

8.0 APPRAISAL

8.1 SUMMARY OF THE FINDINGS

The results indicated that participants in the TYM group experienced significant improvements in PTSD symptoms, anxiety, depression, and psychosocial functioning compared to those in the TAU group. The feasibility aspects of the TYM have been discussed under seven dimensions, including safety and acceptability. These findings suggest that the TYM can serve as a potentially useful add-on intervention in managing PTSD. This study contributes to the emerging field of tele-yoga and highlights the importance of culturally and contextually adapted mental health interventions. Such approaches are crucial for addressing the global burden of PTSD.

8.2 CONCLUSION

Our study evaluated the feasibility and potential efficacy of the tele-yoga module (TYM) for managing PTSD. We followed a systematic methodology to develop, scientifically validate, and test the potential utility of TYM in participants with PTSD. The developed program was safe, feasible, and useful. The feasibility study results showed significant improvements in PTSD symptoms, anxiety, depression, and psychosocial functioning. The intervention also showed high acceptability and adherence rates, suggesting that tele-yoga may be a useful tool to bridge the gap in PTSD care by providing accessible, stigma-free mental health support.

8.3 IMPLICATION AND APPLICATION OF THE STUDY

The application of this study lies in its potential to inform clinical practice. PTSD recovery centers and rehabilitation programs may consider integrating TYM as part of their holistic treatment plans. This intervention could be used alongside counselling, medication, and other therapies to support the physical and mental health of individuals in recovery. The study also highlights the feasibility of implementing tele yoga in real-world treatment settings, suggesting that with proper training and support, yoga can be incorporated as a regular therapeutic offering for individuals with PTSD.

At Individual level – After initial supervised training it can be practiced individually

- In clinical settings – For therapeutic purposes for patients individually or in groups
- At community level – In person or tele-yoga therapy mode
- For further research – as a base template for further clarity about yoga practices for PTSD

8.4 STRENGTH OF THE STUDY

One of the key strengths of this study is that it is the first study to integrate different aspects of Tele yoga including yoga-based counselling and apply it to a clinical population. In terms of developmental accuracy, when compared to previous yoga module studies, TYM has a high methodological quality. The methodology combines a thorough systematic review with expert interviews, providing a robust foundation for the development of our TYM module. Moreover, the study integrates trauma-informed treatment guidelines frameworks and practices to manage symptoms for PTSD.

8.5 LIMITATION OF THE STUDY

Our study had a few limitations. Firstly, we were unable to isolate the effects of medications or concurrent psychotherapy from the overall outcomes. Although the between groups comparison demonstrates the impact of the TYM, a method to adjust for medication levels would have more accurately presented TYM's unique effects. It was an unblinded, two-group, non-randomized design, with participants recruited irrespective of the type of trauma severity, duration, or medication status. While these broad criteria may affect interpreting efficacy, the heterogeneous participant group demonstrates the safety and feasibility of tele-yoga for varied PTSD cases. We relied solely on self-report data for inclusion and exclusion criteria that could lead to inaccuracies. The study sample was primarily female (n = 49/60). Selection bias might be present, as participants self-selected, potentially favoring those familiar with yoga or other treatment modalities.

8.6 SUGGESTIONS FOR FUTURE STUDIES

Future RCTs could incorporate objective outcome variables and explore additional interdisciplinary domains. Our sampling procedure may have also introduced self-selection bias, as the feasibility phase of our study utilized a two-group and non-randomized design. This resulted in a predominantly female sample (49 out of 60 participants), and selection bias may have occurred, as participants who already favored yoga might have chosen the yoga group. Additionally, retaining participants for the entire study duration was particularly challenging in the control group, as evidenced by the high rate of missing values. Future studies should aim for methodological innovations to address these challenges. Participant heterogeneity was another factor; we recruited individuals with a wide range of trauma severities, durations, and medication statuses. While this may have diluted the observed effect sizes, such diversity can yield more realistic clinical effects. Despite such non-restrictive inclusive criteria, the recruitment process was lengthy, which may reflect the stigma associated with PTSD in the community. Future studies could consider investigating the exclusive effects of tele-yoga using a more rigorous RCT design and relevant objective clinical measures. It would also be beneficial to understand various mediators and moderators related to PTSD.

Through our attempt to validate the tele-yoga module for PTSD, we hope that the profound benefits of yoga will also reach the most isolated and non-seeking individuals in our society, who are often left to fight their inner battles with trauma all alone. Echoing the sentiment of an anonymous quote on PTSD, “*Your trauma is not your fault, but healing is your responsibility,*” we believe that tele-yoga can play a crucial role in supporting individuals as they undertake their healing journeys.

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Appendix-I
Institute Ethical Committee letter (IEC)

**स्वामी विवेकानन्द योग अनुसंधान संस्थान**
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**Institutional Ethics Committee (IEC)-SVYASA
Clearance Certificate**

Dear Mr. Katla Naresh Date: 30th November, 2021

The institutional Ethics committee (IEC) of Swami Vivekananda Yoga Anusandhana Samsthana (Deemed-to-be University under Section 3 of the UGC Act, 1956) reviewed your application in the committeeⁿ meeting held on 23rd October, 2021 (Online) based on:

I. Documents

1. Covering Letter
2. Project Application
3. Project Proposal
4. Informed consent form
5. Undertaking

II. Presentation to IEC on 23rd October, 2021

III. Your clarification provided to the comments of the members made during presentation.

After perusal of this information, IEC has decided to approve your study. Details of approval are as follows:

Certificate Reference Number: RES/IEC-SVYASA/217/2021

Project Title: "Development, Content Validation and Feasibility of a Tele-Yoga Module for Post-Traumatic Stress Disorder."

Nature of Study: PhD

APPROVED

INSTITUTIONAL ETHICS COMMITTEE
SVYASA, BANGALORE



स्वामी विवेकानन्द योग अनुसंधान संस्थान
Swami Vivekananda Yoga Anusandhāna Samsthāna

(Declared as Deemed-to-be University under Section 3 of the UGC Act, 1956)
Ekmath Bhavan, # 19, Gavipuram Circle, Kempegowda Nagar, Bangalore - 560 019
Ph: 080 - 2661 2669, Telefax: 080 - 2660 8645
E-mail: svyasa@svyasa.org Website: www.svyasa.org

Authorised Personnel: Mr. Katla Naresh, Dr. Judu Ilavarasu, Dr. Hemant Bhargav, Dr. Bharath Holla

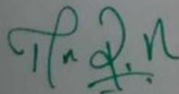
Approval Period: 02 Years

Condition of approval

- Research must be conducted according to the approved proposal.
- Report has to submitted to IEC on completion of study.
- Violation/deviation from the approved proposal has to be notified to IEC.
- The authorised personnel will comply to request for audit from IEC.
- IEC retains right to withdraw or amend this approved clearance certificate.

