ISRCTN57551461 https://doi.org/10.1186/ISRCTN57551461

Do patients with social anxiety disorder who receive psychotherapy have any benefits if additional treatment with an antidepressant is added?

Submission date
19/01/2018

Recruitment status
No longer recruiting

Registration date
02/02/2018

Overall study status
Completed

Last Edited
17/03/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Social anxiety disorder, also called social phobia, is characterized by an intense anxiety or fear in social situations. The individual fears being judged, negatively evaluated, or rejected. People with social anxiety disorder may worry about acting or appearing visibly anxious (e.g., shacking, blushing, stumbling over words), or being viewed as stupid, awkward, or boring. These situations are avoided or endured with extreme discomfort. Treatment is based on medication (most commonly antidepressants) or psychotherapy. There is no consensus if combining medication and psychotherapy would result in additional improvement. The aim of this study is to investigate exactly that, specifically if combining a specific antidepressant (sertraline) and two different kinds of psychotherapy (psychodynamic (PDT) or cognitive-behavioural therapy (CBT)) would work better.

Who can participate?
Individuals aged 18 to 65 with social anxiety disorder

What does the study involve?
Participants are randomly allocated to receive either PDT or CBT. The same patients are also randomly allocated to receive either sertraline or placebo (dummy drig), resulting in four different treatment combinations: sertraline + PDT; sertraline + CBT; placebo + PDT; and placebo + CBT. The treatment lasts 20 weeks. Participants are assessed before treatment and at weeks, 1, 4, 8, 12, 16 and 20.

What are the possible benefits and risks of participating?
Participants have a chance to receive either treatment with medication called sertraline or psychological therapy with a specialised therapist or treatment with a combination of both, which may help to treat their social anxiety disorder. The information from this study will help to show whether combining sertraline and psychotherapy is better than psychotherapy alone and which kind of psychotherapy is better for combining with medication. Participants are asked

about how they are feeling when they complete the questionnaires and this may be a bit upsetting for them. The treatment may cause some distress and anxiety but has been shown to be very effective. Sertraline could be related to some side effects (like nausea, sexual dysfunction and insomnia) that are generally well tolerated.

Where is the study run from?
Sao Paulo University Medical School (Brazil)

When is the study starting and how long is it expected to run for?
March 1996 to November 2016

Who is funding the study?
Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP; Brazil)

Who is the main contact?
Dr Marcio Bernik
marcio.bernik@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Marcio Bernik

ORCID ID
https://orcid.org/0000-0001-7922-6747

Contact details
Ambulatório de Ansiedade, Instituto de Psiquiatria, Hospital das Clínicas da FMUSP. R. Dr. Ovídio Pires de Campos, 785 CEP: 05403.010 – Caixa Postal 3671
São Paulo
Brazil
-
+ 55 (0)11 26616988
marcio.bernik@gmail.com

Additional identifiers

Protocol serial number
1997/11285-1

Study information

Scientific Title
In social anxiety disorder, does concomitant treatment with sertraline and psychotherapy improve social skills acquisition? A double-blind, double dummy randomized controlled trial

Study objectives

1. Combining pharmacotherapy with an SSRI and psychotherapy would be superior to psychotherapy alone in the treatment of SAD patients
2. Group cognitive-behavioural therapy (GCBT) would be superior to group psychodynamic therapy (GPT)
3. Group cognitive-behavioural therapy and group psychodynamic therapy are different regarding possible additive or synergistic effects with a selective serotonin reuptake inhibitor

Ethics approval required
Old ethics approval format

Ethics approval(s)
The hospital ethics committee (CEAPESQ), 12/03/1997, ref: 021/97

Primary study design
Interventional

Study design
Single-centre double-blind double-dummy randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Social anxiety disorder

Interventions
Participants were assessed prior to treatment (week -2) for diagnostic confirmation, consent form completion, assessment of inclusion and exclusion criteria. Potential participants were selected and randomly assigned to one of the four treatment groups using a 1:1:1:1 randomization schedule (using a programed Excel Microsoft Office spreadsheet). A research assistant not involved in other steps of the study performed the procedure. The four treatment conditions were:
1. Sertraline + group cognitive-behavioral therapy (Ser-GCBT)
2. Sertraline + group psychodynamic therapy (Ser-GPT)
3. Placebo + GCBT (Pla-GCBT)
4. Placebo + group psychodynamic therapy (Pla-GPT)

Therapists provided treatment in GCBT and GPT following a standardized treatment manual for GCBT and psychodynamic instructions for GPT. GCBT involved twenty 90-minute sessions. Subjects assigned to GCBT received training in anxiety-management skills and social skills followed by behavioral exposure to anxiety-provoking situations. GPT involved twenty 90-minute sessions of psychodinamic psychotherapy without training in anxiety-management skills, social skills or behavioral exposure. All therapy sessions were recorded and 30% were randomly selected and analyzed by independent raters for adherence to the treatment manual. All therapists providing GCBT were experienced behavior therapists and therapists providing GPT were also experienced therapists of mostly psychodynamic background.

