

Development and Testing of an Audio-Visual Self-Help Yoga Manual for Indian Caregivers of Persons with Schizophrenia Living in the Community: A Single-Blind Randomized Controlled Trial

Abstract

Background: To test the feasibility and effectiveness of an audio-visual self-help audio-visual yoga manual on burden of Indian caregivers of persons with schizophrenia, living in the community. **Methods:** An earlier developed yoga program for caregivers of schizophrenia was remodeled into an audio-visual self-help manual in three languages and validated by mental health and yoga experts. 48 consenting primary family caregivers of outpatients with schizophrenia were screened, recruited, and allotted randomly to Yoga or Care as Usual Group. Participants in Yoga group were taught yoga from the self-help manual (1 session of 1 h every month for 5 months). The caregivers were asked to follow the manual for the remaining month at home. Assessments of burden, perceived stress, quality of life, and anxiety-depression were conducted by a rater blind to the group status at baseline and at the end of every month. **Results:** Post factoring for missing data, Repeatedmeasure ANOVA was conducted; which showed that there was no significant difference between the group that practiced the selfhelp yoga manual and the care as usual group. The caregivers who practiced yoga at home maintained an average of 50% attendance and “very well” level of yoga performance. **Conclusion:** The audio-visual self-help yoga manual was found to be feasible to use by the caregivers even though its effectiveness could not be ascertained due to high attrition.

Keywords: Caregivers burden, feasibility testing, self-help yoga manual

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Introduction

In India, majority of the family caregivers take on the burden of caring for their relative with schizophrenia at their home in the community. Due to the stressful demands of caring, they often experience significant burden^[1] and sometimes border close to clinical depression. Yoga has been found to be effective in the management of stress.^[2] Further yoga, which originated in India, is seen to be a more practical intervention for caregivers to practice in the community.

Jagannathan *et al.*,^[3] in a randomized controlled study provided caregivers of in-patients with schizophrenia yoga intervention. It was noticed that irrespective of the intervention, with reduction in patient symptoms, the burden of the caregivers also reduced. Further, the yoga intervention given was provided only for a period of 7 days, which experts in the field of yoga believed to be insufficient. Varambally *et al.*^[4] in another controlled

study found that caregivers of outpatients with psychosis were able to learn and retain yoga practices for a period of 1 month, leading to reduced burden and improved quality of life. However, a large proportion of caregivers were unable to enroll and adhere to the study protocol due to inability to attend yoga sessions at centers far away from their community.

Based on the results of the above two studies, the current study was designed, with the aim of testing the feasibility of a self-help audio-visual yoga manual on burden of Indian caregivers of persons with schizophrenia, living in the community. The researchers believe that this self-help audio-visual yoga manual would be a novel and viable option to encourage caregivers to adopt yoga at their homes in the community.

Methods

This study was funded by the Indian Council of Medical Research, New Delhi, India. It

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was reviewed and approved by the Institute Ethics Committee, at National Institute of Mental Health and Neurosciences, Bengaluru. Written informed consent was obtained from the mental health professionals and yoga therapist who helped in the remodeling of the self-help manual and family caregivers who participated in the feasibility study.

The research was conducted in three phases. In Phase I, the earlier developed and validated yoga program for caregivers of schizophrenia^[5] was remodeled into a self-help written manual with an audio-visual digital versatile disc (DVD). In Phase II, this redeveloped and validated self-help manual was tested for its feasibility on five caregivers of outpatients with schizophrenia. In Phase III, the self-help yoga manual was tested for its effectiveness on burden of Indian caregivers of persons with schizophrenia, living in the community.

