

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

<b>Submission date</b> 30/03/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/03/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/12/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

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)

### **Secondary outcome measures**

No secondary outcome measures

### **Overall study start date**

01/08/2003

### **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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Not Specified

**Target number of participants**

60

**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)

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

http://www.nictt.org

## 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

**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?
<a href="#">Results article</a>	results	02/06/2007		Yes	No