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A randomised controlled trial of brief cognitive therapy for social phobia (social anxiety disorder)

Submission date	Recruitment status
30/03/2006	No longer recruiting
Registration date	**Overall study status**
30/03/2006	Completed
Last Edited	**Condition category**
05/02/2015	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
069777

Study information

Scientific Title
A randomised controlled trial of brief cognitive therapy for social phobia (social anxiety disorder)

Study objectives
To determine whether a new and brief (seven session), self-study augmented version of cognitive therapy for social phobia is as effective as the established, full length (14 session) treatment programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Department of Institute of Psychiatry and South London and Maudsley NHS Trust, ref: 05/Q0706/237

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
Social Phobia

Interventions
Patients suffering from social phobia who are referred to the Centre for Anxiety Disorders and Trauma at the Maudsley Hospital will be invited to participate in the trial. Patients who agree to be included will initially be randomly allocated to:
1. Brief (seven sessions), self-study augmented cognitive therapy
2. Full cognitive therapy (14 sessions)
3. A 14 week wait-list control condition

Patients initially allocated to wait will subsequently receive brief or full cognitive therapy (further random allocation). Full cognitive therapy will be identical to the full cognitive therapy

programme used in our recent randomised controlled trials. The self-study modules cover all the main steps in therapy and are completed in the days before a treatment session. The modules were developed and refined over a 12 month period in consultation with patients from the Centre for Anxiety Disorders and Trauma.

The aim of the modules is to speed up therapy by allowing therapists to focus more closely on areas that need a therapist's skill. As social phobia is a chronic condition, it is important that treatments have a sustained effect. For this reason, the proposed research trial includes a one year prospective follow-up after the end of treatment. In our previous trials of cognitive therapy, we have found that therapy gains are largely maintained at one year follow-up and we expect the same to be true in this trial. Other assessments will be at pre-treatment, mid-treatment, post-treatment and three month follow-up.

Intervention Type
Behavioural

Primary outcome measure
The primary outcome measure for the trial is a social phobia composite measure that is created by combining scores from seven independent assessor and patient scales that are well validated measures of social phobia related symptomatology. Scores on each scale are standardised (M = 0, SD = 1) across pre-treatment and post-treatment assessments by converting to Z scores. The composite at each assessment occasion is the mean of the Z scores on that occasion. This procedure has been used in our last two social phobia trials as well as in other trials in the field.

The seven scales that make up the social phobia composite are:
1. The mean assessor rating of social phobia related fear and avoidance from the anxiety disorders interview schedule for DSM-IV
2. Patient completed Social Phobia Scale
3. The Social Interaction Anxiety Scale
4. The Liebowitz Social Anxiety Scale
5. The Social Phobia and Anxiety Inventory
6. The Fear of Negative Evaluation Scale
7. The Social Phobia Weekly Summary Scale

Secondary outcome measures
1. General mood (assessed by the Beck Anxiety Inventory and the Beck Depression Inventory) and Disability (assessed by the Sheehan Disability Scales)
2. The proportion of patients who continue to meet diagnostic criteria for social phobia at post-treatment and follow-up and the proportion of patients who continue to meet diagnostic criteria for avoidant personality disorder at 12 month follow-up

Overall study start date
14/02/2006

Completion date
01/02/2009

Eligibility

Key inclusion criteria

1. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (American Psychiatric Association, 1994) criteria for social phobia
2. Duration of at least six months
3. Social phobia considered to be the patient's main problem
4. Age 18 to 65 years
5. No psychotropic medication or on a stable dose for at least two months without symptomatic improvement and willing to keep dosage constant during the trial
6. Agree not to start any additional non-protocol treatment during the trial
7. Willing to accept random allocation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Current alcohol or substance dependency (abuse but not dependency is acceptable)
2. Current or past psychosis
3. Borderline personality disorder (other personality disorders are not a reason for exclusion)
4. Unable to read English
5. Social phobia previously treated with an adequate course of an appropriate course of cognitive behaviour therapy or exposure therapy

Date of first enrolment
14/02/2006

Date of final enrolment
01/02/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Institute of Psychiatry
London
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SE5 8AF

Sponsor information

Organisation
King's College London and the South London and Maudsley NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.iop.kcl.ac.uk

ROR
https://ror.org/015803449

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

International 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2011		Yes	No