Phase 1 – Redevelopment and validation of self-help manual

The earlier developed and validated yoga program for caregivers of schizophrenia^[5] was successfully remodeled into a self-help manual and DVD and validated (Face and content). The job of developing the self-help yoga manual and DVD was outsourced to a private vendor outside the institute. The videoshooting for the DVD took place at S-VYASA campus. S-VYASA provided technical expertise as well as a trained yoga therapist as a model for the whole shooting. The entire process, i.e., video and photo shoot of the yoga procedures and editing of the video was monitored and supervised by (Co-I) and his team from S-VYASA. Parallel to video shooting, the manual was developed as a self-help format and translated into Kannada and Hindi Languages by respective language translators. Both the language translations content were edited and validated by the yoga experts ($n = 7$). Once the video editing and content of the manual in all three languages were finalized and validated by the experts, the voice over to the video was initiated using the content of respective language's manual. The final draft of the video with voice over and manual in all three languages was presented to all coinvestigators of the study as well as to the experts from S-VYASA for their feedback. After 2–3 iterations, the manual and DVD was approved. The final manual and DVD was in English, Kannada, and Hindi languages, with an aim to help reach out to a large section of caregivers living in rural/semi-urban/urban India.

Phase 2 – Feasibility Testing of the manual

Primary caregivers of outpatients diagnosed with schizophrenia (according to ICD 10, F20, F25, and F29) with a minimum of 3 months duration of illness, with a Clinical Global Inventory–Severity Scale^[6] score of 4 and below, between 18 and 60 years of age, who continued to care for the patient even after discharge from the hospital, who were willing to participate weekly once

in a yoga training for a period of 1 month, who knew Kannada, English, or Hindi languages and were ready to provide consent to participate in the study were recruited. Participants were excluded if the caregivers were diagnosed with severe psychiatric or neurological disorders. Caregivers also were excluded if they had another relative with psychiatric or neurological illness and/or if their patient relapsed with psychiatric symptoms during the course of the study. Caregivers who have undergone formal yoga training (certificate course from a recognized institute) and who were practicing yoga regularly for the past 1 month or who had undergone yoga training program from SVYASA University were not included in the study.

This redeveloped and validated self-help manual was tested for its feasibility on five caregivers of outpatients with schizophrenia for the period of 1 month. The five caregivers were taught the yoga practices by a trained yoga therapist, from the self-help manual in three parts (1 session of 1 h every week for 3 weeks) during their weekly follow-up visits followed by the fourth session inclusive of all three parts as a concluding session. The caregivers were asked to follow the manual and practice the exercises taught to them for the remaining days till the next follow-up date. The yoga therapist maintained a log of the caregiver's practice schedule and attendance at home to check their adherence. The yoga instructor also recorded the performance of caregivers at each follow-up visit.

At every weekly follow-up Burden, (Burden Assessment Schedule),^[7-17] Quality of Life (WHO Quality of Life–Brief Questionnaire),^[7] Stress using (Perceived Stress Scale [PSS])^[8] and Anxiety and depression (Hospital Anxiety and Depression Scale [HADS])^[9] was assessed. All the assessment tools were administered by a Research Scientist 1 (RS1) in the local language (Kannada or Hindi) for the benefit of clients who spoke and understood only the vernacular language. A feedback form to assess the Program, Handouts (Yoga Manual and Video), and Trainer (a mix of qualitative and quantitative data) was taken during the time the first, second, and third assessments were conducted.

Data were analyzed using the Statistical Package for the Social Sciences (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp). The sociodemographic data were analyzed using descriptive statistics, the results were analyzed using nonparametric statistics (Friedman's Chi-square test) and the qualitative feedback was content analyzed.

Phase 3 – Testing for effectiveness

To test the effectiveness of the self-help yoga manual, a directional hypothesis was adopted: (H1): Self-help yoga manual (Y) independently enables caregivers of outpatients with schizophrenia to reduce burden of caregiving than caregivers who are not provided any yoga manual (Care as Usual; CAU) (YT > CAU).

To achieve a target sample of 60 (30 in each group: Yoga Therapy – YT and Care As Usual – CAU), a sample of 1040 participants were screened with predefined inclusion and exclusion criteria, as mentioned in Phase 2. The caregivers who met the inclusion and exclusion criteria were screened using the Self-Reporting Questionnaire^[10] and whoever scored 8 and below (having no mental health problems) were offered to participate in the study. The CONSORT diagram detailing the process of screening is given in Figure 1

This study used a two-group single-blind, randomized control design. RS1 explained the content of the consent and study process to the participants, including the randomization process. Whoever accepted and agreed to participate in the study by signing the written consent, were recruited into the study and their sociodemographic

details were procured along with baseline assessments by RS1, who was blind to the randomization status. To maintain rater blinding, assessment was conducted by RS1 and group allocation status was managed by Research Staff 2 (RS2) (yoga therapist), and this was done in two separate places. The randomization was made in opaque sealed envelopes by the principal investigator and managed by RS2. Once the baseline assessments were completed, the participants were sent to yoga center to meet RS2 for the randomized allotment. For each patient, RS2 opened one opaque-sealed envelope having the group allocation. He was thus unaware of the group status of the next recruited patient (allocation concealment). RS2 would tear the group allocation envelope in front of the participant and let them know in which group they were allotted, i.e., YT or CAU.

