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Randomized controlled trial of cognitive behaviour therapy for repeated consultations for medically unexplained complaints: a feasibility study in Sri Lanka

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ABSTRACT

Background. Research on the management and the outcome of treatment of medically unexplained symptoms is very limited. Development of simple but effective techniques for treatment and demonstration of their effectiveness when applied in primary health care are needed.

Methods. A randomized controlled trial was carried out with follow-up assessments at 3 months after baseline assessments using the Short Explanatory Model Interview (SEMI), General Health Questionnaire (GHQ-30), Bradford Somatic Inventory (BSI) and patient satisfaction on a visual analogue scale. The study was carried out in a general out-patient clinic in Sri Lanka.

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.

Results. Eighty patients out of the 110 patients referred, were eligible. Sixty-eight were randomly allocated equally to the control and treatment groups. All 34 in the treatment group accepted the treatment offer and 22 completed between three and six sessions. At 3 months, 24 in the treatment and 21 in the control group completed follow-up assessments. Intention-to-treat analysis revealed significant differences in mean scores of outcome measures (adjusted for baseline scores) between control and intervention groups respectively – complaints 6·1 and 3·8 ($P = 0{\cdot}001$), GHQ 10·4 and 6·3 ($P = 0{\cdot}04$), BSI score 15·6 and 13·2 ($P \leqslant 0{\cdot}01$), visits 7·9 and 3·1 ($P = 0{\cdot}004$).

Conclusions. Intervention based on cognitive behavioural therapy is feasible and acceptable to patients with medically unexplained symptoms from a general out-patients clinic in Sri Lanka. It had a significant effective in reducing symptoms, visits and distress, and in increasing patient satisfaction.

INTRODUCTION

Somatic symptoms unexplained by physical diagnosis are a heterogeneous group (Bass & Benjamin, 1993), and occur with depressive disorder, anxiety disorder, hypochondriasis and the other somatoform disorders (Goldberg & Huxley, 1980; Srinivasan & Srinivasan, 1986; Chandrasekar *et al.* 1987; Mayou, 1991; Bass & Benjamin, 1993; Üstün & Sartorius, 1995). They are common throughout the world (Goldberg & Huxley, 1980; Srinivasan & Srinivasan, 1986; Chandrasekar *et al.* 1987; Bass & Benjamin, 1993; Üstün & Sartorius, 1995) but less well described in the developing world (Harding *et al.* 1980; Chandrasekar *et al.* 1987; Üstün & Sartorius, 1995). Some of these patients repeatedly consult health-care providers (Harding

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et al. 1980; Srinivasan & Srinivasan 1986; Chandrasekar *et al*. 1987; Üstün & Sartorius, 1995) and this problem is expensive in terms of the disproportionate consumption of health resources and its cost (WHO, 1984; Smith, 1986; Shaw & Creed, 1991). Research on the best management and the outcome of treatment of this clinical problem is very limited (Mann *et al*. 1981; Smith, 1986; Liposki, 1988; Goldberg *et al*. 1989; WHO, 1990; Sharpe *et al*. 1992).

The International Study of Mental Illness in General Health Care (Üstün, & Sartorius, 1995) recommended the development of techniques for treatment and demonstration of their effectiveness when applied in primary health care. Cognitive behavioural therapies (CBT) focus on teaching people how to control their presenting complaints of disturbed emotions, thoughts and behaviours (Andrews, 1991). However, only one recently conducted randomized controlled trial (Speckens *et al*. 1995) using CBT for patients with medically unexplained complaints (as a heterogeneous group) could be identified.

In keeping with this aim, a study of cognitive behavioural therapy in Colombo, Sri Lanka was carried out under optimal conditions using a psychiatrist trained in cognitive behavioural therapy. Sri Lanka is an island with a population of 18 million and a literacy rate of 92%, (Annual Health Bulletin of Sri Lanka, 1997).

METHOD

Study setting

The study was conducted in a general outpatient clinic that provided primary care, at Sri Jayewardenepura General Hospital, Colombo, where patients initiated their own visits, without prior appointments. Patient recruitment took place from consecutive patients attending the clinic from 15 December 1997 to the end of March 1998, the treatment and reassessments continued until the end of June 1998.