Please contact undersigned member Secretary if you have any queries / need clarification.

IEC wishes you all the best.


Dr. Ramesh M N
Member Secretary,
Institutional Ethics Committee,
S-VYASA, Bengaluru.

Member Secretary
Institutional Ethics Committee
Swami Vivekananda Yoga Anusandhana Samsthana (S-VYASA)
No. 19, Ekmath Bhavan, Gavipuram Circle
K.G. Nagar, Bangalore-560019



NATIONAL INSTITUTE OF MENTAL HEALTH AND NEURO SCIENCES
(INSTITUTE OF NATIONAL IMPORTANCE)
PB No 2900, HOSUR ROAD BENGALURU 560029 (INDIA)

Dr. Shivarama Varambally
Professor, Head i/c Dept of Integrative Medicine
and Member Secretary, Human Ethics Committee for
Research in AYUSH and Integrative Medicine,

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Fax: 91-80-26564830/26566811
E-mail: intmed@nimhans.ac.in

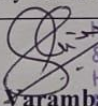
No. NIMHANS/HECAIM/6th/MEETING/2020-21

Date: 13.09.2022

Human Ethics Committee for Research in AYUSH and integrative Medicine

Approval Letter

1.	Name of the Investigator	Naresh Katla Ph.D. Scholar Department of Yoga and Physical Science. S-VYASA, deemed to be University, Bengaluru.		
2.	Reference Number of the Investigator:	Letter Dated 28.06.2022 and 09.09.2022		
3.	Title of the proposal submitted for ethical clearance	Non-Funded Ph.D. Thesis Title: "Development, content validation and feasibility of a tele-yoga module for post-traumatic stress disorder".		
4.	Nature of the proposal submitted for ethical clearance	Research project		
5.	Tick on the relevant box (Self-explanatory)	New Review √	Revised Review	Expedited Review
6.	Duration of the Research Project	3 years		
7.	Date of Ethics Committee Held	2 nd August 2022		
8.	Date of the previous review, if revised application	None		
9.	Clear statement of the decision reached The research project and study related documents were circulated to all the members of the ethics committee who revied and discussed the ethical issues involved. After consideration, the committee decided to approve the research project in-principle. A letter was sent to you seeking clarifications/documents vide email/letter dated 01.09.2022. In response to this, you have submitted required clarifications/documents vide email/letter dated 09.09.2022, which have been reviewed and deemed satisfactory. Hence the research project and study documents are approved with respect to ethical aspects. Decision of the EC: The research project and study related documents are approved with respect to ethical aspects.			
10.	Validity of the Ethics Approval	3 years from the date of ethics approval		


Head, Dept. of Integrative Medicine
& Member Secretary,
Human Ethics Committee for
Research in AYUSH and Integrative
Medicine, NIMHANS, Bengaluru

Dr. Shivarama Varambally
Professor, Head i/c Dept of Integrative Medicine

APPENDIX-II

Socio-demographical details of Experts

No.	Field	Information
1.	Full Name:	
2.	Gender:	
3.	Age:	
4.	Email Id:	
5.	Country:	
6.	Designation and Affiliation:	
7.	School of Yoga you belong to:	
8.	Highest Educational Qualification:	
9.	Years of experience in yoga therapy for Mental Health:	
10.	Years of experience in Psychology:	
11.	Years of experience in yoga therapy for PTSD patients:	
12.	Years of research experience:	
13.	Months/Years of experience handling yoga sessions via Online mode:	

APPENDIX-II

Socio-demographical details of Participants

No.	Field	Information
1	Name:	_____
2	Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female
3	Date of Birth:	d____/ m____/ y_____
4	Age:	_____
5	Telephone:	_____
6	Emergency contact:	_____
7	Email:	_____
8	Address:	_____ Rural/Urban _____ _____
9	Education:	<input type="checkbox"/> Primary <input type="checkbox"/> Secondary <input type="checkbox"/> Higher Secondary <input type="checkbox"/> Graduation <input type="checkbox"/> Post Graduation
10	Total Years of Education:	_____
11	Marital status:	<input type="checkbox"/> Married <input type="checkbox"/> Unmarried <input type="checkbox"/> Separated <input type="checkbox"/> Divorced <input type="checkbox"/> Widow
12	Occupation:	<input type="checkbox"/> Student <input type="checkbox"/> Professional <input type="checkbox"/> Business <input type="checkbox"/> Service <input type="checkbox"/> Other <input type="checkbox"/> Unemployed
13	Income:	Rs._____ per month/annum
14	Religion:	<input type="checkbox"/> Hindu <input type="checkbox"/> Muslim <input type="checkbox"/> Sikh <input type="checkbox"/> Christian <input type="checkbox"/> Buddhist <input type="checkbox"/> Other
15	Diagnosis:	
16	Ongoing Treatment:	<input type="checkbox"/> Medications <input type="checkbox"/> Psychotherapy or Counseling <input type="checkbox"/> No treatment
17	Diet:	<input type="checkbox"/> Vegetarian <input type="checkbox"/> Non-Vegetarian
18	Earlier Yoga Practice:	<input type="checkbox"/> Yes <input type="checkbox"/> No
19	Type of Trauma:	<input type="checkbox"/> Loved one death <input type="checkbox"/> Childhood trauma <input type="checkbox"/> Accidents <input type="checkbox"/> Sexual abuse <input type="checkbox"/> Domestic violence <input type="checkbox"/> Natural disasters <input type="checkbox"/> Property loss
20	Duration of Trauma:	_____ months/years
21	Comorbidity:	_____

APPENDIX-III
INFORMED CONSENT FORM (FOR EXPERTS)

Title: Development, Validation, and Feasibility Testing of Tele-Yoga Module for Post-Traumatic Stress Disorder (PTSD)

Information to the Participants:

We understand that you are an expert in the field of yoga. Studies have proven that yoga can be beneficial for persons with mental health disorders. Tele-Yoga Module (TYM) is a holistic model inclusive of yogic practices and philosophy, which is culturally appropriate to cater to persons with PTSD.

In this proposed research, we are developing, validating, and feasibility testing the TYM for persons with PTSD in the community. This study is conducted as a part of the Ph.D. program in the Division of Life Science and Yoga of Anvesana, S-VYASA.