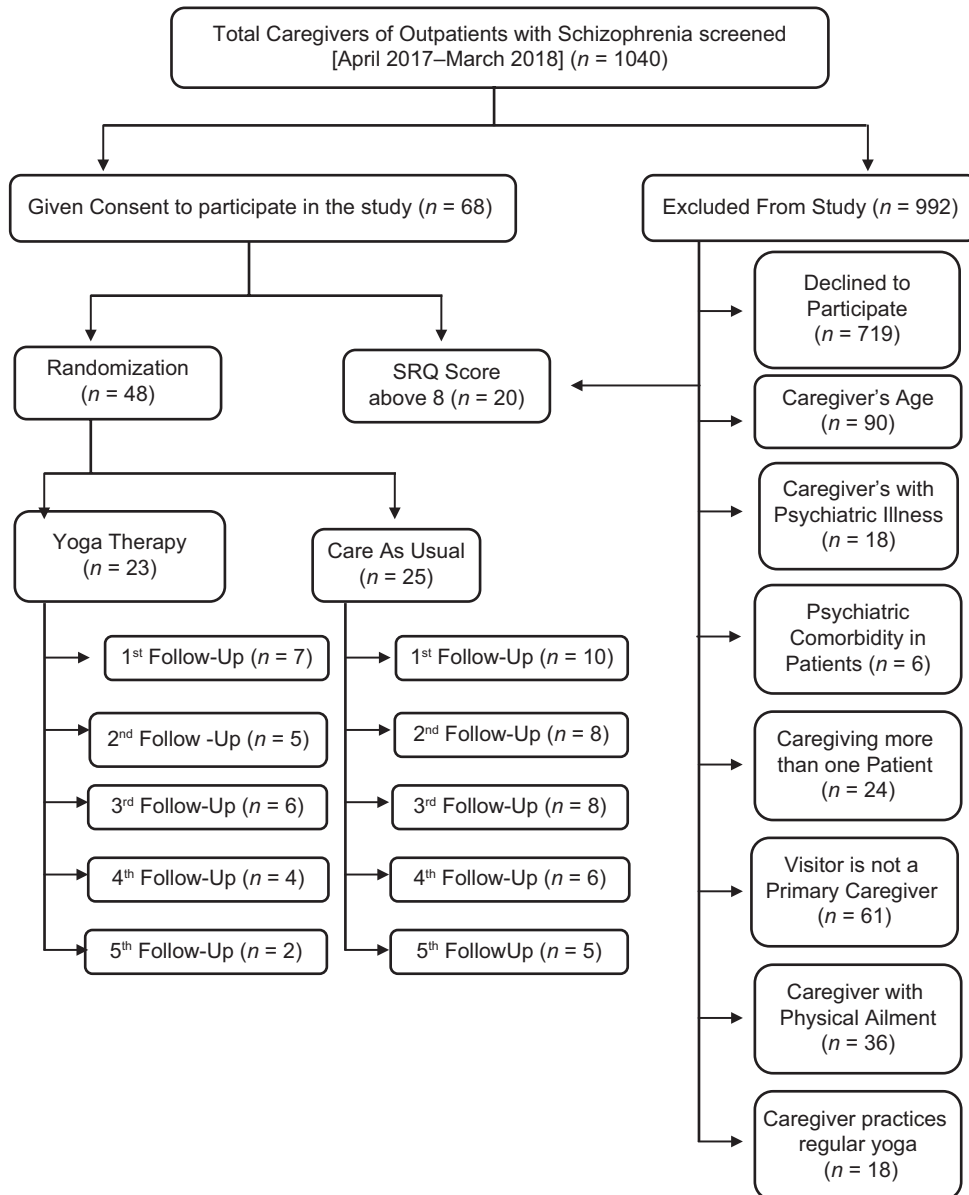


Figure 1: Consort diagram depicting the detailed process of screening

Participants who were allotted to Yoga group (YT) were taught the yoga exercises from the self-help manual in three parts (1 session of 1 h every month for 3 months) during their monthly follow-up visits. The manual contained step-wise details of the yoga asanas/pranayama along with pictures for ease of practice. Further, a DVD of the yoga practices was attached to the written manual to help the caregivers to follow the practices through audio-visual medium. The caregivers were asked to follow the manual and practice the exercises taught to them for the remaining month till the next follow-up date.

Participants who were allotted to waitlist control group (CAU) did not receive yoga training. Instead, they were available for assessments for the 5-month period and were called for follow-up to the outpatient Department once in a month. Normal consultation time spent with the caregiver/patient at the initial contact was 3 h. The caregivers in this group (CAU) were however taught the yoga exercises from the self-help manual in three parts (1 session of 1 h every month for three months) during their monthly follow-up visits only postcompletion of the data collection timelines (after completion of their day 150 assessments).

At every monthly follow-up, Burden, (Burden Assessment Schedule),^[6] Quality of Life (WHO Quality of Life–Brief Questionnaire),^[7] Stress using (PSS),^[8] and Anxiety and depression (HADS)^[9] along with yoga performance was assessed.

Data were analyzed using the Statistical Package for the Social Sciences (SPSS, Version: IBM-SPSS 24). The socio-demographic data were analyzed using descriptive statistics, and the results were analyzed using parametric statistics (Repeatedmeasure ANOVA [RMANOVA]) as the data was normally distributed. Missing data analysis was also conducted.

Results

Phase I

The manual contained step-wise details of the yoga asanas/pranayama along with pictures for ease of practice. The audio-visual format of the yoga practices was added to the written manual to help the caregivers to follow the practices through audio-visual medium. The entire yoga program consisted of Yoga practices and Satsang (Philosophy of Yoga) which was broken down into three parts (The final manual is can be obtained from the authors on request).