Screening and checking for eligibility

The primary-care doctor in his/her routine consultation sessions identified patients who had repeated consultations for medically unexplained symptoms. Patients between the ages of 16–65 years, were referred to the research psychiatrist (A. S.) to establish whether inclusion criteria, were satisfied. Those patients who were selected had the project, including the random treatment assignment, explained to them. The non-clinical research assistant (S. W.) obtained informed consent. Usually the patients were seen on the same day or given next available appointment, usually within a week, depending on whether they were one of the 15 randomly assigned to be co-assessed by the other psychiatrist. Patients who refused or who did not fulfil inclusion criteria were referred back to the primary care doctor with a report.

Subjects

Inclusion criteria

Patients with medically unexplainable multiple complaints were defined as having $\geqslant 5$ medically unexplainable complaints. Medically unexplained symptoms were defined as 'Incompatibility of the clinical presentation with a known physical illness and/or absence of relevant positive physical signs and/or laboratory investigations not supporting a diagnosis of a physical illness'.

A comprehensive physical examination was also carried out by A. S. Previous laboratory investigation results were rescrutinized. Patients with overt disease were excluded.

A symptom was defined as 'a distinctive subjective sensation or a personal observation in relation to the body, which the patient describe as abnormal'. Even if the same symptom (e.g. pain) was experienced at different anatomical sites it was counted as a separate symptom. Different symptoms in the same anatomical site were counted as separate symptoms (Sumathipala, 1990).

To determine the number of presenting complaints two specific open-ended questions were used (Sumathipala, 1990): (*i*) What are your symptoms/problems, why are you here today?; and, (*ii*) Are there any other symptoms/problems? The second question was asked only after the first question had been answered. The above strategy was used to standardize the manner in which the complaints were generated.

A consultation was defined as an encounter between the patient and a person who practices Western or traditional medicine as a profession. The number of consultations during the previous 6 months, as reported by the patient, was noted

during the index consultation. If the patient had consulted a health-care provider at least once during the immediate 6 months preceding the index consultation for the same symptoms, then the index consultation was considered as a repeat consultation. Any available hospital records, other forms of documentation including prescriptions, investigation results or brief notes were used to verify the information.

Exclusion criteria

Patients with organic psychiatric disorders such as dementia, alcohol dependence, psychosis, or active suicidal thoughts and those currently having psychiatric treatment were excluded.

Assessments and instruments

Enrolled patients were interviewed by A. S. using the Short Explanatory Model Interview (SEMI) (Lloyd *et al*. 1998) and its case vignettes. This instrument elicits the patient's explanatory model by a brief interview, generating data on, assumptions, beliefs, thoughts about their illness and its causes, fears about their future, reduction in usual functions and increase in dysfunctional behaviours including details of medical and other care utilization, and the patient's expectations and satisfaction. The second research psychiatrist (R. H.) as an observer, co-rated 13 (out of an expected 15) randomly selected out of the total of 68 patients, for reliability and comparability.

The non-clinical research assistant (S. W.) completed, a translated version of the Social Stress and Support Interview (SSSI) (Jenkins *et al*. 1981) (data are not included in this paper), a translated version of the Bradford Somatic Inventory (BSI) (Mumford *et al*. 1991) and also recorded sociodemographic data. The patients were then requested to complete the Sri Lankan version (Sinhala) of the General Health Questionnaire-30 (GHQ-30) (Goldberg & Blackwell, 1970). The translated version has been validated (De Silva & Samarasingha, 1990) and used in Sri Lanka (Sumathipala, 1990; De Silva, 1990; De Silva & Samarasingha, 1990). A cut-off score of 6/7 was used. The patient then provided information on satisfaction with previous treatment on a visual analogue scale of 0–5 and, if a carer was present, the non-professional carer's satisfaction was also assessed on a visual analogue scale of 0–5.