The study will be conducted in three stages:

Study I: Development of TYM for PTSD.

Study II: Validation of TYM with experts.

Study III: Feasibility Testing.

Your consent is sought to take part in Study II. If you consent to take part in this phase of the study, the investigator will send you the list of yoga practices that help with PTSD. The information collected from you will be helpful in validating the PTSD. The whole response may take about 30 minutes.

Please note that you have the right to refuse to take part in the study at any time. Please also note that the information you are going to divulge to us will be kept in utmost confidentiality.

Once validated, this module will be pilot tested on adults between 18-60 years of age to assess its feasibility.

The validation for the current study would be conducted through the Delphi method. We will share the final module with you after the overall expert consensus is achieved.

In this, I would like you to rate the practices with a focus on:

1. Their usefulness and contra-indications/adverse effect
2. Time duration for individual section wise practices
3. Sequence of practices
4. Dose, frequency and module duration.

KINDLY ANSWER ALL THE QUESTIONS IN THE GIVEN FORMAT FOR VALIDATING THE MODULE.

Undertaking by the Investigator: Your consent to participate in the above study is sought. You have the right to refuse consent or withdraw the same during any part of the study without giving any reason. I undertake to maintain complete confidentiality regarding the information obtained from the expert during the study. If you have any doubts about the study, please feel free to clarify the same. Even during the study, you are free to contact the investigator/s for clarifications if you so desire. The phone number of the investigator/s is given below:

Investigators' Mobile Numbers:

Mr.Naresh Katla: 9030077282

Dr. Hemant Bhargav: 080-26995983

Consent:

I have been informed about the procedures of the study. I understand that I have the right to refuse my consent or withdraw it at any time during the study. I am aware that by participating in this investigation, I will have to give time for an interview by the investigating team.

I, _____, the undersigned, give my consent to be an expert in this investigation/study program.

I, _____, the undersigned, give/do not give consent for my interview to be audio/video taped.

Signature of the Expert: _____
(Name and Address)

Signature of the Investigator: _____
(Name and Designation)

Date _____

APPENDIX-IV

Informed Consent Form for Paarticipantes



INFORMED CONSENT TO PARTICIPATE IN RESEARCH

**SWAMI VIVEKANANDA YOGA ANUSANDHANA
SAMSTHANA (SVYASA) DEEMED TO BE UNIVERSITY**

Vivekananda Road, Kallabalu Post, Anekal Taluk, Jigani, Bengalore,
India

research@svyasa.org, Phone: 080-22639983.

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

**SWAMI VIVEKANANDA YOGA ANUSANDHANA SAMSTHANA (SVYASA)
DEEMED TO BE UNIVERSITY** Vivekananda Road, Kallabalu Post, Anekal Taluk,
Jigani, Bangalore, India, research@svyasa.org, Phone: 080-22639983

Title of the Project: **“DEVELOPMENT, CONTENT VALIDATION AND
FEASIBILITY OF A TELE-YOGA MODULE FOR POST-TRAUMATIC STRESS
DISORDER.”**

Principal investigator: Katla Naresh (PhD scholar)

Co-Principal Investigator: Dr. Judu Ilavarasu, Ph.D. (YOGA), Dr. Hemant Bhargav,
MBBS, MD, Ph.D. (YOGA), Dr. Bharath Holla, MBBS, MD, Ph.D. (Psychiatry)

Organization: Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA) Deemed to be
University and NIMHANS, Bangalore.

This informed consent has two parts:

PART I: Information sheet (to share information about the research)

PART II: Certificate of Consent (for signature if you allow us to conduct the study)

PART I: Information Sheet

Introduction

I am Katla Naresh., PhD Scholar at SVYASA Yoga University. We are conducting a research project to develop, content validation and feasibility of a tele-yoga module for post-traumatic stress disorder and to evaluate how well the module works. I am sharing with your relevant information and inviting you to be part of this research. You need not decide today whether to participate or not in the research. You can talk to anyone you feel comfortable with about the research before you decide to take part in the research.

I will share some information about the research. There may be some words that you may not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have any questions later, you can ask me.

Purpose of the Research:

Post-traumatic stress disorder (PTSD) is a serious health issue that has underlying societal and health consequences. There are different methods to manage PTSD and one of them is through Yoga. Yoga, meditation, and lifestyle modification are practiced along with the other ongoing treatment. Based on the available scientific and literary evidence, a Tele Yoga Module has been designed and validated to improve factors related to persistent re-experiencing of the trauma or flashback of the event, avoidance of any reminders of the traumatic thought or discussion or place, numbing of positive emotions, social withdrawal, and periods of increased autonomic. Practices include meditation, yoga *āsanas* (postures), *Prāṇāyāma* (breathing exercise), and yogic terms for counseling. This study aims to find out how doable is the newly developed and validated Tele-Yoga Module for PTSD.

To the best of our knowledge, not much empirical literature is available on yoga and PTSD. Hence, there is a requirement for such a study that tests the feasibility and acceptability of the tele-yoga module for PTSD.

Procedure for the research:

Participant selection: We are inviting adult males and females who suffer from PTSD to take part in this research. The Yoga practices will be done through online mode. Applications such as Zoom/Facebook/WhatsApp/Google Meet would be utilized for online video conferencing depending on your preferences. Your opinion on the Tele Yoga Module will be of great value to assess how doable it is and if any changes must be made.

Type of Research Intervention:

This research will involve you practicing yoga postures and breathing exercises and participating in counseling sessions along with the other conventional treatments. At the end of the study, we will take your feedback about the Yoga intervention.

Selection of participants:

People who meet the eligibility criteria will be selected for study, following are the selection criteria:

- Diagnosis of PTSD as per PCL-5 (score of >33)
- Both genders and aged between 18 to 65 years.
- With or without comorbidity (Anxiety and Depression).
- Ongoing psychotherapy or medications
- Able to read/understand/speak English.
- Those having access to regular internet access via an electronic device

Participants unwilling to participate, those who have been diagnosed with psychotic disorders, those who have acute suicidality or could be of imminent danger to others and those who need intensive treatment due to high risk or continued heavy use will be excluded from this study.

Voluntary Participation- Your participation in this research is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating even if you agreed earlier.

