Psychological treatment based on cognitive-behavioural therapy principles for managing medically unexplained somatic complaints

Q1: Is psychological treatment based on cognitive-behavioural therapy principles (such as reattribution, graded activities) better (more effective in symptom reduction) than treatment as usual for managing medically unexplained somatic complaints (in absence of depression)?

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 not medically unexplained somatic complaints (or medically unexplained complaints, MUCs). The package will not cover differential diagnosis of somatoform disorders and functional somatic syndromes, which are a common source of MUCs.

Patients seek frequently help for MUCs in medical care across cultures (Kirmayer & Young (1998); Simon & Gureje (1999)). In the context of the essential mental health care package, clinicians will be expected - as part of routine adequate clinical care - to rule out medical causes through necessary investigations and treat/refer when an underlying physical disease is suspected. When necessary investigations are negative and when no underlying physical disease is suspected, the clinician would need guidance on how to manage the MUC.

In the package, depression is a priority condition. Accordingly, when MUCs are comorbid with depression, depression would be treated first (see scoping questions on depression for further information). MUCs frequently also occur without depression - or despite treatment of depression.

Cognitive-behavioural therapy (CBT) for MUCs is a therapy that is typically studied when administered by specialized clinicians. Yet, its components (e.g. reattribution, graded activities) may be applied for the management of MUCs in non-specialized care (Goldberg et al, 1989). This scoping question will address CBT for MUCs.

Of note, the scoping questions covers a highly diverse literature because MUCs are part of presentations of functional somatic syndromes, sub-threshold or full somatoform disorders, mood and anxiety disorders, and/or yet-to-be identified physical or neurological disorders, amongst others.

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, behavioural 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 that the components work (in questions involving GRADEing these reviews have been downgraded).

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

Population:	adults with medically unexplained somatic complaints
Interventions:	psychological treatment based on CBT principles
Comparisons:	usual care
Outcomes:	treatment effectiveness in reducing medically unexplained somatic complaints
	improvement in functioning
	adverse effects

List of the systematic reviews identified by the search process

INCLUDED IN GRADE TABLES OR FOOTNOTES

Deary V, Chalder T, Sharpe M (2007). The cognitive behavioural model of medically unexplained symptoms: a theoretical and empirical review. *Clinical Psychology Review*, 27:781-97.

Kroenke K (2007). Efficacy of treatment for somatoform disorders: a review of randomized controlled trials. *Psychosomatic Medicine*, 69:881-8.

(comment: despite the title, it reviews 10 studies on MUCs)

EXCLUDED FROM GRADE TABLES AND FOOTNOTES

Allen L et al (2002). Psychosocial treatments for multiple unexplained physical symptoms: a review of the literature. *Psychosomatic Medicine,* 64:939-50. (Reason for excluding: relatively old review)

Burton C (2003). Beyond somatisation: a review of the understanding and treatment of medically unexplained physical symptoms (MUPS). .*British Journal of General Practitioners*, 53:231-9. (Reason for excluding: relatively old review)

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Henningsen P, Zipfel S, Herzog W (2007). Management of functional somatic syndromes. *Lancet*, 369:946-55. (Reasons for excluding: (a) covers functional somatic syndromes only (b) search strategy poorly describes inclusion/exclusion criteria)

Jackson J, O'Malley P, Kroenke K (2006). Antidepressants and cognitive-behavioural therapy for symptom syndromes. *CNS Spectrums*, 11:212-22. (reason for excluding: older than other review by same author: Kroenke (2007)

Kroenke K, Swindle R (2000). Cognitive-behavioral therapy for somatization and symptom syndromes: a critical review of controlled clinical trials. *Psychotherapy and Psychosomatics*, 69:205-15. (Reason for excluding: relatively old review)

Looper K, Kirmayer L (2002). Behavioral medicine approaches to somatoform disorders. *Journal of Consulting and Clinical Psychology,* 70:810-27. (Reason for excluding: relatively old review)

Nezu AM, Nezu CM, Lombardo ER (2001). Cognitive behavioural therapy for medically unexplained symptoms: a critical review of the treatment. *Behaviour Therapy,* 32:537-83. (Reason for excluding: relatively old review)

Raine R et al (2002). Systematic review of mental health interventions for patients with common somatic symptoms: can research evidence from secondary care be extrapolated to primary care? *British Medical Journal*, 325:1082. (Reason for excluding: relatively old review)

Sumathipala A (2007). What is the evidence for the efficacy of treatments for somatoform disorders? A critical review of previous intervention studies. *Psychosomatic Medicine*, 69:889-900.

