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Comparing cognitive behavior therapy (CBT) and treatment with the antidepressant paroxetine with paroxetine alone in patients with social anxiety disorder

Submission date
14/10/2019

Recruitment status
No longer recruiting

Registration date
26/10/2019

Overall study status
Completed

Last Edited
27/09/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Both cognitive behavior therapy (CBT) and paroxetine (PX) are the preferred treatments for social anxiety disorder (SAD). But in literature there have been divided opinions for the efficacy for combination of these treatments. This study intended to evaluate whether combination of CBT and PX would be superior to monotherapy of PX in the treatment of SAD. Design: Single centre, rater-blind, non randomised study. Participants: Consenting 40 adult participants who received CBT+PX or PX only assigned by treating clinicians. Outcome measures: Liebowitz Social Anxiety Scale (LSAS), Social Interaction Anxiety Scale (SIAS) and Fear of Negative Evaluation-Brief Version (BFNE) were assessed at baseline (0 week), and immediate post-treatment (16 -18 weeks for CBT+PX and 16-20 weeks for PX only), and at follow ups two months after post treatment. Results: Both treatment groups have significant difference in mean scores in all outcome measures in post treatment and follow-up stages compared with pre-treatment scores. But CBT+PX has a better treatment and maintenance gain as compared to PX alone in post-treatment and follow-up stages. Conclusions: In SAD management combinations ofSocial anxiety disorder (SAD), also known as social phobia, is an anxiety disorder characterized by a significant amount of fear in one or more social situations, causing considerable distress and impaired ability to function in at least some parts of daily life.[1]:15 These fears can be triggered by perceived or actual scrutiny from others. Individuals with social anxiety disorder fear negative evaluation from other people. CBT+PX is superior to PX alone and the treatment gains are also better maintained in former than later. There were no risk for participants in this study. We are thankful for the support received from the Quality of Life Research and Development Foundation (QoLReF) and the Institute of Insight, UK.

Background and study aims
Social anxiety disorder (SAD), also known as social phobia, is anxiety associated with fear in social situations. People with SAD fear being judged by other people. SAD causes distress and can stop people doing some normal activities of daily life. Cognitive behavior therapy (CBT) is a type of talking therapy that aims to challenge a person's negative thoughts, beliefs and attitudes. CBT and the antidepressant drug paroxetine (PX) are preferred treatments for social

anxiety disorder (SAD). Research has not yet shown whether a combination of CBT and PX is more effective than PX alone. This study aims to investigate whether a combination of CBT and PX is better than PX alone in the treatment of SAD.

Who can participate?
Adults with a diagnosis of social phobia or SAD

What does the study involve?
The decision of whether the patients should have CBT and PX or PX alone was taken by the treatment team, including psychiatrists and psychologists, and took into account the preference of the participant. All patients received PX tablets and participants in the CBT+ PX group also received eight sessions of CBT, with each session lasting approximately one hour.

What are the possible benefits and risks of participating?
PX is a standard treatment for SAD and side effects are usually mild. There are no known risks of CBT. Participants might benefit from the additional CBT.

Where is the study run from?
The Mental Health Institute of SCB Medical College, Cuttack (India)

When is the study starting and how long is it expected to run for?
The study started from August 2017 to July 2019.

Who is funding the study?
The Mental Health Institute of SCB Medical College, Cuttack (India)

Who is the main contact?
1. Dr. Narendra nath Samantaray, Narendra.samantaray@gmail.com
2. Nirupama Behera, nirupamabhr1@gmail.com

Contact information

Type(s)
Public

Contact name
Dr Narendra Samantaray

ORCID ID
https://orcid.org/0000-0001-9414-9946

Contact details
MHI, SCB Medical College
Cuttack
India
753007
8763331977
narendra.samantaray@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
N/A

Study information

Scientific Title
Effectiveness of cognitive behavioral therapy on social anxiety disorder and fear of negative evaluation: A comparative study

Acronym
CBT for SAD

Study objectives
There will be no significance difference in the treatment of social anxiety disorder between combined treatment with cognitive behavior therapy and paroxetine and paroxetine monotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/05/2018, Institutional Ethics Committee, S.C.B Medical College, Cuttack (Mangalabad, Cuttack-753007; no telephone number; no email), ref: 693/04.05.18; 626

Study design
Single-centre rater-blind quasi-randomized prospective observational study

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
All the consecutive social anxiety disorder (SAD) patients attending the study centre were assessed and informed about both treatment modalities in SAD. Treatment decisions of paroxetine (PX) alone or PX+CBT were taken by the treating team, involving consultant psychiatrists and clinical psychologists following discussion with the patients. Patients were given choice to choose the treatment modalities. Assessment for recruitment continued from October 2017 and continued until February 2019 until there were 20 participants in each arm of the study. Final sample of 40 participants was available following 52 screenings for the study. The reasons for non-participation were long distance of travel to treatment centre and three were concerned about the stigma of repeated attendance in psychiatry.

CBT was based on Rapee's model for SAD and used metaphor based conceptualization. The main steps in treatment were as follows: metaphor-based cognitive conceptualization, cognitive restructuring, exposure and behavioural experiments without use of safety behaviours and use of external focus of attention, and extensive home work sessions focusing both exposure and restructuring. In the CBT+PX group each participant were exposed to 8 sessions of CBT approximately 60 min. These were delivered by a master-level trainee pursuing an MPhil in clinical psychology and supervised by registered clinical psychologists. The other group received PX only. In both groups, the initial dosage of PX was 20 mg per day which later ranged from 20 to 60 mg/day. All the participants were followed up and monitored by consultant psychiatrists for the entire duration of the study.

Intervention Type
Behavioural

Primary outcome(s)
1. Impact of social phobia assessed using the Liebowitz Social Anxiety Scale (LSAS) at baseline (0 week), and immediate post-treatment (16-18 weeks for CBT+PX and 16-20 weeks for PX only), and at follow-up 2 months after post treatment
2. Distress when meeting and talking with others assessed using the Social Interaction Anxiety Scale (SIAS) at baseline (0 week), and immediate post-treatment (16-18 weeks for CBT+PX and 16-20 weeks for PX only), and at follow-up 2 months after post treatment

Key secondary outcome(s))
Social anxiety assessed using the Fear of Negative Evaluation-Brief Version (BFNE) at baseline (0 week), and immediate post-treatment (16-18 weeks for CBT+PX and 16-20 weeks for PX only), and at follow-up 2 months after post treatment

Completion date
05/07/2019

Eligibility

Key inclusion criteria
1. Diagnosis of social anxiety disorder based on ICD-10 classification of mental and behavioural disorders: diagnostic criteria for research
2. Informed consent given
3. Aged 18 years or over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Current level of severe depression with suicidal ideation
2. Substance dependence
3. Comorbid psychosis

Date of first enrolment
04/05/2018

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
India

Study participating centre
S.C.B Medical College, Cuttack
MHI, SCB Medical College, Cuttack, Odisha
Cuttack
India
753007

Sponsor information

Organisation
Srirama Chandra Bhanja (SCB) Medical College

ROR
https://ror.org/050b05p79

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Srirama Chandra Bhanja (SCB) Medical College & Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The pre-treatment, post-treatment and follow-up datasets of outcome measures generated during the current study are available upon request by specifying the need from Nirupama Behera, Clinical psychology trainee, Dept. of Clinical Psychology, Mental Health Institute (Centre of Excellence), SCB Medical College & Hospital, Cuttack-753007. Email: nirupamabhr1@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/11/2020	27/09/2021	Yes	No