Q7: Is graded self-exposure based on the principles of cognitive-behavioural therapy better (more effective than/as safe as) than treatment as usual in adults with Post Traumatic Stress Disorder (PTSD) symptoms?

Background

The scoping question is reviewed as part of WHO's efforts to develop an essential mental health care package for use in non-specialized care settings in low-income settings. In order to limit the size of the package, eight conditions have been selected as priority conditions, including depression but none of the anxiety disorders. The package will only cover differential diagnosis of the 8 conditions. Yet, the reality is that patients seek help for a much broader range of problems, including symptoms of posttraumatic stress disorder (PTSD).

PTSD and PTSD symptoms (re-experiencing symptoms, avoidance symptoms and hyperarousal symptoms after exposure to potentially traumatic events) are common after potential traumatic events, especially after interpersonal events (such as being the direct victim sexual or physical violence), car accidents and disabling injury. PTSD and its symptoms are frequently comorbid with depression, especially when PTSD is severe. Yet, PTSD may also occur without comorbidity. Non-specialized health care staff should know how to manage PTSD symptoms In situations where there no or few referral possibilities to specialized care, especially in contexts where large numbers of people have been exposed to potentially traumatic events.

Cognitive-behavioural therapy (CBT) for PTSD is a complex psychological intervention that has been subject to numerous trials (Cahill et al, 2009). One potential component of CBT is graded in vivo exposure to feared, avoided, safe reminders. Graded self-exposure is less complex than CBT proper and thus more likely to be feasible in non-specialized health care settings. A simplified versions of CBT for depression - conducted by community health workers - has previously been shown to be effective in Pakistan (Rahman et al, 2008). The present document covers graded self-exposure based on the principles of CBT. The approach taken in this and other scoping questions that discuss "treatment on the principles of CBT" is that "treatment on the principles of CBT" includes application of specific components of CBT (e.g. reattribution, behavioral activation etc). Existing systematic reviews, however, are on CBT proper and not on their components. The strategy has thus been to study systematic reviews on CBT proper and to consider this as indirect evidence for the components. Thus when the evidence is GRADEd the evidence is downgraded because of its indirectness.

Population/Intervention(s)/Comparator/Outcome(s) (PICO)

Population: adults with PTSD symptoms

Interventions: graded self-exposure based on the principles of cognitive-behavioural therapy

Comparisons: treatment as usual

Outcomes: symptom reduction

adverse effects

List of the systematic reviews identified by the search process

INCLUDED IN GRADE TABLES OR FOOTNOTES

Bisson J, Andrew M. (2007). Psychological treatment of post-traumatic stress disorder (PTSD). Cochrane Database of Systematic Reviews, (3):CD003388.

EXCLUDED FROM GRADE TABLES AND FOOTNOTES

(NICE) (2005).Post-traumatic stress disorder: The management of PTSD in adults and children in primary and secondary care. National Clinical Practice Guideline Number 26. London: The British Psychological Society & The Royal College of Psychiatrists. (Reason for exclusion: The 2008 Cochrane review is more updated. Of note both NICE (2005) and the Bisson & Andrew (2007) Cochrane review were led by the same author.)

Cahill SP et al (2009). Cognitive-behavioral therapy for adults. In Foa EB, Keane TM, Friedman MJ, Cohen JA. Effective treatments for PTSD: Practice Guidelines from the International Society for Traumatic Stress Studies. Second Edition. New York: Guilford Publications. (reason for exclusion: no pooled data presented)

PICO Table

Serial	Intervention/Comparison	Outcomes	Systematic reviews used for	Explanation
no.			GRADE	
1.	Graded self-exposure based on the principles of CBT vs usual care	PTSD symptom severity post intervention Depression symptom severity post intervention Anxiety symptom severity post intervention Adverse effects	Bisson & Andrew (2007)	This is an updated Cochrane review

