**ABSTRACT**

**BACKGROUND:** Cognitive Behaviour Therapy (CBT), Self-help and Guided Self Help interventions have been found to be efficacious and cost-effective for victims of trauma but there is limited data from low and middle-income countries on culturally adapted interventions for trauma. **AIMS:** To investigate the feasibility and acceptability of culturally adapted trauma-focused CBT based Guided Self-Help (CatCBT GSH) for female victims of domestic violence in Pakistan. **METHODS:** This randomized controlled trial recruited fifty participants from shelter homes in Karachi and randomized them to two equal groups. The intervention group received GSH in 9 sessions over 12 weeks. The control group was a waitlist control. The primary outcomes were feasibility and acceptability. Secondary outcomes included Impact of Event Scale-Revised (IES-R), Hospital Anxiety and Depression Scale (HADS) and the WHO Disability Assessment Schedule 2 (WHO DAS 2). Assessments were carried out at baseline and at 12 weeks. **RESULTS:** Out of 60 clients who met DSM 5 criteria for PTSD, 56 (93.3%) agreed to participate in the study. Retention to the intervention group was excellent, with 92% (23/25) attending more than 6 sessions. Statistically significant differences were noted post intervention in secondary outcomes in favour of the intervention. **CONCLUSIONS:** A trial ofCatCBT GSH was feasible and the intervention was acceptable by Pakistani women who experience domestic violence. Furthermore, it may be helpful in improving symptoms of PTSD, depression, anxiety and overall functioning in this population. The results provide rationale for a larger, confirmatory randomized controlled trial of CatCBT GSH.

**Key Words:** Trauma, Guided Self Help, Cultural Adaptation, Pakistan

**INTRODUCTION**

Violence against Pakistani women occurs at an alarming prevalence that reflects a significant risk to the health of the victims and their families (LaBore et al., 2019). A study in a Pakistani community sample reported that as much as half of all women in this setting experienced battering or violence (Naeem et al., 2008). Women who experience domestic violence are at high risk of mental health problems (Ayub et al., 2009) and studies have reported high rates of posttraumatic stress disorder (PTSD) and depression in this group (Golding, 1999).

Cognitive behaviour therapy (CBT) is an evidence-based intervention for PTSD that is recommended by national guidelines in most high-income countries (APA, 2017). There is robust evidence that therapist-delivered trauma-focused CBT is useful for the treatment of PTSD (Bisson et al., 2013; Jonas et al., 2013) and can be used in brief format (Wu et al., 2014). Self-help and Guided Self Help interventions have been found to be efficacious and cost-effective (Bower et al., 2001, 2001; Pim Cuijpers & Schuurmans, 2007; G. Lewis et al., 2003; C. Lewis et al., 2019, 2019)

Notwithstanding this, the availability of CBT in Low and Middle Income Countries (LAMICs) remains low (Beck et al., 2016) despite evidence showing it to be an effective treatment for psychiatric problems in these settings (Aslam et al., 2015; Chatterjee et al., 2014; Husain et al., 2014; Naeem et al., 2015a; Naeem et al., 2015b). However given the fact that social and cultural factors influence symptom perception and treatment engagement (Bhikha et al., 2012), interventions need to be tailored to the socio-cultural needs of patients. Converging evidence indicates a strong benefit to culturally adapting interventions (Chowdhary et al., 2014; Griner & Smith, 2006; Rathod et al., 2018).

Our group has culturally adapted and tested CBT in Pakistan and the UK (Aslam et al., 2015; Naeem et al., 2009; Naeem et al., 2015a; Naeem et al., 2015b; Naeem et al., 2016, 2011; Farooq & Ommeren, 2016; Rathod et al., 2010, 2013, 2019). Based on our experience of culturally adapting CBT we have developed culturally adapted self-help manuals for depression, anxiety and stress. The self-help manual for depression and anxiety has been tested in a multicentre randomized controlled trial (RCT) and has been found to be effective (Naeem et al., 2014). Similarly, we recently developed a culturally adapted self-help manual for PTSD (BASID Ki Kahani - story of BASID- Baad uz Sadma Zehni Dabao, literal translation of Posttraumatic Stress). To our knowledge there are no published clinical trials of culturally adapted interventions for PTSD from South Asia.

Herein we report results of a feasibility randomized controlled trial of the “BASID Ki Kahani” manual as Guided Self Help (GSH) delivered by CBT trained therapists to help Pakistani women who have experienced domestic violence and subsequent PTSD. The primary aim of this trial was to assess feasibility and acceptability of culturally adapted trauma-focused CBT-based GSH. We also assessed measures of traumatic distress, depression and anxiety as secondary outcomes.

