



TITLE: Cognitive Behavioural Therapy for Post Traumatic Stress Disorder: A Review of the Clinical and Cost-Effectiveness

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CONTEXT AND POLICY ISSUES:

An estimated 5% of males and 10% of females experience an episode of post-traumatic stress disorder (PTSD) at some point in their lives following a major traumatic event.¹ Symptoms of PTSD include upsetting thoughts, nightmares and flashbacks about the traumatic event, avoidance of reminders of the event, sleep disturbances, numbing of general responsiveness, increased irritability, and hypervigilance.^{1,2} To satisfy the *Diagnostic and Statistical Manual IV* (DSM-IV) criteria for PTSD the symptoms must persist for at least one month and they must cause clinically important distress or reduced day-to-day functioning.¹

PTSD is a complex disorder that often requires a long-term, multi-faceted approach to treatment.² A combination of pharmacotherapy and psychotherapy can be employed.² Cognitive behavioural therapy (CBT) is a form of psychotherapy which is based upon the relationships between thoughts, emotions, and behaviour.² CBT makes use of a number of techniques whose the purpose is to change an individual's distressing emotions by changing his or her thoughts, beliefs, and behaviours.³ The purpose of therapy is to reduce distress or unwanted behaviour by undoing this learning or by providing new, more adaptive learning experiences.³ The behavioural component of CBT aims to reduce dysfunctional emotions and behaviour by altering the individual's behaviour and the factors that control it.³ The cognitive component attempts to reduce dysfunctional emotions and behaviour by altering individual appraisals and thinking patterns.³ In comparison with other psychotherapies, CBT is brief, highly structured, problem-orientated and prescriptive, and individuals are active collaborators.³ The benefit of CBT in PTSD has been demonstrated in a number of studies.^{3,4}

CBT for PTSD may not always available as an alternative in areas without access to psychotherapists trained in this technique. Self-directed CBT (for example through a Web-based or stand alone computer program) or tele-therapy CBT been introduced to help improve access to CBT for patients in remote areas.⁵ However, it is not clear if these alternate delivery strategies are as clinically effective or cost-effective as CBT for PTSD when delivered in the

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traditional, face-to-face manner. Moreover, it is not clear if alternate delivery strategies are appropriate for the entire population with PTSD or whether they are better suited to particular subgroups of the population. This report will review the evidence of clinical and cost-effectiveness of CBT delivered in a self-directed manner or via tele-health applications relative to traditional CBT and guidelines for patient selection. This information could help in decision-making pertaining to which patients could benefit from CBT for PTSD when delivered in these alternative formats.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness of self-directed cognitive behavioural therapy (CBT) or tele-therapy compared with traditional CBT for the treatment of adults with post-traumatic stress disorder (PTSD)?
2. What is the cost-effectiveness of self-directed CBT or tele-therapy compared with traditional CBT for the treatment of adults with PTSD?
3. What are the guidelines for patient selection criteria for self-directed CBT or tele-therapy for the treatment of adults with PTSD?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including OVID's Medline and Embase, the Cochrane Library (Issue 3, 2009), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. The search was limited to English language articles published between 2004 and December 2009. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, controlled clinical trials, and observational studies, economic studies, and guidelines.

SUMMARY OF FINDINGS:

Two studies were identified in which CBT delivered via tele-therapy was compared to a traditional method of delivery (one RCT⁶ and one non-randomized controlled clinical trial (CCT)).⁵ No studies of the cost-effectiveness of self-directed CBT or tele-therapy compared with traditional CBT for the treatment of adults with PTSD were identified with the search strategy. Identified guidelines^{3,7,8} for the management of PTSD did not address patient selection criteria for self-directed CBT or tele-therapy for the treatment of adults with PTSD.

Randomized controlled trials

Characteristics of the identified RCT⁶ are summarized in Appendix 1. This was a single-centre non-inferiority trial of group CBT delivered via tele-therapy or face-to-face contact for PTSD in veterans. The primary objective of the study was to compare outcomes for the two modes of service delivery. This intervention (see Appendix 1) was specific to combat-related PTSD. It was not stated in the report if all participants in each study arm had the intervention delivered to them together as one single group. The report did not state if the same therapist was used for

both study arms. A number of previously developed instruments were used to assess the outcomes of the two modes of delivery (Appendix 2). Primary and secondary analyses were performed. The primary analysis used a non-inferiority approach to statistical testing, whereas the secondary analysis used standard statistical hypothesis testing. Outcomes were assessed immediately post-treatment and three months later.

Ninety-seven male veterans were referred for participation in the study, 38 of which were randomized to face-to-face (n=21) or tele-therapy (n=17) as the mode of CBT delivery. Of these 38 participants, 25 had complete data for at least one instrument and comprised the primary analysis set. Missing data were imputed by carrying the last observation forward (for example, if three month data were missing, the post-treatment data were used). However, the authors only presented the analyses based upon complete data because there was little difference between the results based upon imputed or complete data. Demographic characteristics of the study sample are included in Appendix 2. Of note, 24% of participants had substance abuse disorders despite this being an exclusion criterion. No statistically significant differences in change from baseline were found for the self-reported outcomes between the two modes of delivery post-treatment and at the three month follow-up. For process measures, overall satisfaction, likeliness of using the therapy again, and likeliness of referring a family member or friend did not differ between groups, nor did ratings of the quality of communication or level of comfort with other group members. The only difference between the two methods of delivery was in comfort with talking to the therapist, which was significantly higher in the face-to-face group ($p=0.03$). Group differences for session attendance were not statistically significant. However, the face-to-face group was more likely to have completed homework assignments ($p=0.04$).