Finally, two specially designed diaries were issued to each patient; the first one was to record consultations, symptoms, investigations and treatment by any other doctor during the study period, a typewritten request being made in the diary for the doctors to note these details of consultations. The other diary was for the patient to record their own symptoms, associated cognitions and behaviours during the study period.

Randomization

An epidemiologist who did not take part in the data collection was responsible for randomization. The patients were allocated to the intervention and non-intervention groups by simple randomization, taking the individual patient as a unit. A list of treatment assignments was prepared in advance using simple randomization by random numbers generated from a calculator. These were available in 68 sealed opaque envelops bearing sequential registration numbers on the outside of the envelope. The patient was registered at the time of enrolment into the study, but the corresponding sealed envelope was not opened until the end of the baseline assessment. A. S. opened the envelope to reveal the random treatment allocation. The non-clinical research assistant (S. H.) and the second psychiatrist (R. H.) remained blind to the group status throughout the study.

Intervention

Strategy

The intervention aimed to 'contain' the patient at the level of detection in primary care, by offering structured regular visits to one professional carer thereby hoping to reduce unstructured visits to different practitioners and coordinating the care. The treatment was based on the principles of cognitive behavioural therapy, using modifications of that described by Salkovskis (1989) and Sharpe *et al*. (1992) and Goldberg *et al*.'s (1989) reattribution technique. Through structured sessions, patients were made aware of the psychological component of their condition, and helped to reduce unnecessary medical consultations and investigations. When possible, one non-professional carer (Sharpe *et al*. 1992; Bass & Benjamin, 1993) usually the spouse, was involved; and the nature of the patients difficulties were explained to the carer,

to prevent inappropriate discussions with ill-informed relatives and friends, who could reinforce the preoccupation of the patient that serious illness was present. Diary-keeping was used as an appropriate means of expressing distress, identifying dysfunctional cognition, and also to provide a basis for monitoring symptoms for therapeutic use in cognitive behavioural modification. Through these cognitive and behavioural strategies the patient was encouraged to take responsibility and control over his/her dysfunctional thinking and behaviour. The intervention group was managed by a research psychiatrist (A. S.) using the above specified intervention strategy. A treatment manual was prepared to keep the therapeutic sessions uniform. The CBT was offered in six half-hourly structured sessions over the next 3 months following the baseline assessment. Treatment started either on the same day after assessment, or within the same week.

Management of controls

The controls received assessments but no intervention in terms of a structured therapy. They continued care from their usual carers and could visit the doctors of their choice. As there are no practice lists or registration with a particular general practitioner in Sri Lanka, it was anticipated that they would visit several practitioners (Sumathipala, 1990; Sharpe *et al.* 1992). Initially, they were referred back to the primary-care doctor, who had originally referred the patient. The controlled group received appointments for a follow-up assessment after 3 months.

Outcome variables

These were: (1) level of distress/psychiatric morbidity as measured by the GHQ-30; (2) symptom score assessed by BSI and by the two open-ended questions; (3) the number of, patient initiated visits; and, (4) the patient's perceived satisfaction. A. S. administered, the two initial open-ended questions to elicit the number of complaints and details of medical care utilization since the index assessment. A random sample was co-rated by the second psychiatrist (R. H.) during their follow-up assessment. The non-clinical research assistant administered the Bradford Somatic Inventory and case vignettes from SEMI. The patient completed the GHQ-30. The patient's perceived satisfaction was assessed again by a visual analogue scale of 0–5 and if present, the non-professional carer's satisfaction too was by a visual analogue scale of 0–5.

Sample size calculation

Based on the data from a previous study by Sumathipala (1990) a power analysis was carried out. Assuming the symptoms mean as 6·69 (S.D. 2·1) in the index group, $N = 10$ per group for a simple end-to-end treatment comparison showed a power of 0·8 using a 0·01 level of significance (clinically significant), for an effect size of 0·5 for symptoms, (i.e. control means = 6·69, S.D. 2·1, intervention group mean = 3·32, $> 50\%$ reduction in the mean symptom count). Similarly, based on same study $N = 34$ per group for a simple end-to-end comparison showed a power of 0·8 using a 0·01 level of significance for an effect size of 0·5 for the mean number of consultations (control group mean visits = 8·96, S.D. 8, intervention group mean = 2·21). Therefore, we recruited 34 patients for each group.

