Original Article

Randomized controlled trial evaluating the effectiveness of cognitive behavioural group therapy (CBGT) compared to a waitlist control in the treatment of university students with social anxiety disorder

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Abstract

Background

Social anxiety disorder (SAD) is a common mental illness that causes significant functional impairment. Individually delivered cognitive behavioural therapy (CBT) is an effective but costly intervention with limited access and is poorly scalable to meet the need in the population. In this context, cognitive behavioural group therapy (CBGT) is a more viable option.

Objective

To determine the effectiveness of CBGT as compared to a waitlist control for university students with SAD.

Methods

A single-blind, randomized, controlled trial consisting of an 8-week treatment of CBGT (N=15) versus a waitlist control (N=15) was conducted in university students meeting Diagnostic and Statistical Manual IV (DSM IV) criteria for SAD. The Liebowitz Social Anxiety Scale –Self Rated (LSAS-SR) Sinhala version was administered at screening, baseline, four weeks and eight weeks of the trial. Culturally adapted and modified CBGT was delivered in the Sinhala language to the intervention group by a licensed clinical psychologist.

Results

The mean age of the study population was 22 (SD=1.345) and baseline mean LSAS-SR score was 72.33 in the experimental arm and 69.03 in the wait list control. Repeated measures analysis revealed that the mean total score of the LSAS-SR in the CBGT arm was significantly lower (13.262; p<0.001) post-intervention compared to the waitlist group after controlling for age and gender.

Conclusion

Culturally adapted CBGT in Sinhala for SAD is effective in ameliorating social anxiety symptoms among university students.

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Introduction

Social anxiety disorder (SAD) is one of the commonest psychiatric disorders [1,2]] with a high prevalence noted worldwide [3-6] and usual onset during adolescence [1]. Indeed, a recent study found that 13.3% of university students in Sri Lanka met the criteria for this disorder [7]. Several reports confirm that SAD is often under recognized [1,8,9] and undertreated [9,10], and contributes to adverse impacts on social relationships and education and work function and results in impaired quality of life[11,12]. Furthermore, those with SAD are at a higher risk of substance use problems [13,14].

Psychological or pharmacological interventions or combinations are effective in the treatment of SAD [15,16]. Among psychological interventions, cognitive behavioral therapy (CBT) is shown to be particularly effective and is recommended as the first-line intervention [17]. However, psychological interventions are scarce in most low and middle-income countries (LMICs) [18] due to lack of training, resources, and increased costs. In this context, cognitive behavioural group therapy (CBGT) is a viable, cost effective alternative where the therapist's time can be utilized more efficiently by providing services to a larger number of individuals within the same time frame.

Heimberg et al. [19] were among the first to systematically document the benefit of CBGT for SAD, which was later confirmed by another report demonstrating its long-term benefit [20]. Subsequently, McEvoy [21]) reported the benefit of CBGT for SAD in the community mental health setting. A meta-analysis by Wersebe et al [22] also confirmed that CBGT was superior to control conditions in patients with SAD.

While there is a substantial body of evidence on the benefit of CBGT for SAD from high income countries, there are only a handful of publications from LMICs, and none from South Asia. SAD among university students is of particular concern as it impacts their ability to interact effectively with peers and teachers, often impairing academic performance. Previous reports [23,24,25] have shown the effectiveness for CBGT compared to a waitlist control among university students. Therefore, we decided to replicate this study among a mixed group of university students of both sexes in Sri Lanka to determine whether the same benefit could be demonstrated in a south Asian socio-cultural context.

Objective

To determine the effectiveness of eight, weekly sessions of culturally adapted CBGT for university students with SAD on ameliorating the symptoms of SAD, compared to a waitlist control

Methods

Study design

A randomized controlled trial of eight weeks of CBGT versus a wait list control was conducted among eligible (see below) university students with SAD. The CBGT protocol developed by Heimberg et al. [20] was culturally modified to suit the cultural context of Sri Lankan university students. The original protocol presented by Heimberg et al included an orientation interview and twelve sessions of two-hour's duration; two sessions to introduce the CBT model, cognitive restructuring, thinking errors and homework with eight sessions of in-session exposure followed by an ending session focused on further exposure and goal setting and relapse prevention. During the adaptation process of CBGT to the Sri Lankan setting, the existing intervention was modified. It was subjected to a five-step process guided by the existing theoretical framework and guidelines for cultural adaptation of psychological interventions [26-30]. Step one constituted a review of the literature on existing psychological treatment options for SAD among university students. In step two, discussions were held with experts in the field of psychiatry (a professor in psychiatry and a consultant psychiatrist with special interest in CBT) and psychology (a professor in psychology and 2 clinical psychologists with special interest in anxiety disorders and CBT) to review the existing intervention structure and its suitability for Sri Lankan university students.