Information on the Trial Yoga

After completing the screening, you will join the online Tele yoga program. A psychiatrist will determine whether you can participate in the study according to the eligibility criteria. We will do a general interview to understand your medical history. **You will be in the yoga group or in the group that does the usual treatment completely based on your choice.**

We will ask you to fill out seven questionnaires that assess your PTSD symptoms, anxiety, depression, recovery from stress, psychosocial functional impairment, Vedic personality, and Ayurvedic *tridoṣaas*. All your information will be kept confidential. After that we you will continue the treatment as usual at the center.

For 4 weeks, the Tele Yoga Module will be practiced. This module has been validated and accepted by experts as an add-on technique that can help in the management of PTSD symptoms, you will practice Yoga postures, and breathing exercises and you will have counseling sessions in groups.

After completing treatment, we will take your feedback via a semi-structured interview about the yoga practices. For example, we will ask you how you felt when you did the yoga poses. In addition, we will assess your PTSD symptoms, anxiety, depression, recovery from stress, and psychosocial functional impairment.

Your participation will help us know how doable the module is and what needs to be changed.

**I have checked with the individual, and they understand the risks and discomforts _____
(initial).**

Benefits

Different people can have different types of benefits when practicing yoga. We want to find out how you feel after practicing this Tele Yoga Module. Usually, Yoga postures and breathing exercises can help you to have physical stamina in the long term. It also helps to relax the body and mind. We also believe that the counseling sessions will help you cope better with your thoughts.

**I have checked with the individual, and they understand the benefits _____
(initial).**

Possible limitations to care:

I understand that video session has its own limitations as compared to in-person sessions and some details could potentially be missed out despite the Yoga therapist's/instructor's best effort.

I understand that Tele-Yoga sessions are provided by appointment only and that these sessions are not suitable for help during crisis or emergency

Responsibility for adverse events:

I understand that Tele-Yoga classes does not have any side effects but may make you tired and it can cause some temporary soreness of the muscles of the body, cramps and muscle catch. However, I will follow my Yoga therapist/instructor and keep track of any unwanted effects or any problems, or I may stop one or more practices. At the same time, I agree to not hold my Yoga therapist/instructor responsible, should any adverse events, such as lack of improvement, deterioration or situations of potential risk of harm to self or others, occur during the video session.

I understand that in such situations I may be advised to obtain treatment at the nearest available emergency service.

Confidentiality and Recording

I understand that this audio/ video session is strictly confidential. I agree to use a secure line/ connection for these sessions, in a relatively quiet and private space. I understand that my Yoga therapist/instructor will not audio or video record the session (either on mobile, using an app or online) and will not share the proceedings of this session with any other individual or agency. However, with my consent, my Yoga therapist/instructor could use it to have their work supervised or for training of professionals. Apart from this, the details of the consultation would be shared only with a court of law, if mandated.

Notes of the Tele-Yoga session will be maintained by my Yoga therapist/instructor and stored in a safe location. I understand that these session notes can be made available to me, in the standard session record format, on my explicit request.

I also undertake that the proceedings of these sessions are not to be recorded, shared or disseminated by me or my relatives/ other contacts to any third person or through social media.

However, despite safety measures taken, there are chances for breach in security in technology. In such instances, both patient and Yoga therapist/instructor will not hold the other responsible for the breach.

Information about you that will be collected from the research will be put away and no-one, but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except Dr. Judu Ilavarasu and Dr. Hemant Bhargav, who are my supervisors and is a member of this research study. Any photo/recording taken during the study will not have your recognizable faces. If you choose not to have your photo taken, your choice will be respected.

Sharing the Findings

When we have finished the research, I will meet on videoconferencing with you, and I will tell you about what we learned. Afterward, we will be telling more people, scientists and others, about the research and what we found. We will do this by writing and sharing reports and by going to meetings with people who are interested in the work we do.

Note that at no point your personal information will be shared

Right to Refuse or Withdraw:

You do not have to be in this research if you do not want to. No one will be angry or disappointed with you if you say no. It is your choice. You can think about it and tell us later if you want to be part of this research study. You can say "yes" now and change your mind later and it will still be okay.

Whom to Contact:

If you have any questions, you may ask now or later, even after the study has started. If you wish to ask the questions later, you may contact:

1. Katla Naresh: +91 9030077282; e-mail: knareshyoga@gmail.com
2. Dr. Judu Ilavarasu : +91 9035730812; e-mail: judu@svyasa.edu.in (India)

3. Dr. Hemant Bhargav: +91 8762019348; e-mail: drbhargav.nimhans@gmail.com (India)

PART 2: Certificate of Consent

I hereby provide my informed consent for video/audio sessions for Tele-Yoga session at -----
----- (insert Name of the Professional/ Organization/ Unit providing the Service).

Contact information

My current residential address and phone number:

The contents of this form have been explained to me in a language that I understand

After reading/ listening to and understanding all of the above, I am giving my consent for:

Tele-Yoga for PTSD

Telephone/ audio sessions	Yes	No
Video sessions	Yes	No

By returning this form, I indicate consent for these sessions.

Only if participant consent:

Signature of participant:

Name of participant:

Date: _____

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Katla Naresh

Signature of researcher

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the individual understands that the following will be done:

1. The anthropomorphic information, PTSD symptoms, anxiety, depression, recovery from stress and psychosocial functional impairment, *tridoṣa* and personality type will be taken a maximum of two times.
2. A Yoga intervention as well as treatment as usual will be given to those in the Yoga group. I confirm that the individual was allowed to ask questions about the study, and all the questions asked by him have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this consent form has been provided to the participant.

Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Copy provided to the participant _____ (initialed by researcher/assistant)

APPENDIX –V
Two Case Vignettes

1. Fifty-year-old female, presented with the history of losing her only son due to the COVID-19 in April 2020. She detached herself from others and shows unresponsiveness to the surrounding. There is repetitive talk about the incident for the past 2 weeks. There was no family history of psychiatric illness. She was diagnosed to have post-traumatic stress disorder by mental status examination.

2. Mr. XXX, a 60-year-old man, had a road traffic accident before 3 months which involved his daughter and grandson who had escaped with minor injuries. When Mr. XXX presented for assessment, he was having intrusive memories of the accident every day making him mentally and physically uncomfortable. He was diagnosed with PTSD upon detailed examination.

APPENDIX –VI
Clinical Assessments
PC-PTSD

Description

The Primary Care PTSD Screen for *DSM-5* (PC-PTSD-5) is a 5-item screen designed to identify individuals with probable PTSD. Those screening positive require further assessment, preferably with a structured interview.

Scoring

The measure begins with an item designed to assess whether the respondent has had any exposure to traumatic events. If a respondent denies exposure, the PC-PTSD-5 is complete with a score of 0.