Statistical analysis

Baseline differences of assessments were anlaysed with two-tailed t test for independent samples for continuous variables and chi-square tests for cross-tables in categorical variables.

To determine the efficacy of the treatment, comparison of the outcome measures between intervention and control groups, was carried out by two analyses. The first was by including all patients randomized, on the intention to treat basis, ignoring drop-out and non-available at 3 months follow-up assessment. The Last Observation Carried Forward method was applied on data not available at 3 months assessment. In this method it was assumed that non-available patients continued unchanged.

The second analysis was a less conservative method for comparison of outcome, between intervention and control patients who were available for follow-up assessment at 3 months (protocol analysis). Here the assumption was that the unavailable patients were similar to the available ones.

The continuous data was analysed using general factorial ANOVA, in which the outcome

variable scores were adjusted by using corresponding baseline readings as a covariant. Similarly, all outcome variables were analysed individually as above.

Because of the issues surrounding the handling of missing data by 'last observation carried forward' method during intention-to-treat analysis, a *post hoc* 'sensitivity analysis' was carried out by substituting the worst possible reading for all missing values to see whether the results would still be the same.

Overall design of the study

The study was carried out in a general out-patients clinic. The subjects were patients with medically unexplained multiple complaints and repeated consultations during the previous 6 months. The primary-care doctors identified the suitable patients and referred them to the research psychiatrist (A. S.) to establish whether inclusion criteria, were satisfied. If they were, informed consent was obtained. Unsuitable and non-consenting patients were referred back to the primary-care doctor. The patients were then randomly allocated to the intervention and non-intervention groups. However, random assignment into either group was not revealed until the base-line assessment was completed. The non-clinical research assistant and the second psychiatrist remained blind to the group status throughout the study period.

Patients were then assessed with the Short Explanatory Model Interview (EMI) and its case vignettes by the research psychiatrist (A.S.). The second research psychiatrist (R.H.) rated a randomly selected sub-sample of patients as an observer, for reliability and comparability.

The non-clinical research assistant conducted the remaining parts of the assessment and also collected sociodemographic data. He then issued two specially designed diaries to each patient. One to record consultations, symptoms, investigations and treatment if they visited any other doctor during study period. A typewritten request was made in the diary for the doctors to note these details of consultations. The other diary was to record symptoms, associated cognitions and behaviours by the patient himself.

Patients in the intervention group received six appointments over the next 3 months for CBT and an appointment for re-assessment at the end of the treatment. Control patients received an appointment for re-assessment at 3 months and they were referred back to the primary-care doctors in the out-patient clinic for further management.

RESULTS

Feasibility of recruitment

The total period taken to enrol the required sample size of 68 was 3 months. Seven primary-care doctors worked on a rota and provided a variable number of sessions a week. The number of referrals varied between doctors (range 7–43). A total of 110 patients were referred. Five patients did not attend. Twenty-five did not fulfil inclusion criteria and out of them eight had a diagnosable physical illness. Therefore, 80 were eligible (73%). Out of 80 eligible patients 4 (5%) did not consent and 8 (10%) although eligible did not attend baseline assessment.

Feasibility of the assessments

Sixty-six out of 68 completed the full assessment by A.S. and S.W. The remaining two completed only the SEMI. The complete assessment took between 45–60 min depending on the age and educational background of the patient.

Reliability of inclusion criteria

A random sample of 15 was selected for independent co-rating by the second psychiatrist during the baseline assessments. However, only 13 of these 15 could be rated by him. The mean number of complaints independently recorded at baseline assessment by A.S. was 8 (95% CI 7–8·9) and by R.H. 6·9 (95% CI 6–7·7), this revealed a significant correlation. Reliability analysis using intra-class correlation coefficient was 0·84 (95% CI 0·50–0·95, $F = 6{\cdot}62$, df = 12, P 0·001). Similarly, visits recorded by A.S. was 8·2 (95% CI 4·5–12) and by R.H. 8·9 (95% CI 4·4–13), this too revealed a significant correlation. Intra-class correlation coefficient was 0·99 (95% CI 0·998–0·999, $F = 229.4$, df = 12, P 0·001).

