

Efficacy of Adjunctive Single Session Counseling for Medically Unexplained Symptoms: A Randomized Controlled Trial

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ABSTRACT

Context: Medically unexplained symptoms (MUS) are often poorly responsive to standard treatments. **Aim:** The aim of the study is to assess short-term efficacy of adjunctive single session cognitive behavior therapy (CBT)-based counseling for patients with MUS. **Setting and Design:** Randomized controlled trial at a psychosomatic clinic of a tertiary care hospital. **Materials and Methods:** Patients with MUS were randomized to receive either the single session counseling (intervention group) ($n = 41$) or control group which received treatment as usual ($n = 35$). The counseling intervention focused on three areas – cognitive reattribution, shifting focus, and guided muscular relaxation and lasted around 30 min. The two groups were assessed at baseline and after 1 month for change in outcome measures. **Statistical Analysis Used:** Repeated measures analysis of variance. P value was adjusted for multiple comparisons using Bonferroni correction and set at <0.01 for significance. **Results:** Both groups did not differ on change in the primary outcome measure: Patient Health Questionnaire – 15 scores ($P = 0.055$). However, at follow-up, the intervention group showed statistically greater reduction in the number of workdays lost ($P = 0.005$). Trend level changes were noted for depressive symptom reduction only in the intervention group ($P = 0.022$). **Conclusions:** One session CBT-based therapy demonstrates potentially important benefits over standard care among Indian patients with MUS. Further testing in larger samples with longer follow-up periods is therefore recommended.

Key words: Cognitive behavior therapy, medically unexplained symptoms, psychotherapy, somatization disorder, somatoform disorder

INTRODUCTION


The management of medically unexplained symptoms (MUS) continues to challenge and confound

physicians due to multiple issues. These include the lack of a biological finding in the majority of cases,

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high rates of latent psychiatric morbidity as well as the reluctance on the part of patients to accept psychiatric referrals, and normalizing explanations offered by the clinician.^[1,2] While many of these patients may carry rigid, inflexible attitudes about the nature of their symptoms, it is also true that the majority of sufferers are willing to accept more than one explanation for their symptom, thus presenting significant treatment opportunities for clinicians.^[3,4]

Growing evidence suggests that multipronged treatment strategies including assimilation of principles from cognitive behavior therapy (CBT) may yield significant treatment gains in MUS.^[5-8] A 10-session CBT-based model for managing MUS has been proposed for application in liaison psychiatric settings that emphasizes the practical management of symptoms as opposed to causal discussions.^[9] Numerous studies, mostly from the west, have shown the value of CBT and reattribution techniques in managing MUS^[10-12] but the optimal duration and components of therapy have varied from setting to setting. In this context, it is important to note that Sumathipala *et al.* have published a negative study carried out in an Asian setting, wherein, the authors found that six sessions of CBT work were no more efficacious than structured care for MUS.^[13] This raises interesting questions on cultural background as a determinant of response to CBT in MUS. Guided muscular relaxation therapies have also been widely studied and found to be effective in a variety of settings and syndromes involving MUS.^[1,14] Its positive evidence base, simple yet tangible nature makes it an attractive candidate for inclusion in trials involving behavior modification particularly in low-resource setting.

Against this background, the present study was designed to test the efficacy of add-on single session counseling (SSC), which combines the principles of CBT with guided muscular relaxation, for Indian patients with MUS as compared to treatment as usual (TAU). Specifically, we tested the hypothesis that the proposed SSC intervention would be efficacious in reducing (i) as primary outcome – somatic symptom severity over the 1-month follow-up period and (ii) as secondary outcomes – anxiety and depressive symptoms, number of workdays lost, and number of hospital visits made during the follow-up period. Comparisons of efficacy were made against a psychoeducational control group.