Step three addressed the implications of the changes to the protocol made after discussion among the experts. In step four, the focus was on the development of cultural elements, such as language and metaphors, based on a review of the existing literature, discussions with fifteen Sinhala literate university students to ensure validity and integration of these modifications to the intervention protocol. In the final step a further review was conducted by the above-mentioned experts who reviewed the structure and relevant worksheets utilizing the Delphi method of validation. The culturally adapted and modified CBGT was administered by the same licensed clinical psychologist. This included eight CBGT sessions, where, in the first two sessions the participants received psychoeducation and were introduced to the CBT model for SAD, cognitive restructuring and home-work. During the next five sessions, exposure and cognitive restructuring was conducted. In the final session, the end of therapy work on continuing exposure, goal setting for the future and relapse prevention, integrating the overall modifications and cultural elements, were discussed. The sessions were conducted once a week for the intervention groups with the session duration ranging between an hour to an hour and a half for each group of five participants.

Study setting
The study was conducted at the Universities of Kelaniya and Moratuwa.
Study participants
The study participants were first- and second-year undergraduates of the Universities of Kelaniya and Moratuwa, Sri Lanka. Students above the age of 18 years were invited (Figure 1) to participate through newsletters, notices and digital media. Recruitment was carried out through the months of December 2015 and January 2016. All eligible subjects had to have a primary diagnosis of SAD as per the Diagnostic and Statistical Manual IV (DSM-IV) criteria for the condition as assessed by a single trained medical doctor and a minimum score of 39 on the previously validated Liebowitz Social Anxiety Scale –Self

Rated (LSAS-SR) Sinhala version [3]. The LSAS-SR Sinhala version was culturally validated and adapted to be used among Sinhala speaking university students, to identify individuals with SAD symptoms prior to the commencement of the clinical trial [3].

The exclusion criteria included ongoing participation in CBT, receiving psychotropics for anxiety or depressive disorder (antidepressants, anxiolytics, or hypnotics) and the presence of syndromal (DSM-IV) depression. Any participant at risk of self-harm or with a current or past diagnosis of psychosis, schizophrenia or bipolar affective disorder was excluded. Participants with a primary diagnosis of major depressive disorder, other anxiety disorders, obsessive compulsive disorder, post-traumatic stress disorder or substance use disorder were also excluded. Assessment of exclusion criteria was carried out by a single trained medical doctor.

Around 500 participants were invited, out of which 136 participated in the assessment of eligibility (Figure 1). Of the 136, 83 were excluded for not meeting eligibility criteria and 23 declined to participate. The remaining 30 were randomized to the two arms by random number generation using a computer programme.
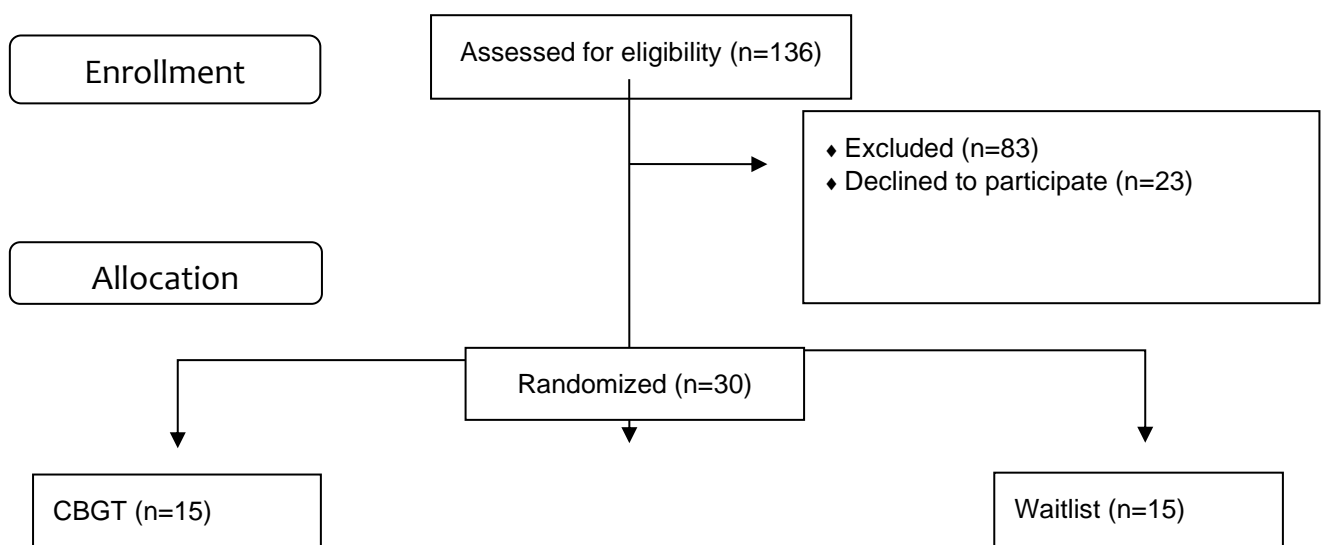