A separate random sample of 11 were co-rated by A.S. and R.H. The mean number of complaints independently recorded at follow-up by A.S. was 3·4 (95% CI 1·5–5·3) and by R.H.

Table 1. *Baseline characteristics of continuous outcome variables by randomization in controlled clinical trial using CBT for medically unexplained complaints*

	Control Mean (S.D.)		Intervention Mean (S.D.)		Difference of the means (95% CI of difference)	*P*
Complaints	8·2	(1·9)	7·8	(1·7)	0·38 (−0·526 to 1·2)	0·4
Visits	7·7	(6·3)	6·3	(4)	1·3 (−1·3 to 4·1)	0·3
GHQ score	11	(6·7)	12·1	(8·6)	−1·1 (−4·9 to 2·6)	0·5
BSI score	18·9	(6·6)	16·2	(5·5)	2·7 (−0·32 to 5·6)	0·08
Age	38·7	(14)	38·1	(13)	0·6 (−6 to 7.2)	0·8

3·1 (95% CI 1·4–4·9), this revealed a significant intra-class correlation of 0·98 (95% CI 0·94–0·99 $F = 135$, df = 10 P 0·001). Similarly, visits records by A.S. and R.H. 2·7 (95% CI 1·4–4) revealed a perfect correlation with an intra-class correlation of 1.

Baseline characteristics

Intervention and control groups comprised 12 and 8 males, and 22 and 26 females respectively (chi-square 1·13, $P = 0·28$). The mean age of the intervention group was 38·1 (S.D. = 13) years and the controls 38·7 (S.D. = 14), (difference of the mean 0·6 95% CI −6 to 7·2).

The cohort was chronically ill, 57% were ill for more than 2 years. Only five of the control subjects and seven of the intervention subjects reported a duration of symptoms of < 6 months, whereas 29 controls subjects and 27 intervention subjects reported having symptoms for ⩾ 6 months (chi-square 0·4, $P = 0·5$). They were over-users of health services with a mean of 14 visits to their doctors per year, more than four times of the national average (Simonov, 1975) and 50% were admitted to hospitals at least once over the last 6 months. Eighty-five per cent of the patients had consulted from four to ten specialists, general doctors or other health-care providers. In spite of these numerous visits only two had visited a psychiatrist. However, they were a dissatisfied, disabled, and distressed group of patients harbouring a significant fear of having serious life threatening illness.

Comparison of other baseline characteristics of continuous outcome variables are given in Table 1.

Treatment and follow-up

The uptake of structured sessions by intervention group

All 34 randomly allocated to the intervention group accepted the treatment offer and attended one session, 29 (85%) attended two sessions, 22 (64%) attended three or more sessions. Twenty of the 22 patients who attended three or more sessions remained in the study, were present at follow-up and reported clinical improvement. Some of these patients who continued to attend, reported feeling better with a lesser number of sessions, but attended only to comply with the treatment. Out of 12 patients who attended either one or two sessions, only four stayed in the study and were present at follow-up.

Therefore, the issue of drop-out from the treatment should be considered as separate from drop-out from the follow-up at 3 months. Both categories revealed a considerable drop-out rates.

Drop-out

Drop-out from the intervention was 15% between the first and second session, 21% between second and third session.

In the intervention group, 24/34 (70%) stayed in the study and were available for the 3 months follow-up. Only 21/34 (62%) in the control group did so. Therefore, the drop-out rate at follow-up was 30% for intervention group and 38% for the control group at 3 months follow-up.

Four of 10 intervention patients and five of the 13 controls who did not complete the follow-up assessments lived more than 40 miles away. Two patients were informed by their doctors that they had physical illness and therefore they did not wish to complete the follow-up assessment. They also felt that they did not have 'the type of illness we think', probably referring to a psychological basis.