MATERIALS AND METHODS

Study design and setting

This was a randomized controlled trial (RCT) carried out in the specialty psychosomatic outpatient clinic at a Government Medical College located

in Puducherry, South India, from June 2015 to June 2016. The clinic team includes a consultant psychiatrist, senior resident (qualified psychiatrist), junior resident (postgraduate trainee), a clinical psychologist, and psychiatric social worker. After detailed evaluation of a case by junior resident and discussion with the consultant, a psychiatric diagnosis is allotted as per International Classification of Diseases-10, clinical descriptions, and diagnostic guidelines.^[15] Subsequently, a detailed management plan is formulated which includes both pharmacological and psychosocial treatment options.

Subjects and methods

Inclusion criteria for participants in the present study included participants aged 18 years or older, presence of single/multiple physical symptoms for at least 3-month duration, and basic/ordered investigations within normal limits following which the symptoms are deemed to be medically unexplained by the treating physician. Patients not having proper referral letters from physicians were excluded as were those above the age of 65 to avoid spurious cases. Other exclusion criteria included Mini-Mental State Examination score <23,^[16] presence of psychotic symptoms, intellectual/hearing or language impairment, and pregnant women or those who have delivered in the last 1 year. Consecutive patients satisfying these criteria were prospectively screened and randomized into one of the two study arms: SSC intervention arm or TAU control arm. The randomization was done using computer-generated random numbers and allocation concealment using sequentially numbered opaque sealed envelopes. The random number sequence was generated and maintained by one of the investigators (VM) not involved directly in patient recruitment or assignment. A total of 84 participants were assessed for eligibility. Of these, 71 were found to be eligible for recruitment and were randomly assigned to either the intervention group ($n = 41$) or TAU control arm ($n = 35$) [Figure 1]. Study procedures were explained in the local language, and written informed consent was obtained from the consenting participants.

Assessments

Both groups were assessed twice: at baseline and 1 month following the intervention on the following outcome measures:

Primary outcome measure

Patient Health Questionnaire (PHQ) – 15: This scale comprises 15 somatic symptoms and is derived from the original PHQ.^[17] Each symptom is scored from “0” (not bothered at all) to “2” (bothered a lot). The PHQ-15 scale has been previously found to be a valid

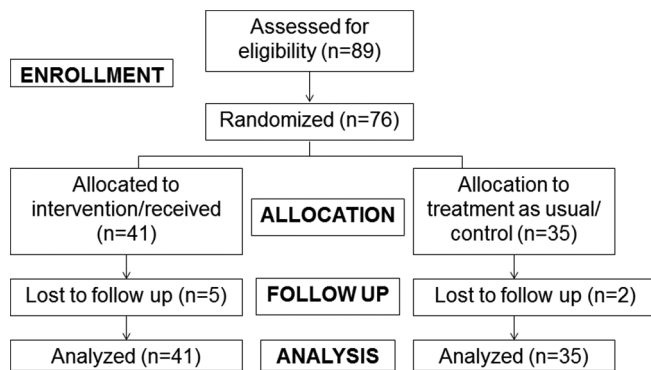


Figure 1: CONSORT flow diagram for the trial

and reliable questionnaire to screen and monitor symptom severity in MUS.^[18]

Secondary outcome measures

1. Generalized anxiety disorder (GAD) – 7: This is a brief self-report measure used both as a screening tool and severity measure of generalized anxiety symptoms with strong psychometric properties.^[19] Prior studies on patients with MUS have used this scale to study clinical outcomes^[20]
2. PHQ – 9: This refers to the 9-item self-administered depression module of the larger PHQ, which in turn is derived from the PRIME-MD scale for assessment of common mental disorders.^[21,22] It is widely used to screen for and monitor depression among patients with MUS^[20]
3. Number of hospital visits in the last month: This was assessed from the patient's self-report and cross-checked with the available informant
4. Number of workdays lost in the last month: This was also assessed from the patient's self-report and cross-checked with the available informant.

Telephonic interviews were used to collect outcomes data in case patients did not present themselves physically at follow-up. A separate investigator (JST) not involved in case recruitment, assignment, or intervention carried out baseline and follow-up assessments. Neither the participants nor study staffs were blinded to intervention/control status of participants.