**MATERIAL AND METHODS**

**Participants**

*Inclusion and exclusion criteria*

Inclusion criteria were: female sex, history of domestic violence, a diagnosis of PTSD using DSM 5 criteria, age 18 to 65 and at least 5 years of formal education. The exclusion criteria were; substance use disorder according to DSM 5 criteria, significant cognitive impairment (for example due to a profound learning disability or dementia) and active psychosis.

**Procedure**

*Study design*

This study is a randomized controlled trial using a pre-post measure and parallel design. It was conducted from July 2018 to June 2019.

*Study sites*

The trial was conducted in one shelter home in Karachi, Pakistan. The shelter home accommodates victims of domestic violence, women at risk of violence from their families after choosing to marry against their approval, and survivors of sexual assaults. Shelter homes provide free lodging, legal and medical help to these survivors.

*Recruitment*

Individuals who had experienced domestic violence and were living in a shelter home were recruited in Karachi, Pakistan. Participants were identified by the shelter home staff initially.

Those considered eligible and who consented to be contacted were then contacted by a member of the research team. A clinical psychologist (ML) assessed them for symptoms of PTSD during a clinical assessment using DSM 5 criteria. Those meeting criteria for PTSD were provided information about the study. After a full description of the study, all participants provided written informed consent before recruitment to the study.

*Trial Intervention: CatCBT based self-help manual for trauma - BASID Ki Kahani*

We developed a self-help manual for depression to improve access to CBT. This manual was found to be effective in a multicentre RCT when used as guided self-help (Naeem et al., 2014). We recently developed a culturally sensitive self-help manual in Urdu for victims of trauma, BASID Ki Kahani. It focuses on stories of four victims of trauma. The book describes how they help themselves with symptoms of PTSD, depression and anxiety using CBT techniques. The self-help manual focuses on psychoeducation, symptom management, graded exposure, cognitive restructuring, behavioural activation, problem-solving, improving relationships and communication skills. The self-help manual consists of seven chapters, with two additional chapters on conflict management and communication skills. The chapters on changing negative thoughts focus on identifying negative thoughts, challenging them and finding alternative thoughts by using diaries. There are also other stories in the manual; for example, the story of an elephant and six blind men to explain the concept of CBT and the story of a lion to explain exposure. The book also uses other examples from local folklore as well as from the Islamic religion. It can be used by patients or carers with at least 5 years of education. For the purposes of the current study, the intervention was facilitated by research assistants (RAs) who were Masters level psychologists. The RAs provided face-to-face guidance on how to use the manual in 9 sessions over a 12-week period. At each session, RAs would elicit feedback of the previous session and give a brief 15 to 20 minute overview on the content of the chapter in the manual that the current session was focussed on. The manual can be downloaded from the Pakistan Association of Cognitive Behaviour Therapy (PACBT) website (<http://www.pacbt.org/>).

*Waitlist Control*

Clients in shelter homes mainly receive help and advice concerning legal and financial issues. Clients are not routinely offered psychological help to deal with their trauma symptoms. When a person needs physical or mental health care, they are referred to a local primary care physician or hospital.

**Measures**

*Assessment of feasibility and acceptability*

Feasibility and acceptability were assessed through recruitment, retention and informal feedback from participants. At the end of the intervention, participants were asked by RAs to describe their experience. They were also requested to name the sessions that they found the most helpful or unhelpful and suggestions to improve the intervention. Those attending less than 6 of 9 (66%) sessions were considered dropouts.

*Assessment of clinical outcomes*

The following assessments were performed at baseline and at the end of the intervention at 12 weeks: Impact of Events Scale revised for PTSD (IES-R) (Weiss & Marmar, 1996), The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) and the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) (Üstün et al., 2010). A data form was used to collect demographic information from participants. All assessment scales were translated in Urdu.

The IES-R (Weiss & Marmar, 1996) is a 22-item self-report measure (for PTSD according to DSM IV criteria) that assesses subjective distress caused by traumatic events. Respondents are asked to identify a specific stressful life event and then indicate how much they were distressed or bothered during the past seven days by each "difficulty" listed. Items are rated on a 5-point scale ranging from 0 ("not at all") to 4 ("extremely"). The IES-R yields a total score (ranging from 0 to 88). The authors recommend using means instead of raw sums for each of these subscales scores to allow comparison with scores from the Symptom Checklist 90 - Revised (SCL-90-R; Derogatis, 1994). In general, the IES-R (and IES) is not used to diagnose PTSD. However, cutoff scores for a preliminary diagnosis of PTSD have been cited in the literature (Murphy et al., 2017). The IES-R is the only validated tool in Urdu in Pakistan (with a reported good reliability; *Cronbach’s alpha* of 0.92) and satisfactory content and convergent validity for that sample (Tareen et al., 2012). Ehring et al. have used the scale in their studies for assessing PTSD in Pakistan (*Cronbach’s alphas* for their two studies were 0.91 and 0.94) (Ehring et al., 2011; Razik et al., 2013).