Differences between and within groups at the 3 month assessment

At the 3 month follow-up analyses, both intention to treat and 'Completers' methods showed statistically significant differences between the two groups on all four outcomes. The

Table 2. *Comparison of outcome measures at 3 months between intervention and control groups by intention to treat analysis and completers analysis*

	Intention to treat with last observation brought forward for missing values. Each outcome adjusted for the baseline score as a covariate					'Completers' analysis on the basis of availability for follow-up assessment. Each outcome adjusted for the baseline score as a covariate				
Variable	Control ($N = 34$) mean (95% CI)	Intervention ($N = 34$) mean (95% CI)	Difference of the means (95% CI)	F	P	Control ($N = 34$) mean (95% CI)	Intervention ($N = 34$) mean (95% CI)	Difference of the means (95% CI)	F	P
Complaints	6·1 (5·1–7)	3·8 (2·8–4·7)	2·3 (0·8–3·7)	12	0·001	4·9 (3·9–5·9)	2·1 (1·3–4·1)	2·8 (1·3–4·1)	16·5	<0·001
Visits*	7·9 (5·6–10·1)	3·1 (0·8–5·3)	4·8 (1·3–8)	9·1	0·004	8·5 (5·4–11·6)	2 (−1·4–4·4)	6·3 (1·8–11·0)	8·1	<0·001
GHQ	10·4 (8·1–12·7)	6·3 (4·1–8·5)	4·1 (0·5–7·6)	4·3	0·04	10·6 (4·7–16·5)	5·7 (2·6–8·1)	4·9 (0·2–9·8)	4·1	0·05
BSI score	15·6 (13·6–17·5)	13·2 (11·3–15·1)	2·3 (0·5–5·2)	6·4	0·01	15 (12·5–17·5)	12 (9·7–14·3)	3 (−0·8 to 6·8)	3·8	0·05

* Number of visits during subsequent 3 months following baseline assessment ×2.
In the case of visits baseline scores were for 6 months prior to baseline assessment, but the reassessment values were for subsequent 3 months. It was not rational to compare the figures for two different duration. Therefore, the number of visits during subsequent 3 months after the baseline assessment was multiplied by 2. Last observation were carried forwards for missing values in the intention to treat analysis.

most remarkable difference observed between groups was the reduction of unstructured visits, followed by the difference in GHQ scores. Symptoms volunteered by the patients were also reduced. However, the least difference was seen in the perceived symptom scores detected by symptom questionnaire.

Considering the within group differences, the mean GHQ score, which was higher for the intervention group at baseline assessment revealed a reduction by about 50% at the 3 month assessments. Symptoms volunteered by patients and also detected by the BSI questionnaire were reduced in both groups.

Comparison of the two groups at the 3 month assessment and analysis by intention to treat and 'Completers' methods are given in Tables 2 and 3.

Post hoc 'sensitivity analysis' carried out by substituting worst outcome measures for missing values and repeating intention to treat analysis, maintained the significant differences between the treatment and control group. Substituting the worse outcome measure for missing values was done in two different ways. The first, was to substitute worse outcome measure recorded for the treatment group at the 3 month assessment (GHQ score = 24, BSI score = 22, complaints = 6, visits = 10) for missing values within the treatment group and to substitute worse outcome measure for the control group at the 3 month assessment (GHQ score = 26, BSI score = 24, complaints = 10, visits = 16) for missing values within the control group. This analysis in fact increased the difference of means for complaints (3·2, 95% CI 2·1–4·9), BSI scores (7·6, 95% CI 3·1–12·1) and maintained the difference of means for visits (4·8, 95% CI 1·98–7·76) and for GHQ scores (4·2, 95% CI–9·6).

The second method was to substitute the worse outcome measures for either group, which were the scores recorded for the control group, for the missing values in both groups. This analysis increased the difference for BSI scores (4·2, 95% CI –1·2 to 9·8), maintained the difference for complaints (2·5, 95% CI 0·7–4·2), reduced, but still revealed a significant difference for GHQ scores (2·5, 95% CI 0·7–4·2) and visits (3·5, 95% CI 0·16–6·9).