Narrative description of the studies that went into the analysis

Thirty-three different trials fulfilled the inclusion criteria of Bisson & Andrew (2009) systematic review of which 18 studies covered CBT vs waitlist / usual care. They describe the large body of 32 studies as follows: "The study populations were varied (i.e. there was significant clinical heterogeneity). Six studies included male Vietnam veterans only; twelve studies considered female assault (mainly sexual assault) survivors; two studies included only road traffic accident survivors; one study was of refugees; one of police officers and eleven studies included individuals from various traumas. The majority of participants satisfied the criteria for a DSM diagnosis of PTSD although some studies included individuals with traumatic stress symptoms who did not fulfill the full DSM criteria. The Vietnam veteran studies were largely from samples of individuals already in care. Other studies often advertised for their participants or used referrals to an established traumatic stress service. The cultural Settings were Anglo-Saxon or Northern European: United States of America (23 studies), Australia (2 studies), United Kingdom (3 studies), The Netherlands (2 studies), Germany (1 study) and Canada (2 studies). The number of patients randomized to the trials ranged from 16 to 360. Four studies included sample sizes of over 100. All studies included individuals at least three months following the trauma (3 months to 30+ years). Most studies did not provide full details of the method of randomization. Blinding of the assessor of outcome measures was performed in 20 of 32 studies. Loss to follow-up was fully reported in eleven studies."

GRADE Tables

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Question: Should graded self-exposure based on the principles of CBT vs treatment as usual be used for symptoms of PTSD?

Settings

Bibliography: Bisson J, Andrew M. (2007). Psychological treatment of post-traumatic stress disorder (PTSD). Cochrane Database of Systematic Reviews,

(3):CD003388.

Quality assessment						Summary of findings						
						No of patients Effect			Importance			
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	graded self-exposure based on the principles of CBT	treatment as usual	Relative (95% CI)	Absolute	Quality	
PTSD symptom severity post intervention (Better indicated by lower values)												

	randomised trials	no serious limitations ²	serious ³	serious ⁴	no serious imprecision	reporting bias ⁵	236	192 ⁶	-	SMD 1.68 lower (2.14 to 1.22 lower) ⁷	⊕OOO VERY LOW	CRITICAL
Depression symptom severity post intervention (Better indicated by lower values)												
	randomised trials	no serious limitations ²	very serious ⁹	serious⁴	no serious imprecision	reporting bias⁵	350	275 ⁶	-	SMD 1.26 lower (1.69 to 0.82 lower)	⊕OOO VERY LOW	IMPORTANT
Anxiety symptom severity post intervention (Better indicated by lower values)												
	randomised trials	no serious limitations	no serious inconsistency	serious ⁴	no serious imprecision	reporting bias ⁵	224	191 ⁶	-	SMD 0.99 lower (1.2 to 0.78 lower)	⊕⊕OO LOW	IMPORTANT
Safety												
	no evidence available					None	0/0 (0%)	0%	RR 0 (0 to 0)	0 fewer per 1000 (from 0 fewer to 0 fewer)		IMPORTANT

Analysis 1.1 subgroup 2 (self-reported data) of the Bisson & Andrew (2009) Cochrane review.

² Drop outs are low (all trials less than 30% DO, see Analysis 1.4 of the Bisson & Andrew (2009) Cochrane review).

³ I-squared is 73%.

⁴ The scoping question is about a population of people with presenting PTSD symptoms, while the review is about people with PTSD as a disorder. Also the reviewed evidence is for CBT proper, while the specific intervention of interest is a component of CBT.

⁵ Inspection of the funnel plots suggest some asymmetry for PTSD symptoms (Figures 1 pages 15 of the Bisson & Andrew (2009) Cochrane review). It is assumed that this asymmetry generalizes and is also there for other outcomes (eg depression).

⁶ The control group is Waitlist/Usual care in Bisson & Andrew (2009) Cochrane review analyses.

⁷ Of note this Bisson & Andrew (2009) Cochrane review also compared CBT vs waitlist with no significant differences for PTSD or depression, although CBT did better at 2-5 months.