The HADS (Hospital Anxiety and Depression Scale) (Zigmond & Snaith, 1983) is a 14 item, self- assessment scale designed to measure anxiety and depression. It has high internal consistency, face validity and concurrent validity. Even-numbered questions relate to depression and odd-numbered questions relate to anxiety. Each question has 4 possible responses. Responses are scored on a scale from 3 to 0. The maximum score is therefore 21 for depression and 21 for anxiety. A score of 11 or higher indicates the probable presence of depression with a score of 8 to 10 being just suggestive of the presence of the respective state. The two subscales, anxiety and depression, have been found to be independent measures. In its current form the HADS is now divided into four ranges: normal (0-7), mild (8-10), moderate (11-15) and severe (16-21). The HADS has been validated in Urdu and has been used previously in Pakistan, showing a good internal consistency with a *Cronbach’s alpha* value of 0.81 (Waqas et al., 2019).

The WHODAS 2.0 (Üstün et al., 2010) is a self-report questionnaire that assesses disability and functioning in the prior month that has been used in Pakistan. The WHODAS 2.0 was developed to assess six different adult life tasks: 1) Understanding and communication; 2) Self-care; 3) Mobility (getting around); 4) Interpersonal relationships (getting along with others); 5) Work and household roles (life activities); and 6) Community and civic roles (participation). There are 36 and 12 item versions of the WHODAS 2.0. We used the 12-item version for this study. The WHODAS 2.0 has been translated in Urdu and has previously been used in Pakistan showing good internal consistency (Federici et al., 2017).

**Data Analysis**

*Sample size and randomization*

This is a first feasibilty study using an RCT design therefore no power calculation was conducted. The results of this study will be used to calculate sample sizes for future larger, confirmatory RCTs. It has been suggested that a sample size of 12 in each arm should suffice for pilot studies (Julious, 2005). Allowing for up to 40-60% dropouts, we, therefore, recruited 50 participants for the study, including 25 participants per arm. Randomization was performed using a web-based platform (www.randomization.com).

*Statistical Analysis*

SPSS frequency and descriptive commands were used to measure descriptive statistics. SPSS explore command was used to measure normality of the data, using histograms and Kolmorogov-Smirnov test. Baseline comparisons were made using Chi-Square and t-test. Comparisons at two-time points in psychopathology and disability were measured using ANCOVA to account for differences at the baseline. To calculate effect sizes we used adjusted means difference as nominator. For denominator we used this formula √((n1-1)SD12+(n2-1)SD22)/(n1+n2-2) (Lakens, 2013). We made additional adjustments by multiplying the results from the above formula with (N-3/N-2.25) and √N-2/N (Durlak, 2009) (PMID: 19223279). We made these calculations in Microsoft Excel.

**RESULTS**

The shelter home staff identified 78 individuals who could potentially meet the inclusion criteria for the study. Research staff contacted this group, and 60 met the DSM 5 criteria for PTSD. Figure 1 shows the recruitment and flow of participants during the trial

Table 1 provides a summary of baseline characteristics of included participants. The majority of participants were married (n=42, 84%) and most had been victims of physical and emotional abuse (n=39, 78%). All participants identified as Muslim with regards to their religious identity. There were no significant differences in demographic or clinical variables between groups at baseline.

**Feasibility and acceptability**

With regards to feasibility of the trial, recruitment was successful and occurred to time and target. Out of 60 clients who met the criteria for PTSD, 56 (93.3%) agreed to participate in the study. As 6 clients left the shelter home before the baseline assessment and randomization, 50 participants completed baseline assessments and were randomized to either the intervention group or waitlist control. Retention to the intervention group was excellent, with 92% (23/25) attending more than 6 sessions. 20 attended all 9 sessions, 3 attended 6-9 sessions and another 2 attended 3-6 sessions.

Informal feedback from the participants and the shelter care staff was positive, describing the intervention as acceptable and helpful. Almost all those who completed the study reported the intervention to be easy to read and understand. Of those who completed the intervention, almost all the participants (21/25) described the sessions on dealing with thoughts to be the most helpful. One participant, in particular, found activity scheduling to be effective, other popular sessions included; fear hierarchy (20/25), awareness about sleep issues and suggestion for improving sleep (18/25) and cognitive restructuring (19/25).