No physical disorders were detected on any patient who attended the 3 month assessment.

Table 3. *Comparisons of satisfaction between intervention and control patients before* (*baseline*) *and after intervention* (*at* 3 *months*), *by intention to treat analysis with last observation carried forwards*

	Baseline		3 months follow-up	
	Control	Intervention	Control	Intervention
Satisfied/very satisfied	4	10	5	20
Equivocal	3	5	6	5
Dissatisfied/very dissatisfied	22	16	22	8

$\chi^2 = 0{\cdot}85$, df = 2, $P = 0{\cdot}65$.
$\chi^2 = 5{\cdot}9$, df = 2, $P = 0{\cdot}05$.

DISCUSSION

Our study revealed that cognitive behaviour therapy is as feasible in a developing country as elsewhere. The specific treatment strategy in which cognitive behavioural therapy was the major component, had a positive impact on the patient in terms of reducing distress, symptom perception, patient-initiated unstructured visits and increasing perceived satisfaction.

Several other studies carried out in general hospital settings have reported that individual or group CBT was effective for patients with medically unexplained symptoms (Speckens *et al*. 1995) or for allied group of patients such as hypochondriasis (Stern & Fernandez, 1991; Avia *et al*. 1996; Warwick *et al*. 1996), irritable bowel syndrome (Dulman *et al*. 1996) or non-cardiac chest pain (Mayou *et al*. 1997) but another study (Saunders *et al*. 1997) found no evidence of efficacy of a brief intervention based on CBT principles, for patients with non-cardiac chest pain. However, the authors themselves of latter study have raised the issues of methodological problems limiting the certainty of the conclusions about the efficacy.

Baseline characteristics of the patients and mean group values of our study shows that the two groups were comparable with regard to the gender, age, duration and outcome measures. The main method of data analysis used, 'intention to treat' assume that non-available patients continued unchanged and therefore undermine the spontaneous improvement. The second analysis used only the data available at follow-up and may lose the randomization effect. Intention to treat analysis and protocol analysis represent different extremes so that, if they lead to the same conclusions, then the strength of the conclusion is considerably increased (Lewis & Machin, 1991). Our analyses using both approaches revealed significant differences on all four outcomes between the two groups at the 3 month follow-up. Difference of the GHQ scores, even if taken alone will be in favour of a clinically significant difference.

Because of the issues surrounding treatment of missing data (Lewis & Machin, 1991; Everitt, 1998; Hotopf *et al*. 1999) and the limitations of the 'last observation carried forwards' method in over-estimating as well as under estimating treatment effect, we carried out a *post hoc* 'sensitivity' analysis. The results were still positive. Therefore, we can safely conclude that there is evidence of a substantial treatment effect of the intervention.

As there are several components in the management strategy, one cannot make conclusions from this study about the relative effect of each component. With regard to the issue of the optimum number of treatment sessions and duration of treatment, they will depend on the intensity of the distress and chronicity of the illness. In our study, in which we judge by two features, namely staying in the study and clinical improvement, retaining the patient for up to three sessions seems to be important. These three sessions covered the essentials components. The patients who followed the first three or more sessions stayed with the study and showed clinical improvement Therefore, these three sessions could be considered the minimum adequate course of treatment. Mynors-Wallis, (1995) using problem-solving, offered six sessions but considered four to be a minimum for an adequate course of treatment. Speckens *et al*. (1995) offered a variable number of sessions ranging from six to 16.

One of the main limitations was the substantial loss to follow-up in both groups at the 3 month reassessments. However, this was more for the control group. Drop-out from the trial is non-random and this can introduce confounding back into the design, (Hotopf, 1999).