If a respondent indicates a trauma history – experiencing a traumatic event over the course of their life – the respondent is instructed to answer five additional yes/no questions (see below) about how that trauma has affected them over the past month.

Preliminary results from validation studies suggest that a cut-point of 3 on the PC-PTSD-5 (e.g., respondent answers "yes" to any 3 of 5 questions about how the traumatic event(s) have affected them over the past month) is optimally sensitive to probable PTSD. Optimizing sensitivity minimizes false negative screen results. Using a cut-point of 4 is considered optimally efficient. Optimizing efficiency balances false positive and false negative results. As additional research findings on the PC-PTSD-5 are published, updated recommendations for cut-point scores as well as psychometric data will be made available.

Example

In the past month, have you ...

1. had nightmares about the event(s) or thought about the event(s) when you did not want to?	YES	NO
2. tried hard not to think about the event(s) or went out of your way to avoid situations that reminded you of the event(s)?	YES	NO
3. been constantly on guard, watchful, or easily startled?	YES	NO
4. felt numb or detached from people, activities, or your surroundings?	YES	NO
5. felt guilty or unable to stop blaming yourself or others for the event(s) or any problems the events may have caused?	YES	NO
Total score is sum of "YES" responses in items 1-5.	TOTAL SCORE	

PC-PTSD-5

Sometimes things happen to people that are unusually or especially frightening, horrible, or traumatic. For example:

- a serious accident or fire
- a physical or sexual assault or abuse
- an earthquake or flood
- a war
- seeing someone be killed or seriously injured
- having a loved one die through homicide or suicide.

Have you ever experienced this kind of event?

YES

NO

If no, screen total = 0. Please stop here.

If yes, please answer the questions below.

In the past month, have you...

1. had nightmares about the event(s) or thought about the event(s) when you did not want to?

YES

NO

2. tried hard not to think about the event(s) or went out of your way to avoid situations that reminded you of the event(s)?

YES

NO

3. been constantly on guard, watchful, or easily startled?

YES

NO

4. felt numb or detached from people, activities, or your surroundings?

YES

NO

5. felt guilty or unable to stop blaming yourself or others for the event(s) or any problems the event(s) may have caused?

YES

NO

PCL-5

Instructions: Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then circle one of the numbers to the right to indicate how much you have been bothered by that problem in the past month.

In the past month, how much were you bothered by:	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Repeated, disturbing, and unwanted memories of the stressful experience?	0	1	2	3	4
2. Repeated, disturbing dreams of the stressful experience?	0	1	2	3	4
3. Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?	0	1	2	3	4
4. Feeling very upset when something reminded you of the stressful experience?	0	1	2	3	4
5. Having strong physical reactions when something reminded you of the stressful experience (for example, heart pounding, trouble breathing, sweating)?	0	1	2	3	4
6. Avoiding memories, thoughts, or feelings related to the stressful experience?	0	1	2	3	4
7. Avoiding external reminders of the stressful experience (for example, people, places, conversations, activities, objects, or situations)?	0	1	2	3	4
8. Trouble remembering important parts of the stressful experience?	0	1	2	3	4
9. Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	0	1	2	3	4
10. Blaming yourself or someone else for the stressful experience or what happened after it?	0	1	2	3	4
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame?	0	1	2	3	4
12. Loss of interest in activities that you used to enjoy?	0	1	2	3	4
13. Feeling distant or cut off from other people?	0	1	2	3	4
14. Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?	0	1	2	3	4
15. Irritable behavior, angry outbursts, or acting aggressively?	0	1	2	3	4
16. Taking too many risks or doing things that could cause you harm?	0	1	2	3	4
17. Being "superalert" or watchful or on guard?	0	1	2	3	4
18. Feeling jumpy or easily startled?	0	1	2	3	4
19. Having difficulty concentrating?	0	1	2	3	4
20. Trouble falling or staying asleep?	0	1	2	3	4

Vedic Personality Inventory (VPI)

The Vedic Personality Inventory

1 = Very Strongly Disagree 2 = Strongly Disagree 3 = Somewhat Disagree 4 = Neutral
5 = Somewhat Agree 6 = Strongly Agree 7 = Very Strongly Agree

- | | | | | | | | | |
|-----|--|---|---|---|---|---|---|---|
| 1. | I am straightforward in my dealings with other people. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 2. | I have very little interest in spiritual understanding. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3. | I am satisfied with my life. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 4. | Fruits and vegetables are among my favorite foods. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 5. | All living entities are essentially spiritual. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 6. | In conducting my activities, I do not consider traditional wisdom. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 7. | I often act without considering the future consequences of my actions. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 8. | I usually feel discontented with life. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 9. | I become happy when I think about the material assets that I possess. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 10. | I am good at using willpower to achieve goals. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 11. | I enjoy spending time in bars. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 12. | Cleanliness is very important to me. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 13. | Others say that my intelligence is very sharp. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 14. | I often feel depressed. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 15. | I often put off or delay my responsibilities. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 16. | I greatly admire materially successful people. | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

17. When I speak, I really try not to irritate others. 1 2 3 4 5 6 7
18. I believe life is over when the body dies. 1 2 3 4 5 6 7
19. I often feel helpless. 1 2 3 4 5 6 7
20. I enjoy foods with strong tastes. 1 2 3 4 5 6 7
21. I am constantly dissatisfied with my position in life. 1 2 3 4 5 6 7
22. Having possessions is very important to me. 1 2 3 4 5 6 7
23. When things are tough, I often bail out. 1 2 3 4 5 6 7
24. I often feel like a victim. 1 2 3 4 5 6 7
25. I feel that my knowledge is always increasing. 1 2 3 4 5 6 7
26. I prefer city night life to a walk in the forest. 1 2 3 4 5 6 7
27. For me, sex life is a major source of happiness. 1 2 3 4 5 6 7
28. I take guidance from higher ethical and moral laws
before I act. 1 2 3 4 5 6 7
29. I enjoy intoxicating substances (including coffee,
cigarettes and alcohol). 1 2 3 4 5 6 7
30. I often feel greedy. 1 2 3 4 5 6 7
31. I become greatly distressed when things don't work
out for me. 1 2 3 4 5 6 7
32. I am often angry. 1 2 3 4 5 6 7
33. I often feel fearful. 1 2 3 4 5 6 7
34. I do not have doubts about my responsibilities in life. 1 2 3 4 5 6 7
35. I often feel emotionally unbalanced. 1 2 3 4 5 6 7
36. I enjoy eating meat. 1 2 3 4 5 6 7
37. I am self-controlled. 1 2 3 4 5 6 7
38. I am very dutiful. 1 2 3 4 5 6 7