Interventions

Participants randomized to the intervention group ($n = 41$) received the SSC for MUS. The session lasted for about 30 min and the intervention focused on the following areas:

1. Validating the patients' complaints through empathic listening: The patients were allowed to elaborate their complaints. They were encouraged to dwell on its links with stressful life events to emphasize the fluctuating nature of symptoms and role of stress in influencing its severity

2. Reattribution: Here, patients were encouraged to make the link between physical and psychological symptoms in keeping with the reattribution theory^[23]
3. Emphasize working around rather than working on the symptoms: The patients were told that the aim of therapy was to increase their coping with symptoms and enhance functioning rather than reduce symptoms
4. Relaxation techniques: This was included due to its wide evidence base in MUS.^[1,14] Patients were given verbal instructions on progressive muscular relaxation techniques focusing on affected body parts (e.g., head and neck relaxation for unexplained headache) as a strategy to counter symptoms as and when they become discomforting.

The intervention sessions were administered by a single qualified psychiatrist (BS). In addition, both groups received standard care that included appropriate pharmacotherapy for symptoms as indicated. The control group (TAU) received brief psychoeducation that focused on disseminating information about the origins, meaning, impact of symptoms in day-to-day life, and management options. However, the reattribution component and muscle relaxation were not included in the content for control group psychoeducation. The study protocol had prior approval from the Institute Ethics Committee. The trial was registered with the Clinical Trials Registry of India (CTRI/2016/07/007082).

Statistical analysis

The analysis was carried out using SPSS version 21 (IBM Corp., NY, USA). The baseline characteristics and outcome measure scores between the intervention and control groups were compared using Student's *t*-test or Chi-square test. Repeated measures analysis of variance (RMANOVA) was used to ascertain the significance of the intervention on the change in outcome measures over follow-up. For participants who were lost to follow-up, intention to treat analysis was carried out using last observation carried forward method. To reduce Type I error, Bonferroni correction was applied for multiple pairwise comparisons, and $P < 0.01$ was considered as statistically significant.

RESULTS

The present analysis was based on 76 patients (41 in intervention group and 35 in control group). The demographic and basic clinical characteristics of cases and controls are shown in Table 1. The intervention (SSC) group had higher number of participants of the female gender as compared to controls (TAU) ($P = 0.007$). There were no significant

differences across the groups with respect to other baseline parameters. The baseline clinical parameters which served as outcome measures also did not differ between groups [Table 2].

The changes from the baseline in the primary and secondary outcomes are shown in Table 3. For the participants who had lost to follow-up, intention to treat analysis was carried out. The intervention and

control groups differed on change in PHQ-9 scores and the number of workdays lost in last 1 month from baseline.

RMANOVA was used to assess the significance of the change in the outcome variables in the pre-post design, with group (intervention versus control) and gender as between-group factors and pre-post assessments as the within-group variable. Gender was used as a factor as it differed between the intervention and control group at baseline. For PHQ-15, time (i.e., follow-up) was not associated with significant decrease in the scores (Pillai's Trace $F = 3.811$, $P = 0.055$ and partial $\eta^2 = 0.054$). Group allocation or gender also did not significantly affect the findings.

Regarding secondary outcomes, the scores on GAD-7 decreased with time (Pillai's Trace $F = 8.713$, $P = 0.004$ and partial $\eta^2 = 0.115$), but group membership (intervention versus control) or gender did not have a moderating influence on the outcome. The scores on PHQ-9 significantly decreased with time (Pillai's Trace $F = 9.512$, $P = 0.003$ and partial $\eta^2 = 0.124$). The time X group interaction suggested a trend level significance with the reduction in scores more pronounced in the intervention group (Pillai's Trace $F = 5.530$, $P = 0.022$ and partial $\eta^2 = 0.076$). Further, only time had a significant effect on the number of visits to the hospital in a month (Pillai's Trace $F = 22.949$, $P < 0.001$ and partial $\eta^2 = 0.255$), suggesting that the number of visits decreased in both groups. For the number of workdays lost in a month, both time (Pillai's Trace $F = 19.684$, $P < 0.001$ and partial $\eta^2 = 0.230$) and time X group interaction were significant (Pillai's Trace $F = 8.281$, $P = 0.005$ and partial $\eta^2 = 0.111$). This suggested that the number of workdays lost decreased in both groups, and the decrease was more in the intervention (SSC) group.