Phase II

Five caregivers gave their consent for the feasibility study and all of them completed the 4 weeks follow-up assessments except the 5th person who missed the last follow-up. Although all the outcome variables were normally distributed at baseline, as the sample size was small ($n = 5$), nonparametric tests were used to analyze the

data. The results of Friedman Chi-square test across the timelines showed significant improvement in burden and stress scores of the caregivers over the period of 4 weeks. All the caregivers were able to follow-up the instructions given and practices taught by the yoga therapist and were practicing the same in their houses regularly, i.e., average of 20 days in a given month.

The caregivers provided feedback that the overall pace and length of program was neutral to excellent with scores ranging from 3 to 5. With respect to usefulness and ease of understanding the video and manual, rating ranged between Excellent and Good, with scores of 4–5. Overall rating of trainer was Good–Excellent with scores ranging between 4 and 5. The qualitative feedback supported the quantitative Likert ratings and could be divided into three broad themes with supporting quotes of the caregivers:

Theme 1: What caregivers I valued in the program

- “It is short, easy to learn and good” (C1, 26 years, female)
- Suryanamaskara and other exercises were good” (C4, 27 years, female)
- “I liked the way the yoga teacher taught and explained the details of the practices” (C5, 42 years, female).

Theme 2: Suggestions to improve the programme

- “The contact sessions can be conducted at different locations in Bangalore if possible” (C1, 26 years, female)
- “Group session rather individual would be better” (C3, 20 years, male)
- “Want little more information of the practices if possible” (C4, 27 years, female).

Theme 3: Caregiver's overall experience of the programme

- It is a very good initiative with easy and effective yoga techniques (C1, 26 years, female)
- “It helped relieve stress and tension and made me feel healthy to take care of my patient” (C2, 55 male)
- “I felt calm–peace of mind and had relief” (C3, 20 years, male)
- “This programme is very good. It totally relaxed me gave me more peace of mind” (C5, 42 years, female).