39. When I give charity, I often do it grudgingly. 1 2 3 4 5 6 7
40. Self-realization is not important for me. 1 2 3 4 5 6 7
41. I often feel dejected. 1 2 3 4 5 6 7
42. I carry out my responsibilities regardless of whether
there is success or failure. 1 2 3 4 5 6 7
43. I often neglect my responsibilities to my family. 1 2 3 4 5 6 7
44. I am easily affected by the joys and sorrows of life. 1 2 3 4 5 6 7
45. I often whine. 1 2 3 4 5 6 7
46. Regardless of what I acquire or achieve, I have an
uncontrollable desire to obtain more. 1 2 3 4 5 6 7
47. I am currently struggling with an addiction, physical
or psychological, to some type of
intoxicant (including caffeine, cigarettes and alcohol). 1 2 3 4 5 6 7
48. I often envy others. 1 2 3 4 5 6 7
49. My job is a source of anxiety. 1 2 3 4 5 6 7
50. I never think about giving up my wealth and position
for a simpler life. 1 2 3 4 5 6 7
51. It often happens that those things that brought me
happiness later become the source of my
suffering. 1 2 3 4 5 6 7
52. I often feel mentally unbalanced. 1 2 3 4 5 6 7
53. I don't have much will power. 1 2 3 4 5 6 7
54. I often neglect my responsibilities to my friends. 1 2 3 4 5 6 7
55. I often act violently towards others. 1 2 3 4 5 6 7
56. I am good at controlling my senses and emotions. 1 2 3 4 5 6 7

Brief - Inventory Psychosocial Functional

B-IPF

Subject ID# _____

B-IPF

Overall, in the past 30 days:	Not at all	Somewhat					Very much	N/A
1. I had trouble in my romantic relationship with my spouse or partner.	0	1	2	3	4	5	6	7
2. I had trouble in my relationship with my children.	0	1	2	3	4	5	6	7
3. I had trouble with my family relationships.	0	1	2	3	4	5	6	7
4. I had trouble with my friendships and socializing.	0	1	2	3	4	5	6	7
5. I had trouble at work.	0	1	2	3	4	5	6	7
6. I had trouble with my training and education.	0	1	2	3	4	5	6	7
7. I had trouble with day to day activities, such as doing household chores, running errands and managing my medical care.	0	1	2	3	4	5	6	7

The B-IPF total score is calculated by summing the scale items completed by the respondent, dividing by the maximum possible score based on the number of applicable items, and multiplying by 100. B-IPF total scores represent an index of overall functional impairment, with higher scores indicating greater functional impairment.

Brief Resilience Scale (BRS)

Please respond to each item by marking <u>one box per row</u>		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
BRS 1	I tend to bounce back quickly after hard times	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
BRS 2	I have a hard time making it through stressful events.	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
BRS 3	It does not take me long to recover from a stressful event.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
BRS 4	It is hard for me to snap back when something bad happens.	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
BRS 5	I usually come through difficult times with little trouble.	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
BRS 6	I tend to take a long time to get over set-backs in my life.	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

Scoring: Add the responses varying from 1-5 for all six items giving a range from 6-30. Divide the total sum by the total number of questions answered.

My score: _____ item average / 6

Hamilton Anxiety Rating Scale (HAM-A)

Reference: Hamilton M. The assessment of anxiety states by rating. *Br J Med Psychol* 1959; 32:50–55.

Rating Clinician-rated

Administration time 10–15 minutes

Main purpose To assess the severity of symptoms of anxiety

Population Adults, adolescents and children

Commentary

The HAM-A was one of the first rating scales developed to measure the severity of anxiety symptoms, and is still widely used today in both clinical and research settings. The scale consists of 14 items, each defined by a series of symptoms, and measures both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Although the HAM-A remains widely used as an outcome measure in clinical trials, it has been criticized for its sometimes poor ability to discriminate between anxiolytic and antidepressant effects, and somatic anxiety versus somatic side effects. The HAM-A does not provide any standardized probe questions. Despite this, the reported levels of inter-rater reliability for the scale appear to be acceptable.

Scoring

Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild severity, 18–24 mild to moderate severity and 25–30 moderate to severe.

Versions

The scale has been translated into: Cantonese for China, French and Spanish. An IVR version of the scale is available from Healthcare Technology Systems.

Additional references

Maier W, Buller R, Philipp M, Heuser I. The Hamilton Anxiety Scale: reliability, validity and sensitivity to change in anxiety and depressive disorders. *J Affect Disord* 1988;14(1):61–8.

Borkovec T and Costello E. Efficacy of applied relaxation and cognitive behavioral therapy in the treatment of generalized anxiety disorder. *J Clin Consult Psychol* 1993; 61(4):611–19

Address for correspondence

The HAM-A is in the public domain.

Hamilton Anxiety Rating Scale (HAM-A)

Below is a list of phrases that describe certain feeling that people have. Rate the patients by finding the answer which best describes the extent to which he/she has these conditions. Select one of the five responses for each of the fourteen questions.

0 = Not present, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Very severe.

1 Anxious mood 0 1 2 3 4

Worries, anticipation of the worst, fearful anticipation, irritability.

2 Tension 0 1 2 3 4

Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.

3 Fears 0 1 2 3 4

Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.

4 Insomnia 0 1 2 3 4

Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.

5 Intellectual 0 1 2 3 4

Difficulty in concentration, poor memory.

6 Depressed mood 0 1 2 3 4

Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.

7 Somatic (muscular) 0 1 2 3 4

Pains and aches, twitching, stiffness, myoclonic jerks, grinding of teeth, unsteady voice, increased muscular tone.

8 Somatic (sensory) 0 1 2 3 4

Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.

9 Cardiovascular symptoms 0 1 2 3 4

Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.

10 Respiratory symptoms 0 1 2 3 4

Pressure or constriction in chest, choking feelings, sighing, dyspnea.

11 Gastrointestinal symptoms 0 1 2 3 4

Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.

12 Genitourinary symptoms 0 1 2 3 4

Frequency of micturition, urgency of micturition, amenorrhoea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence.

13 Autonomic symptoms 0 1 2 3 4

Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.

14 Behavior at interview 0 1 2 3 4

Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.