Dimsdale JE et al (2009). Somatic Presentations of Mental Disorders: Refining the Research Agenda for DSM-V. Arlington, VA: American psychiatric Association. (Reasons for excluding: (a) most of the studies covered overlap with those identified by Kroenke (2007) and Deary et al (2007) and (b) data on the wider category of MUCS presented intermixed with results on those for somatic syndromes)

Narrative description of the studies that went into the analysis

What follows is a description of the 2 aforementioned reviews. The description is limited to studies on MUCs that have not been identified as being part of somatoform disorders or functional somatic syndromes. However, it is noted that all of the reviews provided similar positive evidence for CBT for the category MUCs as for the categories somatoform disorders and functional somatic syndromes.

Review 1: Deary V et al (2007)

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The direct evidence on CBT is described by the review as following:

" In the last five years four systematic reviews of treatment studies have been published (Kroenke & Swindle, 2000; Allen et al, 2002; Looper & Kirmayer, 2002; Raine et al, 2002) of the MUCs literature, each with a slightly different slant. Allen et al, (2002) took the self-declaredly controversial approach of combining all the RCTs of general psychosocial treatments for medically unexplained symptoms (MUS), Irritable bowel syndrome (IBS), chronic fatigue syndrome (CFS) and fibromyalgia into one analysis. Their aggregate analysis found that overall treatment effect sizes are “modest at best” with few intention to treat analyses and very little definition of clinically significant improvement across conditions. Theirs is the most pessimistic analysis, and includes non-CBT therapies. The overall conclusion of the other reviews is for a modest effect size of CBT for MUCs, smaller than in anxiety and depressive disorders, but still clinically significant."

The paper then proceeds with a specific analysis of papers on "general medically unexplained symptoms" (as opposed to CFS or IBS).

"[In a systematic review] Looper & Kirmayer (2002) reported three randomized controlled trials of individual CBT for primary care patients presenting with medically unexplained symptoms and concluded that CBT demonstrated a moderate effect size [ranging between 0.36 and 0.54] for reduction in somatic symptoms. Two of these studies also reported a significant reduction in psychological distress, one did not. In addition they reported on Hellman et al (1990) randomized study of two CBT groups compared to an attention control group. Both CBT groups produced significant reductions in somatic symptoms and distress, this effect being largest in the group that specifically addressed illness behaviours and beliefs. Kroenke (2007) also reported on Lidbeck (1997) randomized trial of a group treatment in primary care which produced decreased symptom pre-occupation and medication use compared to a waiting list control. There was no observed effect on psychological distress, though in a follow up study Lidbeck (2003) reported that improvement in somatic preoccupation was maintained and that there was additional reduction in anxiety measures. Since these reviews were published, other studies have been reported. Larisch et al (2004) studied the effects of a re-attribution intervention delivered by 23 trained general practitioners (GPs), comparing their patient outcomes to 19 untrained GPs. They found no significant impact on psychological symptoms (both Kroenke & Swindle, 2000; Allen et al, 2002 noted this general trend) but some improvement in physical symptoms. Bleichhardt et al (2004) and Hiller et al (2003) both performed RCTs in tertiary care with CBT having small but significant effects on physical symptoms and Hospital Anxiety and Depression (HAD) scores. In summary there is evidence for a moderate beneficial effect of CBT for MUS in general. "

Review 2. Kroenke,K (2007)

Kroenke' search identified 5 studies on CBT for MUCs.

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Reference	N	Treatment, No. Sessions (hrs)	Control	Follow-up (mo)	Effect size (somatic complaints)/comment
Hellman et al (1990)	61	CBT-group, 6 (1.5 hr)	Stress management	6	0.38-0.88 (depending on outcome)
Speckens et al (1995)	79	CBT, 6 to 16 (1 hr)	Usual care	12	0.54 (at 6 months), 0.36 (12 months)
Lidbeck (1997)	50	CBT-relaxation, 8 (3 hr)	Wait list	6	less medication
McLeod et al (1997)	36	CBT-group, 6	Waitlist	6	0.43
Martin et al (2007)	140	CBT-group, 1 (3.5 hr)	Wait list	6	less utilization/medication

A total 3 of 5 studies found positive results for CBT in terms of somatic complaints and 2 had effects on medication use.