Table 1: Baseline characteristics of cases and controls

Variable	Cases (n=41), n (%)	Controls (n=35), n (%)	Comparison (P)
Age	37.6 (9.4)	42.5 (12.6)	$t=1.886$ (0.077)
Gender			
Male	7 (17.1)	16 (45.7)	$\chi^2=7.339$ (0.007)*
Female	34 (82.9)	19 (54.3)	
Marital status			
Married	31 (75.6)	32 (91.4)	$\chi^2=3.332$ (0.07)
Not married	10 (24.4)	3 (8.6)	
Education			
Up to 10 th grade	35 (85.4)	30 (85.7)	$\chi^2=0.002$ (0.966)
10 th grade and above	6 (14.6)	5 (14.3)	
Occupation			
Employed	25 (61.0)	20 (57.1)	$\chi^2=0.115$ (0.734)
Not employed	16 (39.0)	15 (42.9)	
Family status			
Nuclear	32 (78)	29 (82.9)	$\chi^2=0.276$ (0.599)
Extended/joint	9 (22)	6 (17.1)	
Religion			
Hindu	38 (92.7)	34 (97.1)	$\chi^2=1.089$ (0.580)
Christian	2 (4.9)	1 (2.9)	
Islam	1 (2.4)	0	
Residence			
Rural	25 (61.0)	25 (71.4)	$\chi^2=0.917$ (0.338)
Urban/semi-urban	16 (39.0)	10 (28.6)	
Per capita income (INR/month)			
<3000	25 (61.0)	21 (60.0)	$\chi^2=0.008$ (0.931)
3000 and above	16 (39.0)	14 (40.0)	

Data represented as mean (SDs) or frequency (%). Comparisons done using Student's *t*-test or Chi-square test, * $P < 0.05$. SDs – Standard deviations

Table 2: Baseline outcome characteristics of cases and controls

Variable	Cases (n=41)	Controls (n=35)	Comparison (P)
Primary outcome			
PHQ-15	7.4 (4.1)	7.2 (5.6)	$t=0.215$ (0.831)
Secondary outcome			
GAD-7	3.2 (3.7)	3.3 (3.9)	$t=0.025$ (0.980)
PHQ-9	3.6 (4.6)	2.7 (4.4)	$t=0.834$ (0.407)
Number of hospital visits in last month	4.4 (3.3)	5.2 (5.7)	$t=0.778$ (0.439)
Number of workdays lost in last month	16.0 (12.3)	13.9 (23.0)	$t=0.661$ (0.511)

Data represented as mean (SDs), comparisons done using Student's *t*-test. PHQ – Patient health Questionnaire; GAD – Generalized anxiety disorder; SDs – Standard deviations

DISCUSSION

The present study shows that a single session of structured counseling for MUS is no more efficacious than routine care in the short-term for control of somatic symptoms and associated anxiety but may improve work productivity and depressive symptoms. Therefore, this intervention may hold some promise in Indian settings. Martin *et al.*,^[24] in a methodologically similar study, evaluated the efficacy of an SSC on MUS and found that both the intervention and waitlisted control groups had comparable improvement over 6 months on an array of healthcare utilization parameters, somatization severity, and absenteeism from work. Nonsuperiority of cognitive behavioral intervention delivered by family physician was also

Table 3: Comparison of intervention and control groups from baseline to 1-month follow-up

