

## Short Communication

# Developing and validating the coping intervention program on burden and wellbeing of family members of chronic mentally ill patients

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## ABSTRACT

Suffering psychological distress and shouldering burdens while caring for a mentally ill relative affects not only the caregiver's quality of life and health, but due to the increasing demands and responsibilities, there is an increasing concern about their ability to manage or cope up. Coping Intervention Program was formulated for family members who are giving care to the mentally ill people, after the thorough literature review, feedback from mental health expert and caregivers (during validation process), and a pilot study (for feasibility and preliminary effectiveness). Throughout, the focus was on simplicity, feasibility, and applicability across single settings (inpatient) and modalities (face-to-face/direct intervention). After much review Coping Intervention program took about 6 months to develop. The primary caregivers assessed the clarity, comprehension, and usefulness of the intervention. The final components included introductory interaction, audio-visual content, booklet, and clarification session. Lived problem solving session was used and educational session on effective coping strategies was adopted through audio visual content, psychoeducational approaches through booklet and audio-visual content, and practice sessions on mindfulness-based therapy and progressive muscle relaxation therapy through audio instructions. Pilot testing of Coping Intervention program suggested its feasibility in administration. Coping Intervention program was developed and validated through an interactive process, keeping cultural contextuality in mind. The investigators were planning to test its efficacy in a robustly designed study.

**Keywords:** Coping intervention, Burden, Family members, Caregiver, Chronic mental illness

## INTRODUCTION

Chronic mental illness refers to conditions with persistently debilitating psychiatric symptoms and severely impaired function. Individuals with chronic mental illness suffer from symptoms that may interfere with their ability to perform activities of daily living and to participate in work, school, and interpersonal relationships.<sup>1</sup> At times in their lives, these individuals often require significant care from family, friends or relatives and from mental health care providers.<sup>2</sup> So the

caregiver plays a very vital role in the care of a mentally ill person.<sup>3</sup> Suffering psychological distress and shouldering burdens while caring for a mentally ill relative affects not only the caregiver's quality of life and health, but also their productivity as an individual and their ability to provide quality care for the ill relative, thereby worsening the ill relative's health and decreasing the likelihood of recovery or health improvements.<sup>4</sup> The studies have shown that Psycho-education of the caregiver and skills training on mood and coping mechanisms can reduce the caregiver burden. Specific

management strategies have to be designed in account to improve the caregiver efficiency to manage both patient and themselves. Increase in the deinstitutionalization of patients suffering from chronic mental disorders has led families, by choice or necessity, to assume responsibility for the care of their relatives at home.<sup>5</sup>

Caregiver-focused interventions help to improve the experience of caring, coping and quality of life and reduce psychological distress or burden of those caring for people with severe and chronic mental illness. Interventions for caregivers should be considered as part of integrated services for people with severe mental health problems.

A systematic review and meta-analyses of randomised controlled trials (RCTs) of interventions delivered by health care professional to family members who provide support to someone with severe mental illness. The evidence is derived from studies of those caring for people with chronic mental illness showed that if interventions provided early to them then there was benefit to improve the wellbeing of caregivers.<sup>6</sup>

Currently, an estimated 25% of the global population is suffering from mental health conditions, placing it as one of the most important factors contributing to the disease burden. Correspondingly, around 450 million people across the world are experiencing mental or behavioral disorders.<sup>7</sup> Depression holds the highest proportion of 4.3% of the global burden of diseases and is among the largest single cause of mental illness worldwide.<sup>8</sup> Nearly 30% of people from all parts of the world suffer from mental illness in a year. With the increasing prevalence of psychiatric illnesses, more psychiatric patients are treated at home as compared to obtaining in-hospital treatment, which may unintentionally increase the burden of the caregivers of these psychiatric patients.<sup>9</sup>

**METHODS**

The development and validation of Coping intervention Program was conducted in 4 phases; they are as follows; An extensive review of literature, Discussion with experts, Development of the intervention package and Stabilizing the face and content validation.

**Extensive review of literature**

An extensive search was done from several databases such as PubMed, Science direct, Google scholar, Researchgate. Various search terms used for understanding the concept and to develop the intervention programme such as “Coping Interventions program” OR “psychological intervention” OR “Educational program” AND “caregivers of people with” OR “ Family members of persons with” AND “mental illnesses” OR “serious mental illness” OR “schizophrenia” OR “bipolar disorder” to find out various interventions already available that target reducing burden and improving

coping and wellbeing of caregivers of people with mental illnesses. While reviewing the literature the researcher has referred several studies which include meta-analysis, RCTs, intervention, longitudinal, descriptive and explorative studies. Two recent systematic reviews focusing on interventions for caregivers of persons with mental illness at multiple time points to evaluate the short-term, medium-term and long-term effects of these interventions on carers of patients with SMI were also referred to while planning the components of the current intervention.<sup>7,8</sup>

**Table 1: Profile of subject experts (n=7).**

S. no.	Variable	Category	N
1	Age (years)	30- 50	3
		Above 50	4
2	Gender	Male	4
		Female	3
3	Working experiences (years)	10 – 20	2
		Above 20	5
4	Specialization	Clinical psychiatry	2
		Clinical psychology	1
		Mental health nursing	3
		PHD scholar (nursing)	1

**Discussion with experts**

After the review of literature, a draft of the intervention program was prepared and this was discussed individually with several experts of the field of mental health. These experts belonged to multidiscipline (Faculties of Psychiatric Social Work, Psychiatry, Clinical Psychology, Psychiatric nursing and mental health education departments).