Methodological limitations of the systematic reviews

- They cover a highly diverse literature (e.g., individual MUCs, functional somatic syndromes, somatoform disorders)
- None of the recent reviews provided meta-analyzed effect sizes – likely due to the diversity of the studied populations. The evidence was thus not GRADEd
- All of the reviews recommended CBT – irrespective whether the MUC was a stand alone complaint, or part of functional somatic syndromes or somatoform disorder.
- None of the reviews distinguish between (a) MUCs with comorbid depression and (b) MUCs without comorbid depression. The evidence is thus indirect given that the scoping question is on MUCS without comorbid depression.

Additional relevant information

Raine et al (2002) in a systematic review of the effectiveness of mental health interventions for patients with common somatic symptoms found that CBT and behaviour therapy were effective in both primary and secondary care in patients with back pain, although the evidence is more consistent and the effect size larger for secondary care. The authors explanations for this finding included (a) people in secondary care were more ill and (b) people in secondary care got more (sessions of) treatment.

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Sumathipala et al (2000, 2008) conducted 2 trials on CBT in Sri Lanka. In both trials the intervention group received six, 30 min sessions based on the principles of cognitive-behavioural therapy over a period of 3 months. The control group received standard clinical care. In the first, small trial, the intervention was conducted by specialist who received referrals from PHC and the intervention was compared with usual care. In the second, larger trial, the intervention was conducted by primary health care (PHC) physicians, with a control group receiving structured care (same intensity as treatment group but then without elements of CBT). In both trials patients treated with CBT improved substantially but in the second trial the control group (receiving structured care) improved as much as the CBT group.

A larger amount of evidence exists specifically for CBT for functional somatic syndromes. For example, a Cochrane Review on psychological treatments for the management of irritable bowel syndrome concluded that that cognitive behavioural therapy may be effective immediately after finishing treatment (Zijdenbos et al, 2009). The standardized mean difference (SMD) for symptom score improvement at 3 months was 0.58 (95% CI 0.36 to 0.79) respectively compared to usual care. Yet, the same review also highlighted that it was unclear whether the effects of these therapies are sustained thereafter.

BMJ Clinical Evidence (Reid et al, 2008**)** classified CBT as beneficial for chronic fatigue syndrome with quality of evidence rated as low (for overall improvement after 5 years) or very low (for the outcomes quality of life, functioning and fatigue) with no information on adverse effects.

A narrative review by Henningsen et al, 2007 in The Lancet identified positive effects of CBT in a wide range of functional syndromes. The evidence of CBT from functional syndromes converges with the evidence for CBT for MUCs.

Reference List

Allen L et al (2002). Psychosocial treatments for multiple unexplained physical symptoms: a review of the literature. *Psychosomatic Medicine,* 64:939-50.

Bleichhardt G, Timmer B, Rief W (2004). Cognitive-behavioural therapy for patients with multiple somatoform symptoms — a randomized controlled trial in tertiary care. *Journal of Psychosomatic Research,* 56:449–54.

Burton C (2003). Beyond somatisation: a review of the understanding and treatment of medically unexplained physical symptoms (MUPS). .*British Journal of General Practitioners*, 53:231-9.

Deary V, Chalder T, Sharpe M (2007). The cognitive behavioural model of medically unexplained symptoms: a theoretical and empirical review. *Clinical Psychology Review*, 27:781-97.

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Gask L et al (1988). Improving the psychiatric skills of the general practice trainee: an evaluation of a group training course. *Medical Education*, 22:132-8.

Goldberg D, Gask L, O'Dowd T (1989). The treatment of somatisation: teaching the skills of reattribution. *Journal of Psychosomatic Research,* 33: 689-95.

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Henningsen P, Zipfel S, Herzog W (2007). Management of functional somatic syndromes. *Lancet*, 369:946-55.

Hiller W, Fichter M, Rief W (2003). A controlled treatment study of somatoform disorders including analysis of healthcare utilization and costeffectiveness. *Journal of Psychosomatic Research,* 54:369−80.