Fall off in the uptake of intervention by the treatment group between the second and third session is also a cause for concern. However, these 'drop-outs' should be evaluated in the

context of Sri Lankan health care and the characteristic of disproportionate consultations of these patients to different doctors. In Sri Lanka there are no formal general practice lists and the patients are free to consult any doctor they wish. Even in the public sector patients can bypass the referral system. There are no formal psychological services available to these patients. Psychological interventions including CBT was a novel experience for these patients. Only two patients had previously consulted psychiatrists. Psychiatric referrals are usually unpopular with these patients and rarely result in effective treatment (Mayou *et al*. 1997*b*). The treatment in our study was administered by a psychiatrist. This factor may also have contributed to the drop-out although A.S. was working in a general out-patient clinic.

The cohort was a chronically ill, distressed, dissatisfied, disabled group of heavy users of health services and other care facilities. Distance to travel, continued denial of psychological component and iatrogenic reinforcement of patients preoccupation with physical disease also appear to have contributed. Hence the level of drop-out from the treatment was not too surprising and the substantial treatment effect witnessed should not be undermined because of that fact. However, future efforts should take into consideration factors that would increase compliance, as staying with the study was associated with a good prognosis. More intensive treatment by increasing the frequency of sessions, particularly by offering the first three sessions at weekly interval will be worth considering. In a larger scale study it will be important to follow-up the patients actively for assessments even if they drop out from the study.

The overt reduction of symptoms among the control group could have several causes. These chronically ill, distressed, dissatisfied, disabled, heavily investigated overusers of health care, may have had a non-specific therapeutic impact by having an opportunity to undergo a detailed assessment and an opportunity to express their explanatory model. Other possible reasons would be the enthusiasm of the primary-care doctors, non-specific effect of the project not only on the patients but also on the doctors. The above possibilities are reflected in increased satisfaction of control patients although it is significantly less than in the intervention group. Spontaneous improvement of at least some of the patients, particularly of those with a shorter duration would also have contributed. Speckens *et al*. (1995) also observed a similar improvement in their controls but did not witness a reduction of the visits that occurred in the current study.

Other methodological issues included, variability of referral rates by different doctors, and the possibility of non-detection, affecting enrolment of a representative sample from the out-patient department. Secondly, A. S. who recorded the number of complaints and number of visits at the follow-up assessment, was not blind to the treatment assignment. However R. H. and S. H. were blind. We attempted to minimize these limitations using two structured questions and pre-defined criteria to elicit the number of complaints and comparing agreement between A. S. and R. H. on two different random samples, one at baseline and one at follow-up assessments. The findings revealed a significantly high agreement between A. S. and R. H. on the number of complaints and a perfect agreement between A. S. and R. H. on the number of visits. Inclusion of BSI as an independent method for symptom score further minimizes the above weakness. Thirdly, sample size was calculated using only two outcome variables. Hence, power for some of the variables was not sufficient. It was also not a sample stratified for all covariants. All outcome measures were self-reported, which may raise the issue of information bias.

Attempt at ICD-10 or DSM-IV diagnosis would have been of academic interest. However, this was not within the aims of the study and was not included as a part of the assessment process due to many reasons. Current systems for classifying functional somatic symptoms remain unsatisfactory (Escobar *et al*. 1998), because some patients with somatic complaints have neither physical nor severe mental illness (Wessley, 1996). Therefore preoccupation with traditional psychiatric diagnostic categories may hinder the understanding of this category of patients (Mayou, 1991). CBT takes an integrated approach in keeping with the evidence that the purpetuation of unexplained somatic symptoms is best understood in terms of an interaction between physiological processes, psychological factors and social context (Mayou *et al*. 1997) and instead of being concerned with possible

causes of illness, CBT focuses on teaching people how to control their present symptoms of disturbed emotions, thoughts and behaviour (Andrews, 1991).

Implications for future research/clinical practice

Our findings suggest that the implications of an effective intervention will not only contribute to the clinical outcome for the patient and family but also to the disproportionate health-care cost incurred by these patients. Therefore, cost analysis of the morbidity and cost-effectiveness of the intervention should be considered in future work. Further research should also clarify the transferability of the strategy and management technique, to primary-care physicians. This study, which is the first of this nature from the developing world, has demonstrated that a specific management strategy based on CBT is feasible and effective in the management of medically unexplained multiple complaints and repeated consultations. Strategies to increase compliance would be worth considering.

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