Figure 1: Flow chart showing recruitment for the study

Outcome measures

The primary outcome was at least a five point reduction from the initial LSAS-SR scores while the secondary outcome was complete remission as measured by a score of 39 or less in the validated Sinhala version of the LSAS-SR.

Measurements

DSM IV diagnostic criteria were used to make a diagnosis of social phobia and the validated Sinhala version of the LSAS-SR was used to screen for social phobia and to measure the improvement of symptoms at four and eight weeks.

Bias

CBGT was conducted by the same clinical psychologist who adapted the intervention to maintain the fidelity of the process.

Study size

The initial sample size to achieve the primary endpoint in 60% of the participants at a power of 80% and an alpha error of 5% was 50 participants in each arm. However, an interim analysis was conducted when the first 15 participants from each group completed the study procedures as an obvious benefit was evident and there was deterioration in the wait listed controls. The interim analysis found the intervention group to show significant benefit over the waitlist controls, both statistically and clinically. For ethical reasons, the trial was terminated at this time point.

Statistical Analysis

Statistical analysis was conducted, blind to intervention status, using a mixed-model repeated measures analysis to compare primary and secondary outcomes over time (at four and eight weeks) and between groups.

Logistics and funding

The study was conducted with the support of research grants from the National Research Council of Sri Lanka (13-115) and from the University of Kelaniya (RP/03/04/14/01/14).

Ethical considerations

Ethics clearance was obtained from the Ethics Review Committee of the University of Kelaniya (P/60/05/2013). The trial was registered in the Sri Lanka Clinical Trials Registry (trial number-SLCTR/ 2015/013). Those participants who had symptoms of depression, self- harm ideas or any other mental illness were offered referral to the nearest and/or preferred psychiatry clinic.

Results

The mean ($\pm$SD) age of the experimental arm (participants receiving CBGT) was 22years ($\pm$1.345) while the mean age ($\pm$SD) of the waitlist control arm was 22.3 years ($\pm$1.870). There were eight males and seven females in the CBGT arm and there were six males and nine females in the waitlist arm. Following eight weeks of the intervention, repeated measure analysis revealed that the CBGT group's mean LSAS-SR score was 13.262 (p< 0.001) less than that of the waitlist control (Table 3). In the multivariable model, the CBGT intervention was a significant predictor of LSAS scores after eight weeks while controlling for baseline and 4-week LSAS scores, age and sex (Table 1).

Table 1: Repeated measure analysis of the CBGT arm compared with the waitlist control group.

Variable	Regression coefficient	Standard error of the coefficient	t-value (p-value)	95% confidence interval of the coefficient
Intercept	28.552	25.166		
CGBT group[1]	-13.262	3.498	-3.791 (0.001)	(-20.482) – (-6.042)
LSAS score baseline	-0.097	0.126	-0.770 (0.449)	(-0.358)-0.163
LSAS score at 4weeks	0.947	0.105	9.023 (<0.001)	0.730-1.164

| Male[2] | 3.973 | 3.496 | 1.137 (0.267) | (-3.241)-11.188 |
| Age in years | -0.919 | 1.093 | -0.841 (0.409) | (-3.175)-1.336 |

[1]Compared to the waitlist group
[2] Compared to females.