⁸ Analysis 1.2 of the Bisson & Andrew (2009) Cochrane review.

⁹ I-squared is 81%.

¹⁰ Analysis 1.3 of the Bisson & Andrew (2009) Cochrane review.

Reference List

Basoglu M et al (2005). Single-session behavioral treatment of earthquake-related posttraumatic stress disorder: a randomized waiting list controlled trial. *Journal of Traumatic Stress*, 18:1-11.

Bisson J, Andrew M. (2007). Psychological treatment of post-traumatic stress disorder (PTSD). Cochrane Database of Systematic Reviews, (3):CD003388.

Cahill SP et al (2009). Cognitive-behavioral therapy for adults. In Foa EB, Keane TM, Friedman MJ, Cohen JA. Effective treatments for PTSD: Practice Guidelines from the International Society for Traumatic Stress Studies. Second Edition. New York: Guilford Publications.

(NICE) (2005). Post - traumatic stress disorder: The management of PTSD in adults and children in primary and secondary care. National Clinical Practice Guideline Number 26. London: The British Psychological Society & The Royal College of Psychiatrists.

Rahman A et al (2008). Cognitive behaviour therapy-based intervention by community health workers for mothers with depression and their infants in rural Pakistan: a cluster-randomised controlled trial. *Lancet*, **372:902-9**.

Richard MH et al (2004). Risky and protective contexts and exposure to violence in urban African American young adolescents. *Journal of Clinical Child and Adolescent Psychology*, 33:138-48.

From evidence to recommendations

Factor	Explanation					
Narrative summary of the	There is very low quality evidence for a large effect favoring graded self-exposure based on the					
evidence base on the scoped	principles of CBT over care as usual for the reduction of PTSD symptoms ($N = 9$; $n = 428$; SMD - 1.68					
question	(95% CI -2.14 to -1.22) and depression symptoms (N = 14; n = 625; SMD = - 1.26 l (95% CI - 1.69 to -					
	0.82)					
	There is very low quality evidence for a large effect favoring graded self-exposure based on the principles of CBT over care as usual for the reduction of anxiety symptoms ($N = 11$; $N = 415$; $N = -11$) and $N = -11$.					

	0.99 (95% CI - 1.20 to -0.78).
Summary of the quality of evidence on the scoped question	Very low (see GRADE Table)
Additional evidence (eg related evidence that was not scoped	The Cahill et al review (2009, p. 194) specifically identified and reviewed 2 studies that studied in vivo exposure (Richards et al, 2004; Basoglu, 2005) - identifying substantial improvement in PTSD symptoms.
Balance of benefits versus harms	No meta-analyzed data are available for adverse effects. However, harm cannot be ruled out, especially in situations where there is no follow-up support to see how patients fared and to provide further clinical care.
Define the values and preferences including any variability and human rights issues	A key concern with clinical presentations of PTSD symptoms is the inappropriate use of any non-evidence based therapies. Providing an evidence-informed alternative treatment has benefits beyond therapeutic efficacy in reducing the use of non-evidence based treatments with adverse health consequences. Psychological treatment based on CBT principles has value in that it may possibly build the capacity of the person to address stressors and unpleasant cognitive and emotional experiences in the long-term.
Define the costs and resource use and any other relevant feasibility issues	There are likely costs of training and therapist time; and opportunity costs of travel and time for sessions.
Final recommendation(s)	

Final recommendation(s)

If it is possible to continue to follow-up the patient, graded self-exposure based on the principles of cognitive-behavioural therapy should be considered in adults with PTSD symptoms.

Strength of recommendation: STANDARD		

Update of the literature search – June 2012

In June 2012 the literature search for this scoping question was updated. The following systematic reviews were found to be relevant without changing the recommendation:

NICE National Clinical Guideline Number 123. Common Mental Health Disorders. National Institute for Health and Clinical Excellence, 2011

NICE National Clinical Guideline Number 113. Generalized Anxiety Disorders. National Institute for Health and Clinical Excellence, 2011