Hamilton Depression Rating Scale (HDRS)

Reference: Hamilton M. A rating scale for depression. *J Neurol Neurosurg Psychiatry* 1960; 23:56–62

Rating Clinician-rated

Administration time 20–30 minutes

Main purpose To assess severity of, and change in, depressive symptoms

Population Adults

Commentary

The HDRS (also known as the Ham-D) is the most widely used clinician-administered depression assessment scale. The original version contains 17 items (HDRS₁₇) pertaining to symptoms of depression experienced over the past week. Although the scale was designed for completion after an unstructured clinical interview, there are now semi-structured interview guides available. The HDRS was originally developed for hospital inpatients, thus the emphasis on melancholic and physical symptoms of depression. A later 21-item version (HDRS₂₁) included 4 items intended to subtype the depression, but which are sometimes, incorrectly, used to rate severity. A limitation of the HDRS is that atypical symptoms of depression (e.g., hypersomnia, hyperphagia) are not assessed (see SIGH-SAD, page 55).

Scoring

Method for scoring varies by version. For the HDRS₁₇, a score of 0–7 is generally accepted to be within the normal

range (or in clinical remission), while a score of 20 or higher (indicating at least moderate severity) is usually required for entry into a clinical trial.

Versions

The scale has been translated into a number of languages including French, German, Italian, Thai, and Turkish. As well, there is an Interactive Voice Response version (IVR), a Seasonal Affective Disorder version (SIGH-SAD, see page 55), and a Structured Interview Version (HDS-SIV). Numerous versions with varying lengths include the HDRS₁₇, HDRS₂₁, HDRS₂₉, HDRS₈, HDRS₆, HDRS₂₄, and HDRS₇ (see page 30).

Additional references

Hamilton M. Development of a rating scale for primary depressive illness. *Br J Soc Clin Psychol* 1967; 6(4):278–96.

Williams JB. A structured interview guide for the Hamilton Depression Rating Scale. *Arch Gen Psychiatry* 1988; 45(8):742–7.

Address for correspondence

The HDRS is in the public domain.

Hamilton Depression Rating Scale (HDRS)

PLEASE COMPLETE THE SCALE BASED ON A STRUCTURED INTERVIEW

Instructions: for each item select the one "cue" which best characterizes the patient. Be sure to record the answers in the appropriate spaces (positions 0 through 4).

- 1 DEPRESSED MOOD** (sadness, hopeless, helpless, worthless)
- 0 Absent.
 - 1 These feeling states indicated only on questioning.
 - 2 These feeling states spontaneously reported verbally.
 - 3 Communicates feeling states non-verbally, i.e. through facial expression, posture, voice and tendency to weep.
 - 4 Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication.

- 2 FEELINGS OF GUILT**
- 0 Absent.
 - 1 Self reproach, feels he/she has let people down.
 - 2 Ideas of guilt or rumination over past errors or sinful deeds.
 - 3 Present illness is a punishment. Delusions of guilt.
 - 4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations.

3 SUICIDE

- 0 Absent.
- 1 Feels life is not worth living.
- 2 Wishes he/she were dead or any thoughts of possible death to self.
- 3 Ideas or gestures of suicide.
- 4 Attempts at suicide (any serious attempt rate 4).

4 INSOMNIA: EARLY IN THE NIGHT

- 0 No difficulty falling asleep.
- 1 Complains of occasional difficulty falling asleep, i.e. more than 1/2 hour.
- 2 Complains of nightly difficulty falling asleep.

5 INSOMNIA: MIDDLE OF THE NIGHT

- 0 No difficulty.
- 1 Patient complains of being restless and disturbed during the night.
- 2 Waking during the night – any getting out of bed rates 2 (except for purposes of voiding).

6 INSOMNIA: EARLY HOURS OF THE MORNING

- 0 No difficulty.
- 1 Waking in early hours of the morning but goes back to sleep.
- 2 Unable to fall asleep again if he/she gets out of bed.

7 WORK AND ACTIVITIES

- 0 No difficulty.
- 1 Thoughts and feelings of incapacity, fatigue or weakness related to activities, work or hobbies.
- 2 Loss of interest in activity, hobbies or work – either directly reported by the patient or indirect in listlessness, indecision and vacillation (feels he/she has to push self to work or activities).
- 3 Decrease in actual time spent in activities or decrease in productivity. Rate 3 if the patient does not spend at least three hours a day in activities (job or hobbies) excluding routine chores.
- 4 Stopped working because of present illness. Rate 4 if patient engages in no activities except routine chores, or if patient fails to perform routine chores unassisted.

8 RETARDATION (slowness of thought and speech, impaired ability to concentrate, decreased motor activity)

- 0 Normal speech and thought.
- 1 Slight retardation during the interview.
- 2 Obvious retardation during the interview.
- 3 Interview difficult.
- 4 Complete stupor.

9 AGITATION

- 0 None.
- 1 Fidgetiness.
- 2 Playing with hands, hair, etc.
- 3 Moving about, can't sit still.
- 4 Hand wringing, nail biting, hair-pulling, biting of lips.

10 ANXIETY PSYCHIC

- 0 No difficulty.
- 1 Subjective tension and irritability.
- 2 Worrying about minor matters.

11 ANXIETY SOMATIC (physiological concomitants of anxiety) such as:

gastro-intestinal – dry mouth, wind, indigestion, diarrhea, cramps, belching
cardio-vascular – palpitations, headaches
respiratory – hyperventilation, sighing
urinary frequency
sweating

- 0 Absent.
- 1 Mild.
- 2 Moderate.
- 3 Severe.
- 4 Incapacitating.

12 SOMATIC SYMPTOMS GASTRO-INTESTINAL

- 0 None.
- 1 Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen.
- 2 Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for gastro-intestinal symptoms.

13 GENERAL SOMATIC SYMPTOMS

- 0 None.
- 1 Heaviness in limbs, back or head. Backaches, headaches, muscle aches. Loss of energy and fatigability.
- 2 Any clear-cut symptom rates 2.

14 GENITAL SYMPTOMS (symptoms such as loss of libido, menstrual disturbances)

- 0 Absent.
- 1 Mild.
- 2 Severe.

15 HYPOCHONDRIASIS

- 0 Not present.
- 1 Self-absorption (bodily).
- 2 Preoccupation with health.
- 3 Frequent complaints, requests for help, etc.
- 4 Hypochondriacal delusions.