The primary outcome was reached in 13 of the 15 in the intervention group and three of the 15 in the wait listed group. Both trial arms had three patients who achieved the secondary outcome of recovery (Table 2). An increase in the LSAS score (indicating a worsening of the SAD) was observed at eight weeks in nine participants in the control arm when compared to only one participant in the CBGT arm giving a number needed to harm (NNH) of 2 with a risk ratio of 8.5 (OR -21.4).

Table 2: LSAS-SR Sinhala version scores at weeks zero, four and eight for both trial arms.

	Waitlist Group			CBGT Group		
Visit number	**Base line**	**Mid**	**End of treatment**	**Baseline**	**Mid**	**End of treatment**
Days/Weeks Participant	**Week 0**	**Week 4**	**Week 8**	**Week 0**	**Week 4**	**Week 8**
1	46	85	70	56	51	47
2	48	96	94	88	102	78
3	100	96	98	47	50	56
4	47	74	76	94	94	65
5	59	61	61	73	52	46
6	47	21	21	70	81	67
7	51	25	24	69	71	59
8	44	20	19	74	64	32
9	105	105	105	102	67	26
10	89	87	90	46	42	34
11	76	78	82	59	58	48
12	65	63	68	94	86	72
13	84	80	83	62	57	53
14	67	75	74	74	69	65
15	91	89	92	83	77	62
Mean LSAS-SR score	67.03	70.33	70.46	**72.33**	**68.06**	**54**

Discussion

An investigation of university students in India has reported significant disability in work performance, social functioning and family life in the individuals affected by SAD [7]. Another study of university student with SAD notes the frequent use of dysfunctional avoidant strategies to reduce performance anxiety during presentations [6]. Such learnt avoidance behavior can have adverse consequences, long-term. There is no doubt that SAD adversely impacts personal and professional functioning and contributes to poor career development and frequently to underemployment. Often perceived by employers

as lacking in assertiveness, the sufferers face significant disadvantage in the workplace, especially in the developing countries.

Identifying and treating social phobia early in the illness cannot be over emphasized. One well-documented factor affecting long-term functional outcome in SAD is chronicity of the illness and the presence of residual symptoms. This study revealed that a culturally adapted CBGT is effective in reducing symptoms of SAD in a group of university students, compared to a waitlist control. All but one subject benefited from the intervention. These findings are in keeping with previous reports from LMIC which found CBGT to be superior to waitlisted controlling [23, 24, 31].

There are only a few head-to-head comparisons of CBGT and individual CBT conducted in LMIC. One from Iran reports that while CBGT was particularly effective in reducing fear of negative evaluation, overall efficacy was similar with both forms of intervention [25]. While it is clear that CBGT has the distinct advantage of decreased cost, it may also have other added benefits. Groups greatly increase treatment capacity and access. Furthermore, the sense of belonging and sharing of experiences leads to increased motivation and treatment adherence. The social skills of the participants are enhanced by peer interactions which can be harnessed to overcome social anxiety. It is easier, then, to translate these benefits to societal settings. The stigma related to mental illness and treatment may be minimized by interaction with peers with similar disability [32].

A key strength of this study is the cultural adaptation of the intervention to the South Asian context. The CBGT included cross culturally sensitive elements and contextually relevant scenarios. The need to take into consideration cultural nuances in evaluating and treating mental illnesses is well recognized [33]. This would be particularly relevant in administering psychological interventions enabling better acceptability, enhanced participation, and increased effectiveness.

Limitations
A key limitation was that there was no follow up of participants after eight weeks. Thus, we are not sure whether the benefits were sustained in the longer term. We also did not analyze or compare the demographic variables of those who declined to participate with those who consented. Furthermore, the improvement was measured using a self-administered tool rather than by a clinician-rated instrument. The lack of blinding may have contributed to a degree of placebo effect.

Conclusion
CBGT was effective in reducing symptoms of SAD among university students. The study adds to the evidence base on the effectiveness of culturally adapted CBGT for SAD. It is particularly useful as a cost-effective intervention for LMIC that can be offered to young adults to overcome their disability in educational and work settings.

Acknowledgements

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