Variable	Cases (n=41)	Controls (n=35)	Comparison (P)
Primary outcome			
PHQ-15 baseline	7.4 (4.1)	7.2 (5.6)	$t=1.780$ (0.079)
PHQ-15 at follow-up	5.3 (3.2)	6.9 (3.5)	
Change in PHQ-15 scores	-2.1 (4.1)	-0.2 (4.7)	
Secondary outcomes			
GAD-7 baseline	3.2 (3.7)	3.3 (3.9)	$t=0.638$ (0.528)
GAD-7 at follow-up	2.0 (2.2)	1.6 (2.6)	
Change in GAD-7 scores	-1.2 (3.1)	-1.7 (3.1)	
PHQ-9 baseline	3.6 (4.6)	2.7 (4.4)	$t=1.896$ (0.047)*
PHQ-9 at follow-up	1.4 (2.3)	2.3 (3.5)	
Change in PHQ-9 scores	-2.1 (4.4)	-0.4 (2.8)	
Number of hospital visits in last month at baseline	4.4 (3.3)	5.2 (5.7)	$t=0.973$ (0.334)
Number of hospital visits in last month at follow-up	2.1 (1.8)	1.9 (1.1)	
Change in number of hospital visits in last month	-2.3 (3.5)	-3.4 (5.5)	
Number of workdays lost in last month at baseline	16.0 (12.3)	13.9 (23.0)	$t=2.711$ (0.008)*
Number of workdays lost in last month at follow-up	7.9 (8.4)	12.0 (10.3)	
Change in number of workdays lost in last month	22,128.1 (10.6)	-1.9 (7.5)	

Data represented as mean (standard deviations), comparisons done using Student's *t*-test, * $P < 0.05$. PHQ – Patient Health Questionnaire; GAD – Generalized anxiety disorder

noted by investigators studying MUS in a primary care setting.^[25]

In an RCT from Sri Lanka, wherein the investigators compared the efficacy of six sessions of CBT versus structured care consisting of six 30 min sessions with the primary health-care provider, it was observed that CBT was no more efficacious than structured care.^[13] However, a pilot study conducted on a smaller sample showed a superiority of psychiatrist-delivered CBT over standard care.^[26] These two studies are particularly relevant for discussion as they are from culturally similar and geographically proximate backgrounds. Our study provides two important methodological advances over the study by Sumathipala *et al.*^[13] first, all the intervention sessions were administered by a single trained psychiatrist who eliminates potential therapist bias and suggests greater fidelity to protocol; and second, our study had a TAU arm which allowed meaningful comparisons of the experimental intervention with routine care.

The findings of the present intervention in terms of its positive effects on work absenteeism do assume significance. Multiple Indian and foreign studies have highlighted the loss of productivity and economic impact of MUS on its sufferers and emphasized the need for CBT-based interventions in reducing personal distress and disability.^[27-29] Being able to work, even in a somewhat mitigated manner, may reduce guilt feelings of not being able to contribute which will disrupt the cycle of passivity, social isolation, and eventual marginalization seen among patients with MUS.^[30,31] To this extent, the single session intervention described here merits further evaluation. It can also be delivered

even in low-resource settings by personnel with minimal training. No previous study has evaluated the feasibility and efficacy of brief CBT-based treatments in MUS in our setting, and therefore, our findings may serve to catalyze further research along similar lines with longer follow-up periods. Encouragingly, the intervention was overall well received as evidenced by the acceptable dropout rate in the intervention group (17.1%).

The limitations of the study include sampling from a single tertiary care center, short follow-up period, and reliance on patients' self-report for some of the outcome measures such as number of hospital visits in follow-up though we also verified information from the key informant wherever available to minimize recall bias. We also used a strict definition of caseness in MUS which may mean that more cases with greater disability got included. We insisted on a proper referral letter from the physician to minimize errors in recruitment. The strengths of the study include acceptable attrition rates, randomized controlled design, use of prospective assessment, single therapist-delivered intervention, and use of blinded outcome raters.

CONCLUSIONS

Single session counseling based on principles of Cognitive-Behavior Therapy may hold significant promise for Indian patients with medically unexplained symptoms (MUS), especially with regard to increasing work productivity and reducing psychological distress. MUS are a complex, multifaceted condition with impairment in various domains, and it may be too simplistic to expect a single session of CBT to exert immediate therapeutic gains. However, it may also not be prudent to write off CBT given its considerable evidence base in MUS.^[32,33]

In the present study, we have used simple, easy to deliver techniques, and therefore, we suggest that this model be evaluated in multiple settings and over longer follow-up periods. Future research should also focus on effective therapies for sufferers from MUS who may be unwilling to go through the grind of CBT work.

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Conflicts of interest

There are no conflicts of interest.

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