**Development and validation**

Based on the review of the literature and the inputs drawn from the discussion with experts on caregiver burden, psychological wellbeing and use of coping strategies by caregivers of persons with mental illness, the framework of the Coping Intervention was characterized into two broad categories- educational session and Practice session. A detailed draft text was created for educational session as psychoeducation, tentative animated video transcripts, and separate audio transcription for practice session on mindfulness therapy and progressive muscle relaxation therapy for review. The proposed draft, transcript, and videos were sent to mental health experts for feedback. Experts were selected based on experience (>10 years), expertise in the field, and academic background and to represent a panel of mental health professionals currently, involved in the overall care of patients from different related fields like psychiatry, clinical psychology, and psychiatric social work. The tools were validated by seven experts.

**Table 2: Item content validity index (I-CVI), scale content validity index (S-CVI) and kappa index (K) for relevance, suitability and appropriateness.**

S. no.	Components	Relevance			Suitable			Appropriate		
		I-CVI	Kappa value	S-CVI	I-CVI	Kappa value	S-CVI	I-CVI	Kappa value	S-CVI
1	Burnout and self-management strategies (video assisted instruction)	1	1	1	1	1	1	1	1	1
2	Stress management (information booklet)	1	1		1	1		1	1	
3	Problem solving method (video assisted instruction)	1	1		1	1		1	1	
4	Audio instructed progressive muscle relaxation therapy (audio instruction)	1	1		1	1		1	1	
5	Audio instructed mindfulness therapy (audio instruction)	1	1		1	1		1	1	

ICVI=Item-level content validity index, pc (probability of a chance occurrence) was computed using the formula:  $pc = [N/A (N - A)]^*$ . 5 N where N=number of experts and A=number of experts who agree that the item is relevant. Number of experts=7, K (Modified Kappa) was computed using the formula:  $K = (ICVI - PC) / (1 - PC)$

Three (3) experts were from Nursing discipline, one (1) of them was Clinical Psychologist, one (1) of them was PhD Scholar in Nursing, two (2) of them was from the Departments of Psychiatry. The tool was validated by them and they provided valuable suggestion for the tool and modification were made according to expert suggestions.

#### **Face and content validation**

The process of validation and data collection of the intervention program took about 6 months in 2024. The validators were given the draft of intervention package about the details of the session and then they evaluated and filled out the structured questionnaire, on how applicable the techniques used and contents described (content validation) for each session. For face validation of the programme, the researcher asked each of the validator to give their opinion on Coping Intervention through appropriate (Yes) or inappropriate (No) answers. Approval of the intervention program was obtained after the seven experts agreed on the contents and methodology of the program. After seeking the opinion of seven experts a standardized draft of the final version of the Coping intervention was developed. Coping intervention program comprised of four sessions on five components like Burnout and self management strategies, Stress management, Problem solving method and audio instruction on progressive muscle relaxation therapy and mindfulness therapy. There was 100% agreement in all five components. So, Item Wise Content Validity Index (ICVI) are 1 as 100 % agreement in all five components are found. Scale Content Validity Index of the program with all aspect of components is 1. The interpretation

standards for kappa are based on Cicchetti and Sparrow guidelines.

## **RESULTS**

The research team brainstormed and concluded that a clinician provides the intervention with a personalized introductory interaction, multimedia-based audio-visual content, some printed IEC material, and a final one-to-one clarification session. The rationale included using lived caregiving experience through multimedia-based audio-visual content to target reduction of caregiver burden and improvement of coping.

The researcher created a detailed intervention draft (text) based on the internal discussion. This text consisted of all the content that would feed into the final intervention. The researcher also made a tentative video transcript and a separate preliminary animated video for expert panel review. Considering the implementation feasibility of the context, it was decided that the intervention would be multiple educational and practice session. With the finalized text, the investigators designed a multi-modal multiple-session intervention; an implementation tool called the Coping Intervention having the following components.

#### **Printed booklet**

Coping Intervention also focuses on helping caregivers understand the several adoptive and maladaptive coping strategies designed in understandable language for the family members as caregivers.

### Practice session

Audio instructed practice session on mindfulness-based therapy (Body scan meditation) and progressive muscle relaxation therapy was draft for 30 minutes practice in alternate days for 8 weeks.

