controlled trial of cognitive therapy for post-traumatic stress disorder related to civil conflict in Northern Ireland

Submission date	Recruitment status	[ ] Prospectively registered
30/03/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/12/2012	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
037158 and 069777

Study information

Scientific Title

Study objectives
To determine whether cognitive therapy is an effective treatment for Post-Traumatic Stress Disorder (PTSD) resulting from civil conflict.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-traumatic Stress Disorder

Interventions
Patients suffering from PTSD who are referred to the Northern Ireland Centre for Trauma and Transformation (NICTT) in Omagh are invited to participate in the trial. Patients who agree to be included are initially randomly allocated to:
1. Immediate cognitive therapy
2. A 12 week wait-list control condition, followed by cognitive therapy

The treatment programme is the same as that used in NICTT's recently published audit of cognitive therapy in the treatment of PTSD following the 15th August 1998 car bomb in Omagh (Gillespie, Duffy, Hackman & Clark, 2002, Behaviour Research and Therapy, 40, 345-357). Patients allocated to immediate cognitive therapy receive up to 12 weekly sessions in 12 weeks, followed by a review.

Further treatment sessions are provided, if appropriate. Patients initially allocated to the wait list condition receive no treatment in the first 12 weeks but are then offered the same course of treatment. The main assessments are at pre-treatment/wait, 12 weeks, post-treatment and three and 12 month post-treatment follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome measures for the trial are:
1. The Post-traumatic Diagnosis Scale (PDS: Foa et al, 1997, Psychological Assessment, 9, 445-

451)
2. The Beck Depression Inventory (BDI: Beck et al, 1979, Cognitive Therapy for Depression, Guilford Press, New York)
3. The Sheehan Disability Scale (SDS: Sheehan, 1983)

Key secondary outcome(s)
No secondary outcome measures

Completion date
01/03/2006

Eligibility

Key inclusion criteria
1. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (American Psychiatric Association, 1994) criteria for PTSD
2. Have experienced trauma in the context of civil conflict in Northern Ireland or elsewhere
3. PTSD considered to be the patient's main problem
4. Age 18 to 70 years
5. Willing to accept random allocation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. Unable to travel to Northern Ireland Centre for Trauma and Transformation (NICTT) for regular treatment sessions
2. PTSD mainly related to childhood sexual abuse
3. Other severe psychiatric or physical disorder that requires immediate treatment in its own right

Date of first enrolment
01/08/2003

Date of final enrolment
01/03/2006

Locations

Countries of recruitment
United Kingdom

Study participating centre
The Northern Ireland Centre for Trauma and Transformation
Omagh
United Kingdom
BT79 OHW

Sponsor information

Organisation
The Northern Ireland Centre for Trauma and Transformation (UK)

Funder(s)

Funder type
Research organisation

Funder Name
The Northern Ireland Office (UK)

Funder Name
The Wellcome Trust (UK) (refs: 037158 and 069777)

Results and Publications

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	02/06/2007		Yes	No