It was concluded that the findings supported the use of tele-therapy in the treatment of veterans with PTSD, but that caution should be exercised in interpreting the results given the study's limitations. The authors of the study stated the limitations to be low rates of clinical change in either group, the sample size, and the drop-out rate. The authors indicated that these factors may have affected the ability to detect significant differences between groups and may have introduced bias into the comparisons between groups. A number of details of the intervention were not reported, including whether the facilitator or therapist was the same for both interventions. This could impact the degree of clinical change in each group. Further, the size of each group session could not be ascertained from the study report, which would make the intervention difficult to replicate. As well, the training of the individual or individuals delivering the intervention was not reported, which would again make the intervention difficult to replicate. The representativeness of the sample may have been compromised by the proportion of participants that were screened versus randomized. As well, those veterans who referred themselves to the program could be a systematically different subset of the larger population of veterans. It is not clear if the results of this study could be generalized to female veterans with PTSD, other causes of PTSD (i.e., unrelated to combat), civilian populations, and to CBT delivered as a one-on-one intervention. A strength of this study was the use of previously developed, standardized assessment tools to measure the effect of the interventions.

Controlled clinical trials

Characteristics of the identified CCT⁵ are summarized in Appendix 1. This was a non-randomized controlled study of CBT delivered via tele-therapy (n=16) or face-to-face contact (n=32) carried out in Montreal and at a remote location 200 km away from the city. Individuals in

the face-to-face group were recruited in Montreal. Individuals in the videoconferencing group were recruited from Montreal (n=5) and the remote location (n=11). Participants were selected from preexisting wait lists of two anxiety disorders clinics and from newspaper advertisements and radio announcements for the remote location. The primary objective of the study was to compare outcomes for the two modes of delivery, specifically in terms of treatment effectiveness, comfort with the remote communication, and perceptions of videoconferencing. CBT was delivered one-on-one and was tailored to each participant based upon symptom type and severity (see Appendix 1). The interventions were delivered by a core group of psychologists with an average of five years experience with CBT and in depth knowledge of PTSD. These psychologists treated patients in both groups. In addition to the core group, seven other psychologists each treated one to five participants in the face-to-face group. The intervention was an average of 21 sessions in the tele-therapy group and 19 sessions in the face-to-face group. There was a one-month waiting period prior to the initiation of treatment to ensure that symptoms were stable, but this was waived for patients who needed urgent intervention. A number of previously developed instruments were used to assess the outcomes of the two modes of delivery (Appendix 2). These questionnaires were administered at the beginning of the one-month waiting period, pre-treatment, and post-treatment (immediately following the completion of therapy).

Forty-eight participants completed the study, but an additional 20 participants (eight in the tele-therapy group and 12 in the face-to-face group) were enrolled and dropped out or were excluded after the interventions began. Characteristics of the study groups are outlined in Appendix 2. Sexual aggression was the most common traumatic event which precipitated PTSD. After treatment, 81% of participants in the videoconference group and 75% of participants in the face-to-face group no longer met the diagnostic criteria for PTSD. No differences over time were noted between the two treatment conditions for the Modified PTSD Symptom Scale (the primary outcome measure), but both groups improved over time in the frequency and severity of PTSD symptoms. Secondary measures (Beck Depression Inventory, Beck Anxiety Inventory, Assessment of Current Functioning) also indicated statistically significant improvements over time in both groups, but no differences between the two modes of delivery. For videoconferencing process measures, changes between pre-treatment and post-treatment were not statistically significant. From these results, it was concluded that videoconferencing can be an effective means of delivering CBT for PTSD.

Limitations that the authors identified included the lack of random assignment to the delivery modes, sub-optimal image quality and latency with the videoconferencing, and the short-term follow-up, which did not permit the assessment of whether any gains were sustained over a longer duration of time. An additional limitation to this study included a lack of power to detect differences between groups (the authors indicated that 730 participants would have been required to have 80% power to do so). A major limitation to this study was the potential for systematic differences between groups due to the different modes of recruitment used, possible differences between rural and urban residents, differences between the psychologists who delivered the interventions, and the nonstandardized intervention (in terms of content and duration). Further, there was potential for bias in the selection of patients from the waiting lists as this did not appear to be done in a random manner. This could compromise the representativeness of the sample and, hence, the generalizability of the results. As well, the experience of the psychologists in CBT and PTSD could influence generalizability. Finally, the participants in the remote region entered the study via self-referral, which may not make them

representative of the larger population with PTSD as they were likely motivated to seek treatment. Strengths of this study included the use of standardized measures for which evidence of validity and reliability had been previously demonstrated and a therapeutic integrity check to ensure that the principles of CBT were being adhered to in the interventions.