### The context and setting

The experts were made mindful of the context, in which the intervention will be administered. The context was

defined as the region of West Bengal. Intervention is to be administered to primary caregivers of patients with mental illness, who are attending specialized psychiatry clinics for the treatment of their family members. The setting is a Psychiatric hospital with both inpatient and outpatient facility. The intervention is intended to be administered by mental health professionals (such as a psychiatrist, clinical psychologist, social worker, or psychiatric nurse).

**Table 3: The different components of coping intervention program.**

Session	Type of session	Components	Mode of instruction	Time
<b>First</b>	Educational session	Focus on burnout related to care giving and self-management	video assisted instruction with interactive session	45 minutes
<b>Second</b>	Educational session	Use of different coping strategies and stress management	Booklet and interactive session	45 minutes
<b>Third</b>	Educational session	Use of problem-solving method	Video assisted instruction	45 minutes
<b>Fourth</b>	Practice session (for eight weeks in every alternate day)	Mindfulness based therapy and progressive muscle relaxation therapy	Audio based instruction with guidance	30 minutes

### Caregiver feedback

The investigators have designed a multi-modal intervention using the finalized text. This program was then applied to five caregivers in interview sessions. These caregivers were selected based on their active participation and understanding of caregivers' burden and importance of coping and wellbeing. As per the feedback it has been finalized that the program is understandable and feasible for implementation.

### Pilot testing

In the final step, the investigators piloted the intervention program to explore its feasibility of administration and tentative effectiveness. The pilot study was conducted in the inpatient department of a tertiary level Psychiatric Hospital of West Bengal in February 2026. The Institute Ethics Committee approved the pilot research. For the study, "caregiver" was defined as the family members, who has lived with the person with chronic mental illness for more than 6 months of illness, has been the primary support provider, and did not receive any economic retribution for the caregiving. The scale used to evaluate the change in burden, coping and wellbeing status of family members in pre- and post-intervention were the Zarit Caregiver burden Interview schedule, Brief cope scale. psychological well being scale by Ryff. As the study is a single arm pre and post test format so the pilot participants were interviewed for the variable assessment and intervention was administered as per session planned in intervention program.

### DISCUSSION

The development and validation process of coping intervention program was iterative and included literature searches, expert, and caregiver feedback, and also a pilot study. It was observed that the implementation of the program is feasible and it can be applied at outpatient basis also. The researcher has developed and validated a comprehensive Coping intervention program for family members of chronic mentally ill patients that can be evaluated for efficacy in Indian contexts. These were developed following expert interviews, focus groups with various stakeholders, existing literature reviews, and rigorous content validation. The majority of intervention have been implemented in Western nations and some of these interventions include psychoeducation program or family-based therapy. These interventions included mainly the Psychoeducation based individual or group therapy.<sup>14-16</sup> The relatives of patients suffering from schizophrenia, the psychosocial interventions have impact on burden of giving care and quality of lifenin terms of improvement in caregiver support and satisfaction, psychopathology, and disability.<sup>17</sup> The studies which were employed the psychosocial intervention have shown a positive impact with family members if the duration is longer than 3 months.<sup>18</sup> Future studies with longer interventional period might be more useful in bringing the changes in psychopathology not only that mindfulness exercises, relaxation therapy with psycho education on coping, problem solving may bring more impact on wellbeing and coping of family members.<sup>19,20</sup>

### **Strengths and limitations of the coping intervention program**

Very few comprehensive Coping intervention programs exist that are tailored to reduce burden of care and improve coping and wellbeing of family members who are giving care to the chronic mentally ill people. The Coping intervention is based on stress management, psychoeducation on self care, use of adaptive coping strategies and practice session on mindfulness-based therapy and progressive muscle relaxation therapy.

As the original intent of the project was program development and not formal evaluation of the program, the measures used to assess participant feedback were limited and more qualitative, with the goal of refining the program as necessary through this feedback. This Intervention program development was a part of PhD research.

### **CONCLUSION**

The investigators developed and validated the Coping intervention program for the caregivers through a systematic process keeping cultural context in mind. The coping intervention program can be an effective family intervention for Indian caregivers for family members with mood disorders and schizophrenia and obsessive-compulsive disorder. Based on the findings of pilot study, Different sessions of coping intervention for the caregivers are helpful, beneficial and effective. The intervention used in the study is simple, feasible, and could prevent the occurrence of severe mental disorders, without increasing mental burden or reducing the satisfaction of family care givers. Future investigations should focus on obtaining more precise estimates of the contributions of the specific components of this program in reducing burden.<sup>13,14</sup> Overall, this study has important clinical implications for the design and effective teaching and practice session on coping intervention for caregivers experiencing burden and poor psychological wellbeing. So the literature has supported that caregivers may expressed a preference for interventions that are individualized and flexible in their design, with advances in technology offering the potential for support.

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