Phase III

A total of 48 samples were recruited into the study, i.e., 23 in yoga group and 25 in care as usual (control) group. There were different strategies used, to track, contact. and inform recruited caregivers to come for regular follow-ups. Even after regular follow-up calls, sending postal reminders, checking the recruited caregiver's patient file once in month at medical record section, the follow-up rates were poor [Figure 1]. The sociodemographic details of the caregivers in Yoga and CAU group are detailed in Table 1.

Shapiro–Wilk normality test was conducted for both the

Table 1: Sociodemographic details of the caregivers in yoga and care as usual

Variable	Mean (SD)*/n (%)	
	Yoga (n=23)	Care as usual (n=25)
Age of caregiver (years)*	39.96 (10.45)	36.24 (12.89)
Education (years)*	9.95 (4.97)	10.92 (4.63)
Monthly income (rupees)*	12,934.78 (12,299.57)	20,283.96 (24,879.53)
Distance from host institution (km)*	62.304 (85.93)	39.44 (34.09)
Change of transport (number of times)*	1.52 (0.89)	1.2 (1.00)
Number of family members*	4.52 (1.62)	4.48 (1.93)
Caregiver gender		
Male	17 (73.9)	17 (68)
Female	6 (26.1)	8 (32)
Caregiver religion		
Hindu	22 (95.7)	23 (92)
Others	1 (4.3)	2 (8)
Caregiver occupation		
Employed	18 (78.3)	17 (68)
Unemployed	5 (21.7)	8 (32)
Caregiver marital status		
Never married	4 (17.4)	9 (36)
Ever married	19 (82.6)	16 (64)
Region		
Urban	13 (56.15)	16 (64)
Rural	10 (43.5)	9 (36)
Travel mode		
Public	16 (69.6)	17 (68)
Private	7 (30.4)	8 (32)
Medical ailment		
Yes	5 (21.7)	5 (20)
No	18 (78.3)	20 (80)
Yoga practice earlier		
Yes	4 (17.4)	3 (12)
No	19 (82.6)	22 (88)
Diet		
Vegetarian	2 (8.7)	5 (20)
Mixed	21 (91.3)	20 (80)
Substance use		
Yes	7 (30.4)	10 (40)
No	16 (69.6)	15 (60)
Structured training received		
Yes	4 (17.4)	3 (12)
No	19 (82.6)	22 (88)
Activities to take care of own health		
Yes	15 (65.2)	11 (44)
No	8 (34.8)	14 (56)
Language		
Kannada	22 (95.7)	16 (76.20)
English	0	2 (9.5)
Hindi	1 (4.3)	3 (14.3)

Contd...

Table 1: Contd...

Variable	Mean (SD)*/n (%)	
	Yoga (n=23)	Care as usual (n=25)
Relationship with patient		
Spouse	9 (39.1)	3 (14.3)
Child	2 (8.7)	6 (28.6)
Parent	6 (26.1)	6 (28.6)
Sibling	6 (26.1)	6 (28.6)

SD=Standard deviation

group's, for all the four variables at baseline. Burden Assessment Scale, PSS, and WHO-QOL-Brief were normally distributed, whereas the data of the HADS were not normally distributed. There were no baseline differences between the groups across all the outcome variables.

Due to high rates of dropouts over the study timelines, it was decided to do missing data analysis, where the mean scores of the latest follow-up that the client attended was considered as the data for the subsequent follow-ups that he/she missed. Using this method of missing data analysis, further statistical analysis was conducted.

RMANOVA, a parametric test to find the interaction effect over the period of 6 months, was performed for BAS, WHO-QOL-Brief, and PSS. From Table 2, it can be observed that there is no significant difference between those who practiced the self-help yoga manual and those who received care as usual in either of the outcome variables. To understand the effect of the intervention in the two groups on HADS (data not normally distributed) over a period of time, Friedman Chi-square, a nonparametric test was performed. From Table 3, it can be observed that there is no significant difference in the outcome of HADS between those who were doing yoga and those who got care as usual, indicating that both the interventions had an equal effect.