**Clinical measures**

There were statistically significant differences between the two-time points in symptoms of PTSD, depression, anxiety and disability. Table 2 describes these results.

**DISCUSSION**

To our knowledge, this is the first report of a culturally adapted Guided Self help intervention for victims of trauma from South Asia. The study proved feasible, and the intervention was acceptable to participants. The intervention also reduced symptoms of PTSD, depression, anxiety and disability.

Despite the strong evidence for its effectiveness, CBT remains underutilised in LAMICs. One key strategy to improve access to evidence-based care suggested by the World Health Organization (WHO) is through task shifting or task sharing (WHO, 2008). There is evidence to suggest that lay therapist delivered psychosocial interventions are feasible and effective (Jordans et al., 2019; Patel et al., 2017; Rahman et al., 2016). However, LAMICs might not be able to afford lay therapist delivered therapy. Therefore, there is a need to explore further low-cost evidence-based interventions that can be delivered with minimum resources in LAMICs. One such option is CBT-based Self Help and Guided Self Help (CBT GSH), which have a strong evidence base for depression and anxiety disorders in high-income settings (Cuijpers, 1997; Cuijpers & Schuurmans, 2007; Falbe-Hansen, Le Huray, Phull, Shakespeare, & Wheatley, 2009). However, only limited data (Naeem et al., 2014) is available on use of CBT-based GSH from LAMICs.

These results are in line with studies conducted in high-income countries, (Cuijpers et al 1997), as well as with our previous work (Naeem et al., 2014). The results highlight the need for developing culturally adapted therapies that can be delivered using available resources. The cultural relevance of the self-help material may have played a vital role in engaging clients although this theory would need to be tested within the framework of an RCT comparing the BASID Ki Kahani intervention with the Western version of CBT-based GSH, to confirm our hypothesis.

***Strengths and Limitations***

This feasibility study successfully achieved its required sample size and drop out rates were low, which are considerable strengths. However, these might be explained by the fact that clients were bound to shelter homes. Moreover, potential participants were initially identified by shelter home staff prior to a screening with the research team, which may be a source for selection bias when interpreting the feasibility of recruitment. We collected informal feedback from study participants, which was largely positive. However as the qualitative data was not formally analysed, we can not rely on it to confirm that the intervention was acceptable to participants. Notwithstanding this, though they had the option to refuse, most participants completed the intervention. The sample consisted of clients who had experienced trauma and there were significant improvements at the final assessment in terms of posttraumatic stress symptoms, depression, anxiety and disability. The informal feedback collected at the end of the study indicated that the treatment was highly acceptable and helpful to participants. Moreover, the study was conducted in real-life settings in a shelter home and this pragmatic approach to recruitment is reproducible in routine care.

We observed a drop in psychopathology scores in both the treatment arm and control arm, although there was a greater reduction in the treatment arm, which was statistically significant. The improvement in the control arm may be due to the fact that participants in the control arm also received some therapeutic benefit from the structured follow up assessments with the research staff. Moreover, the environment of the shelter home itself provides respite from a traumatic and abusive environment leading to a sense of safety. The significant reduction in symptoms scores in the treatment group may be an indication of treatment effect. Although the effect sizes in the study are large, this is mainly because of the small standard deviations, which are likely to be a function of the small sample size.

**CONCLUSIONS**

Overall, the findings of this feasibility study are encouraging, but they require replication in a larger, confirmatory RCT. If a larger study confirms the clinical findings of our feasibility trial, this low-cost intervention has the potential to be scaled up across LMICs like Pakistan to improve outcomes for female victims of domestic violence who experience symptoms of PTSD. Future work may consider delivering this intervention to victims of other traumas. The current study did not include an assessment of history of other traumas, which may limit our findings to only women with a history of domestic violence. There is also a need to develop self-help CBT material using technologies that do not depend on reading alone, for example, using multimedia and smartphone applications. Self-help interventions can be delivered digitally, have been used for treatment of PTSD, and have been found to be effective (Hedman et al., 2012; Wickersham et al., 2019). Furthermore, digital self-help interventions have been shown to reduce healthcare costs in high-income countries (Alaoui et al., 2017). Mobile cellular phone subscriptions exceed 80% of the population in many low-income countries, and there is a growing evidence base for the efficacy of mobile health interventions in LAMICs (Naslund et al., 2017; Wickersham et al., 2019). Such approaches may help address the significant mental health treatment gap for victims of violence in LAMICs, who experience PTSD and other disabling psychological sequelae.