Limitations

The body of evidence comparing the clinical effectiveness of CBT delivered via tele-therapy compared to the traditional face-to-face mode of delivery for the treatment of PTSD is limited. Two studies,^{5,6} which included a total of 86 participants, were identified. The manner in which these studies were conducted could potentially lead to bias and could limit the generalizability of the results beyond the immediate context as outlined in the previous section. No studies on self-directed CBT were identified. Further, there were no studies of cost-effectiveness comparing the alternate delivery modes and usual face-to-face delivery or guidelines as to which patients with PTSD would be best suited to self-directed CBT or tele-therapy.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

The available evidence suggests that the clinical effectiveness of CBT delivered via tele-therapy in group and one-on-one sessions is comparable to face-to-face delivery. As well, overall participant satisfaction appeared to be comparable between the two delivery modes of group session CBT. However, due to issues with methodologies and factors that limit the generalizability of the results, the evidence should be interpreted with caution. No conclusions can be made about the clinical effectiveness of self-directed CBT, the cost-effectiveness of CBT delivered via tele-therapy or in a self-directed manner, or about which patients are best suited to the alternate delivery formats as no literature was identified. Before alternate delivery methods are widely adopted, more research is needed to determine their clinical effectiveness and to help identify which patients could most likely benefit from these approaches. In the absence of access to face-to-face care, however, tele-therapy with CBT may be an alternative used to treat patients with PTSD who would otherwise be without access to such an intervention.

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APPENDIX 1: Study Characteristics of the Randomized Controlled Trial and Non-Randomized Controlled Trial on Tele-Therapy for CBT

Authors, Year	Population	Inclusion/Exclusion Criteria	Intervention/Comparator
Frueh et al., 2007 ⁶	Treatment-seeking male veterans diagnosed with combat-related PTSD Recruited from a veterans medical centre by clinician or self-referral	Meet diagnostic criteria for PTSD Non-psychotic Not abusing alcohol or other substances.	14 weekly, 90-min group CBT sessions for PTSD (Social and Emotional Rehabilitation) Sessions focused on specifically-targeted social skills training (e.g. assertion, social communication, anger management) and activities to increase social participation. Delivered via: 1) Same room (n=17) 2) Tele-therapy (n=21)
Germain et al., 2009 ⁵	Participants selected from wait lists of two anxiety disorders clinics and via self-referral from newspaper advertisements and radio announcements. Multiple types of trauma included	Exclusion: secondary diagnosis of schizophrenia, organic brain disorder, severe personality disorder, intellectual disability, substance abuse or dependency, or physical condition that would contraindicate participation Could not participate in any other form of psychotherapy during the course of treatment.	Weekly, 60 minute sessions over the course of 16 to 25 weeks depending on the type of trauma experienced and severity. Four modules: a psychoeducational module on PTSD (conceptualization of PTSD, information of normal stress reactions), anxiety management training (problem solving, cognitive restructuring, progressive relaxation), imaginary and in vivo exposure to avoided situations, and strategies to prevent a relapse. Participants may not receive all four modules if not necessary.

CBT = cognitive behaviour therapy; PTSD = post-traumatic stress disorder

APPENDIX 2: Study Outcomes and Baseline Characteristics for Studies on Tele-Therapy for PTSD

Authors, Year	Duration of Follow-up	Outcomes Measured	Characteristics of tele-therapy group	Characteristics of face-to-face contact
Frueh et al., 2007 ⁶	3 months	Self-Report Measures <ul style="list-style-type: none"> Life Events Checklist PTSD Checklist-M Symptoms Checklist-90-Revised Beck Depression Inventory Frequency of Social Activities Quality of Social Relationships Process Outcome Measures <ul style="list-style-type: none"> Charleston Psychiatric Outpatient Satisfaction Scale Treatment Credibility Scale Service Delivery Perceptions Homework Completion Attendance Dropouts 	Male Sex: 100% Average Age: 55 ± 5 years African American: 53% Depressive Disorders: 88% Anxiety Disorders: 76% Substance Abuse: 24% Psychotic Disorders: 38%	Male Sex: 100% Average Age: 56 ± 5 years African American: 57% Depressive Disorders: 81% Anxiety Disorders: 71% Substance Abuse: 24% Psychotic Disorders: 24%
Germain et al., 2009 ⁵	Approximately 20 weeks (varied between individuals)	Self-Report Measures <ul style="list-style-type: none"> Modified PTSD Symptom Scale Beck Depression Inventory Beck Anxiety Inventory Assessment of Current Functioning Process Outcome Measures <ul style="list-style-type: none"> Distance Communication Comfort Scale Videoconferencing Telepresence Scale Videoconference Therapy Questionnaires 	Male Sex: 37.5% Average Age: 43 ± 11 years Mood disorders: 12.5% Anxiety disorders: 18.7% Mood and anxiety disorders: 25%	Male Sex: 41% Average Age: 42 ± 12 years Mood disorders: 28.1% Anxiety disorders: 15.6% Mood and anxiety disorders: 21.9%