Analysis of the yoga attendance at home out of 30 days ranged between 14 days of practice to 16 days of practice (approximately half the number of days of yoga practice). Yoga performance of the caregivers as rated by the yoga therapist when they attended the yoga session at the Yoga Centre showed that out of a total score of 32 (8 domains with minimum score of 1 and maximum score of 4), the average performance score of the caregivers ranged from 23 to 26, which was considered as performed "very well." Further analysis showed no significant correlations between yoga attendance and any of the outcome variables or yoga performance and any of the outcome variables possibly due to low number of sample at every follow-up.

Discussion

The goal of the study was to help reduce the burden and stress of the caregivers of persons with schizophrenia by training them to self-practice yoga in their homes. This was done essentially to help reach yoga to the community

Table 2: Effect of intervention over period of 6 months (interaction effect – repeated measure ANOVA)

Assessments	Mean (SD)										F3	P		
	Yoga (n=23)					Care as usual (n=25)								
	Baseline	1 st F/U	2 nd F/U	3 rd F/U	4 th F/U	5 th F/U	Baseline	1 st F/U	2 nd F/U	3 rd F/U	4 th F/U	5 th F/U		
BAS	64.43 (13.65)	63.21 (13.79)	64.34 (13.43)	63.86 (13.55)	63.30 (13.83)	62.95 (14.55)	60.68 (12.28)	58.72 (12.37)	58.36 (12.17)	57.08 (12.28)	56.56 (12.43)	57.28 (13.31)	0.34	0.88
WHO-QOL -Brief	88.52 (8.96)	88.47 (9.43)	88.21 (9.74)	88.65 (8.51)	88.82 (8.44)	89.04 (8.45)	89.36 (9.34)	91.12 (9.67)	90.92 (8.53)	91.4 (9.12)	88.96 (14.09)	91.4 (14.06)	1.57	0.15
PSS	17.26 (5.37)	17.56 (5.40)	17.09 (4.81)	16.52 (5.70)	17.04 (5.50)	17.17 (5.12)	17.44 (2.86)	16.80 (5.09)	17.64 (3.90)	17.64 (3.710)	17.80 (3.42)	16.88 (4.31)	1.03	0.11

F3=F value indicating interaction effect in RMANOVA. RMANOVA=Repeated-measure ANOVA, SD=Standard deviation, F/U=Follow-up, BAS=Burden Assessment Scale, QOL=Quality of life, PSS=Perceived Stress Scale

and for reducing the logistic barriers to attending and practicing yoga in a tertiary care center.^[11] The qualitative and quantitative results of the feasibility testing phase of the study depict that the audio-visual self-help yoga manual for Indian caregivers of persons with schizophrenia is feasible to practice, helps reduce stress and burden of the caregivers (objectively and subjectively), and can be tested for its efficacy in the future.

The effectiveness of the self-help manual could not be established as no significant difference was observed between those who practiced the self-help yoga manual and those who received care as usual in any of the outcome variables. These results need to be interpreted in the background of poor follow-rates (high attrition) which was as low as 35% at the end of 1st-month follow-up and which dropped further to 14% follow rate. The reasons for dropout (barriers to yoga) as expressed by the caregivers included loss of work day, long distance of travel from their homes, no alternative caregiver to take care of patient, patient getting symptomatically better, and hence caregivers not experiencing burden nor feeling the need for yoga. Most yoga studies depict a yoga adherence rate of 50%^[12] in a community setting. As there was hardly any data to analyze at the end of the 6th-month follow-up, it would be false to interpret that the self-help manual was not more effective than the care as usual group. Both the Pilot Phase and the main study results depicted significant reduction in burden and stress scores at the end of 1 month in those who practiced the self-help manual for the period of the 1 month. If attrition rates in yoga studies can be controlled, the true effectiveness of yoga intervention could be depicted.

Caregivers seemed to be more motivated to attend sessions in the feasibility phase, once week sessions, as compared to the Main study phase, sessions conducted once a month. Thus, a more regular follow-up may be required to maintain follow-rates and adherence to yoga. Even if our study with a longer training period (of 5 months) had shown effectiveness, its wider application in routine clinical practice would have been a daunting task as only a minuscule proportion of caregivers were able to go through longer periods of training. There are many barriers to convince people to travel long distances from their homes to a center for yoga therapy^[11] once they are discharged. In this context, we believe that possible the yoga training programs should be developed for not more than a period of 1 month to help reduce attrition rates. Traditional yoga therapists may argue that a 1 month program could be too short to perceive any effects of yoga.