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Larisch A (2004). Psychosocial interventions for somatizing patients by the general practitioner: a randomized controlled trial. *Journal of Psychosomatic Research,* 57:507−14.

Lidbeck J (1997). Group therapy for somatisation disorders in general practice: effectiveness of a short cognitive-behavioural treatment model. *Acta Psychiatrica Scandinavica,* 96:14−24.

Lidbeck J (2003). Group therapy for somatisation disorders in primary care: maintenance of treatment goals of short cognitive-behavioural treatment one-and-a-half-year follow-up. *Acta Psychiatrica Scandinavica,* 107:449−56.

Looper K, Kirmayer L (2002). Behavioral medicine approaches to somatoform disorders. *Journal of Consulting and Clinical Psychology,* 70:810-27.

Martin A et al (2007). A one-session treatment for patients suffering from medically unexplained symptoms in primary care: a randomized clinical trial. *Psychosomatics,* 48:294-303.

McLeod CC, Budd MA, McClelland DC (1997). Treatment of somatization in primary care. *General Hospital Psychiatry,* 19:251-8.

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Raine R et al (2002). Systematic review of mental health interventions for patients with common somatic symptoms: can research evidence from secondary care be extrapolated to primary care? *British Medical Journal*, 325:1082.

Reid SF et al (2008). Chronic Fatigue Syndrome. *BMJ Clinical Evidence,* 2008:1101

Simon G, Gureje O (1999). Stability of Somatization Disorder and Somatization Symptoms Among Primary Care Patients. *Archives of General Psychiatry,* 56:90-95.

Speckens AEM et al (1995). Cognitive behavioural therapy for medically unexplained physical symptoms: a randomized controlled trial. *British Medical Journal,* 311:1328 –32.

Sumathipala A (2007). What is the evidence for the efficacy of treatments for somatoform disorders? A critical review of previous intervention studies. *Psychosomatic Medicine*, 69:889-900.

Sumathipala A et al (2000). Randomized controlled trial of cognitive behaviour therapy for repeated consultations for medically unexplained complaints: a feasibility study in Sri Lanka. *Psychological Medicine,* 30:747–57.

Sumathipala A **et al (2008**).Cognitive-behavioural therapy v. structured care for medically unexplained symptoms: randomised controlled trial. ***British Journal of Psychiatry,*** 193:51-9.

Zijbendos IL et al (2009). Psychological treatments for the management of irritable bowel syndrome. ***Cochrane Database of Systematic Research Reviews,* (1):CD006442.**

From evidence to recommendations

Factor	Explanation
Narrative summary of the	Although no meta analyses exist, there is consistent positive evidence for CBT for MUCS.

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evidence base	
Balance of benefits versus harms	A common concern about advice on MUCs in a mental health package is the incorrect message to the outside world and to the non-specialized staff that all MUCs result - fully or in part - from psychological factors. This may lead to the neglect of necessary tests/examinations and of referrals. Any advice on psychological treatment based on CBT principles needs to be phrased in such a way to minimize the chance of such harm.
Define the values and preferences including any variability and human rights issues	The key concern with clinical presentations of MUCs is the inappropriate use of investigations and pharmacotherapies (e.g. hypnotics) leading to increased costs of care (often borne by patients) and possible iatrogenic problems. Providing an evidence-based alternative treatment has benefits beyond therapeutic efficacy in reducing the use of non-evidence based treatments with adverse economic and 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. Balanced against this is the cost of inappropriate use of a variety of investigations and pharmacotherapies. Little is known about the feasibility of CBT in non-western settings where much mental health care is provided in primary care settings and is often financed out-of-pocket. In socialized health care systems with relatively strong primary mental health care systems, these issues may be of less concern.

Final recommendation(s)

Psychological treatment based on cognitive-behavioural therapy principles (such as reattribution, graded activities) should be considered in repeat adult help seekers with medically unexplained somatic complaints who are in substantial distress and who do not meet criteria for depressive episode/disorder.

Strength of recommendation: STANDARD

Update of the literature search – June 2012

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

Allen LA, Woodfolk RL. Cognitive behavioral therapy for somatoform disorders. Psychiatr Clin North Am. 2010 Sep;33(3):579-93.