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**Ethical Statement**

The trial protocol was approved by the Pakistan Association of Cognitive Behaviour Therapy (PACBT) institutional review board. All authors have abided by the Ethical Principles of Psychologists and Code of Conduct as set out by the BABCP and BPS.

**Conflicts of interest**

The authors have no conflicts of interest to declare.

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**Figure. 1: CONSORT flow diagram of the trial**

Potential participants identified by workers

(n=78)

Potential participants who agreed to participate

(n=60)

Excluded (n=12)

Refused to participate (n=6)

Fulfilled Inclusion Criteria (n=60)

(Refused to consent=4)

Enrollment

Left the city before baseline assessments=6

Randomized & Completed baseline assessment (n=50)

Allocation

Allocated to control group (n=25)

Allocated to Intervention group (n=25)

Follow up

Completed (n=25)

Completed (n=25)

Assessments

**Table 1: Differences in demographic variables and psychopathology between the Intervention and the Control groups at the baseline.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Intervention  (n=25) | Control (TAU)  (n=25) | P\* |
| Age | 27.4 (4.6) | 26.3 (3.7) | 0.347 |
| Marital status Married  Separated | 23 (92%)  2 (8%) | 19 (76%)  6 (24%) | 0.102 |
| Education 5 to 10  10 to 12  14 or more | 13 (52%)  4 (16%)  8 (32%) | 14 (56%)  5 (20%)  6 (24%) | 0.805 |
| Employment Unemployed  Employed | 8 (40%)  12 (60%) | 3.7 (65%)  7 (35%) | 0.205 |
| Family structure Joint  Nuclear | 8 (32%)  17 (68%) | 10 (40%)  15 (60%) | 0.556 |
| Duration of marriage in years | 4.7(1.9) | 5.0(1.74) | 0.546 |
| Type of domestic violence Phys/Emot  Phys/Emot/Sex  Phys/Sex | 19(76%)  5(20.0%)  1(4.0%) | 20(80%)  5(20%)  0(0.0%) | 0.599 |
| IES 2  HADS Anxiety Subscale  HADS Depression Subscale  HADS TOT  WHO DAS 2 | 35.8(1.5)  16.7(3.4)  15.7(4.3)  32.4(5.4)  12.2(1.8) | 35.0(1.6)  15.6(3.9)  15.6(4.0)  31.2(6.5)  11.9(1.8) | 0.308  0.277  0.973  0.484  0.062 |

The figures for demographic details are Mean (Standard Deviation) for age and clinical metrics, while the rest are Sample Size (% within treatment group).

\*P-values calculated using, non-parametric Mann-Whitney U test for continuous variables (age and clinical metrics) and Fisher’s exact test for the rest of variables that were categorical.

**Table 2: Differences between the treatment and control groups, both uncontrolled and controlled for initial differences. Analyses were carried out using an ANCOVA.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Unadjusted Mean Differences** | | | |  |  |  |  |  | |  | |
|  | Intervention M\*\* (n=25) | Intervention SD\*\*\* | TAU M  (n=25) | TAU SD | Mean difference+ | CI++ | F(df) | Partial eta sq. | Cohen’s d\*\*\*\* | P\* | |
| **IES 2** | 11.4 | 1.5 | 16.3 | 3.4 | -5.2 | -6.4, -3.6 | 41.0(1) | 0.48 | 1.9 | 0.000 | |
| **HADS Anxiety** | 3.7 | 1.6 | 11.3 | 2.9 | -7.7 | -9.1, -6.4 | 126.6(1) | 0.74 | 3.17 | 0.000 | |
| **HADS Depression** | 3.3 | 1.6 | 12.8 | 3.5 | -9.5 | -11.0, -7.9 | 137.9(1) | 0.76 | 3.36 | 0.000 | |
| **HADS TOT** | 7.0 | 2.0 | 24.1 | 4.6 | -17.5 | -19.1, -15.9 | 417.5(1) | 0.90 | 4.75 | 0.000 | |
| **WHO DAS 2.0** | 6.0 | 1.6 | 11.4 | 1.5 | -1.7 | -2.7, -0.6 | 417(1) | 0.50 | 1.05 | 0.173 | |

\* P-values calculated using ANCOVA, controlling for baseline value of the outcome.

\*\* M = Mean,

\*\*\*SD = Standard Deviation.

\*\*\*\* Cohen’s d was calculated by dividing the adjusted difference at end of trial (column 5) by the standard deviation at baseline (column 2).

+ Difference Baseline – Post. Negative values mean improvement.

++ CI = Confidence Interval