Studies have time and again discussed the importance of the length of yoga practice^[13-16] to observe desirable effects. Caregivers who reported that they had practiced yoga, did they practice yogasana at home as well as they did under supervision? This is indeed a genuine concern. Given the

Table 3: Effect of intervention over a period of 6 months (time effect – Friedman Chi-square)

HADS assessment	Mean (SD)					Friedman χ^2	P	
	Baseline	1 st F/U	2 nd F/U	3 rd F/U	4 th F/U			5 th F/U
Yoga (n=23)	7.86 (6.69)	8.34 (7.02)	8.56 (6.90)	7.08 (6.94)	7.04 (6.85)	7.00 (6.88)	8.531	0.129
Care as usual (n=25)	5.56 (5.40)	5.56 (6.22)	5.96 (6.30)	6.4 (6.64)	4.96 (5.23)	3.8 (4.15)	3.816	0.576

SD=Standard deviation, HADS=Hospital Anxiety and Depression Scale, F/U=Follow-up

long duration of illness, there could well be certain degree of cynicism and lack of interest in the caregivers. The seriousness with which they would have adhered to any interventions is doubtful. This observation is vindicated by the fact that <50% of the caregivers in the yoga group reported practicing yoga daily.

Scales used may not have been sensitive in tapping the efficacy of the interventions. The burden scales provide a total burden score which encompasses all components of burden including financial, occupation, family routine, family leisure, family interaction, social relations, and emotional–physical–mental health. Yoga therapy may not necessarily have a bearing on all these components of burden and stress. Although we realized this limitation in the beginning of this study itself, we still decided to use these scales because: (1) they were widely used scales which had no good alternatives and (2) they were clinically meaningful outcomes and we had hypothesized that the interventions would ultimately lead to a reduction in burden through different methodologies (e.g.,: through developing a sense of equanimity by practicing yoga; understanding patient behavior using the skills taught in the psychosocial program). Thus, instead of discounting the effectiveness of the program, any negative result could be viewed as a possible inability of the structured instruments to tap the effectiveness of the program in reducing the burden of the caregivers.

Expectation of the caregivers was to “cure the patient.” Hence, caregivers found it difficult to relate their participation in the yoga intervention. Further as most of the caregivers did not consider the caretaking process to be burdensome or stressful (they considered it as their family responsibility), interventions could have been effective for those caregivers who expressed a felt need for these interventions.

Resilience of Indian caregivers could be higher than reported in the Western studies. A reason for this is the strong family system present in the country which helps the patient and caregivers cope with the illness effectively. By providing interventions to all caregivers, we may be falsely assuming that they all equally burdened by the caretaking process and have poor resilience.

This is one of the first studies in India to have systematically tested the feasibility and effectiveness of audio-visual self-help yoga manual for Indian caregivers of persons with schizophrenia. The self-help yoga manual developed in this

study was observed to be feasible to use by the caregivers qualitatively and quantitatively in reduction of their burden. This manual can thus be provided to caregivers of persons with schizophrenia in the community and can also act as a guide for mental health professionals and yoga therapists in the future. The effectiveness of this manual however could not be conclusive arrived at, due to the poor follow rates (high attrition). In this background, it would be false to interpret that the self-help manual was not more effective than the Care as usual group, as in the Feasibility Phase, time effect results depicted significant reduction in burden and stress scores at the end of 1 month in those who practiced the self-help manual for the period of the 1 month. If attrition rates in yoga studies can be controlled, the true effectiveness of yoga intervention could be depicted. In this context, we believe that future yoga research should provide yoga training for not more than a period of 1 month to help reduce attrition rates. Also as attrition was mainly because of the inability of caregivers to travel to a tertiary care center for yoga training, testing the feasibility and effectiveness of virtual yoga sessions should be the next research questions that should be addressed by yoga researchers.

Conclusion

The self-help audio-visual yoga manual was found to be feasible to use by the caregivers even though its effectiveness could not be ascertained due to high attrition.

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Conflicts of interest

There are no conflicts of interest.

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