Follow up medical/pharmacotherapy consultations involved eight sessions of 45 minutes each that included review and ratings of the severity of subjects' anxiety, their response to treatment, and adverse events. Sertraline or pill placebo were administered on a fixed-flexible schedule beginning with 50 mg per day for sertraline and adjusted up to 200 mg per day. At week 4 and

later, those subjects considered mildly ill or worse and with minimal side effects were eligible for dose increments.

Treatment lasted 20 weeks and patients were re-evaluated at weeks, 1, 4, 8, 12, 16 and 20. Efficacy measures were applied in every visit.

Intervention Type
Mixed

Primary outcome(s)
1. Treatment global clinical response, measured as a score of 1 (very much improved) or 2 (much improved) on the Clinical Global Impression-Improvement scale at week 20
2. Core social symptoms measured using the Scale of Avoidance and Social Discomfort (SASD) at week 20
3. Social skills acquisition, time-by-treatment interaction of the SASD score (week 0 vs week 20) and Multidimensional Scale of Social Expression – Motor Part (M-MSSE) score (week 0 vs week 20)

Key secondary outcome(s)
1. Final social skills measured using final score in M-MSSE at week 20
2. Final social anxiety symptoms measured using final score in SASD at week 20
3. Social anxiety symptoms measured using Fear of Negative Evaluation (FNE) final score at week 20 and time-by-treatment interaction
4. Global symptoms measured using Clinical Global Impression - severity (CGI–S) final score at week 20 and time-by-treatment interaction
5. Improvement in global symptoms measured using Clinical Global Impression – Improvement (CGI–I) final score at week 20
6. Anxiety symptoms measured using Hamilton Anxiety Rating Scale (HAM-A) final score at week 20 and time-by-treatment interaction
7. Depressive symptoms measured using Hamilton Depression Rating Scale (HAM-D) final score at week 20 and time-by-treatment interaction
8. Depressive symptoms as measured using Beck Depression Inventory (BDI) final score at week 20 and time-by-treatment interaction
9. Safety assessed using the SAFTEE questionnaire at the basal visit and at every visit thereafter

Completion date
30/11/2016

Eligibility

Key inclusion criteria
1. Recruitment occurred at the Anxiety Disorders Program of the Institute of Psychiatry, Sao Paulo University Medical School
2. Participants aged from 18 to 65 years were interviewed first by a clinical psychologists using a protocol specific interview and then by a psychiatrist using the Structured Clinical Interview for DSM-IV
3. Social anxiety disorder had to be the primary diagnosis, with or without comorbid depression
4. Symptom duration had to exceed 1 year

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
146

Key exclusion criteria
1. Clinically significant suicidal risk
2. Beck Depression Inventory score greater than or equal to 30
3. Hamilton Depression Rating Scale score greater than or equal to 21
4. Any other primary psychiatric DSM-IV diagnosis
5. Any medical-systemic disease possibly affecting mental condition including epilepsy
6. Intake of more than two units of alcohol/day
7. Current use of antidepressant medications or benzodiazepines

Date of first enrolment
01/05/1999

Date of final enrolment
31/01/2013

Locations

Countries of recruitment
Brazil

Study participating centre
Ambulatório de Ansiedade, Instituto de Psiquiatria, Hospital das Clínicas da FMUSP
R. Dr. Ovídio Pires de Campos, 785
São Paulo
Brazil
05403-010

Sponsor information

Organisation
FAPESP - Fundação de Amparo à Pesquisa do Estado de São Paulo

ROR
https://ror.org/02ddkpn78

Funder(s)

Funder type
Research council

Funder Name
FAPESP - Fundação de Amparo à Pesquisa do Estado de São Paulo (Research Support Foundation of São Paulo State)

Results and Publications

Individual participant data (IPD) sharing plan
Since the dataset is small, individual data may be uploaded as supporting information files accompanying the manuscript. Individual scores of all outcome measures in every visit should then be available as a spreadsheet file. Data on age and gender may also be available, but any information that could be used to identify individual subjects will not. In other words, data will be anonymized to protect patients privacy. In this case, the journal site will serve as public repository not requiring previous request for consultation, just requiring registering in the site. Data will be available as soon as the manuscript is published and will be available indefinitely. Participants gave consent to the use and publication of anonymised data.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/10/2018		Yes	No
Protocol article		29/10/2018	17/03/2023	Yes	No
Dataset		29/10/2018	17/03/2023	No	No