16 LOSS OF WEIGHT (RATE EITHER a OR b)

- | a) According to the patient: | b) According to weekly measurements: |
|--|---|
| 0 <input type="checkbox"/> No weight loss. | 0 <input type="checkbox"/> Less than 1 lb weight loss in week. |
| 1 <input type="checkbox"/> Probable weight loss associated with present illness. | 1 <input type="checkbox"/> Greater than 1 lb weight loss in week. |
| 2 <input type="checkbox"/> Definite (according to patient) weight loss. | 2 <input type="checkbox"/> Greater than 2 lb weight loss in week. |
| 3 <input type="checkbox"/> Not assessed. | 3 <input type="checkbox"/> Not assessed. |

17 INSIGHT

- 0 Acknowledges being depressed and ill.
- 1 Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
- 2 Denies being ill at all.

Total score:

Tele-Yoga Therapy Assessment Scale (TYTAS)

Item	Definition	Rating	Reason for Rating
A. Instruction assessment	Refers to the assessment of the process of delivering instructions of practices by the trainer to the patients with utmost clarity.		
1. Knowledge and competency of anatomy, physiology and techniques	Trainer had 3-Dimensional understanding of body and movements; complex understanding of joints, movements, Range of Motion, Muscles involved with movement. He/ she has included evidence based knowledge of techniques (scientifically proven)		
2. Introduction of self and Clarity (of theme and speech)	Trainer introduced himself/herself, clarified the objective/ goal of class, and had clarity of instructions.		
3. Pace and Delivery of instruction.	The instructions were delivered one at a time, and multiple instructions were avoided. The trainer gave enough gaps between postures to enable the practitioners to understand and feel the practice.		
4. Short and precise instructions:	Too much explanation about the practices was avoided. Instructions were crisp and to the point		
5. Command over language	The trainer, had thorough knowledge of the language, to enable better delivery of instructions. Used words that were easily understandable and that could connect with the general population in class. Jargons or anatomical references were avoided. Used correct pronunciation of words and terms.		
6. Voice modulation/ audibility	The tone used while instructing varied according to the objective of the practice. Tone used was firm while getting into the posture and soft for relaxing practices. The voice was loud enough for the practitioners to understand and to be engaged through practice.		

Item	Definition	Rating	Reason for Rating
7. Personal attention:	The trainer was impartial. Equal attention was given to all students.		
8. Motivating	Trainer used motivating words to appreciate the patient's effort to help them take the practice to the next step.		
9. Interactive	Verbal- Trainer spoke to students casually and affectionately about their health, hobbies etc apart from session. Non- Verbal- Trainer initiated corrections through touch if the patient was open to the same. He/ she had a gentle smile to help take away strangeness.		
10. Approachability	Trainer was friendly and approachable		
D. Program Assessment	Evaluation of the course, length content and quality of the program.		
1. Pace of teaching (simple to complex)	The teaching module was a gradual shift from simple to complex techniques and practices.		
2. Effectiveness of program	The program brought about physical (symptomatic) or/ and psychological (well-being) changes		
3. Clarity and simplicity of material and program	The program was delivered with utmost clarity. The training and material was suitable and easy to understand and practice		
4. Quality of Technical infrastructure (light/ video/ audio output)	The audio, video and lighting were clear and enabled proper hearing and viewing of the practices during relay sessions.		
5. Quality of teachers	Trainer had competence in knowledge about the subject, showed commitment and was able to effectively deliver a session		
6. Length of program	The course duration was appropriate and suitable		
7. Satisfaction with the program.	There was a feeling of goodness with the program. Program met the expectation and needs of the patients. Program content and structure met its objective		

Item	Definition	Rating	Reason for Rating
8. Program take away	The trainer advised components that can be practiced in everyday life.		
9. Program recommendation	You will recommend this program to others.		
10. Holistic program	Program had all the components of Yoga, i.e asana, pranayama, meditation and relaxation		
11. Ambience of place	The place was well-ventilated, spacious, and well-lit.		
12. Overall experience	Overall experience of the program		

APPENDIX-VIII

Qualitative feedback form: Post-intervention

No.	Question
1	Did you feel like you were treated with respect and dignity by the yoga teacher?
2	How would you rate the quality of the Tele-yoga classroom?
3	Do you feel better after your yoga class than you did before class?
4	If so, how long did it last?
5	How long is tele-yoga required to be practiced for recovering from PTSD Symptoms in your opinion?
6	Did you experience any side effects/difficulties during the 3 months of online yoga classes?
7	Should any practices be removed from the yoga module?
8	Do you feel more yoga practices can be included in managing PTSD symptoms? If yes, kindly mention those practices.
9	Do you think yoga therapy alone helps to reduce PTSD symptoms?
10	Do you have any further suggestions for the betterment of the online yoga program for PTSD?

APPENDIX-VIII

Feedback From through Closed-ended Question: Post-Intervention

No.	Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	I enjoyed my online classes overall.					
2	I enjoyed doing yoga at home.					
3	I was able to complete my prescribed duration of self-practice (i.e. 60 min.).					
4	I felt the prescribed minutes (i.e., 60 minutes) per every day was appropriate.					
5	I am satisfied with participating in the Tele-yoga/Online Yoga.					
6	I am satisfied with the instructor(s) for the online Yoga sessions.					
7	Online Yoga has helped me to cope with PTSD Symptoms.					
8	The online yoga classes were easy.					
9	It was easy to find the time to do online yoga.					
10	I will continue participating in online yoga in the future.					
11	I will recommend PTSD individuals to participate in online yoga in the future.					

APPENDIX-IX

Yoga Module Development checklist

Domain	Item No.	Checklist Item	Yes / No
Yoga Module Development	1	Traditional literature review	
	2	Scientific literature review	
	3	Dose, frequency, and duration of intervention	
	4	Involvement of experts, clinicians, and participants in the development phase	
	5	Yoga practice sequence	
	6	Customization of practices	
	7	Instructor qualification	
	8	Reporting adverse effect	
	9	Home practice details	
Yoga Module Validation	10	Professional eligibility of experts	
	11	Diversity of experts	
	12	Details of the items provided to experts	
	13	Involvement of stakeholders	
	14	Expert content validation	
	15	Group discussion	
	16	Use of case vignettes	
	17	Involvement of stakeholders	
	18	Statistical procedure for item retention	
	19	Modifications made after validation	
Yoga Module Feasibility	20	Feasibility phase done	
	21	Measurement of intervention fidelity	

22 Feedback from participants

23 Outcome domain

Total Score — —

___/23

APPENDIX- X
PUBLICATION DETAILS

Sl. No.	Name of the Article / Title	web link of article if published	Name of the Journal and Publisher	Is it indexed journal ? Yes/No If yes provide details	Impact Factors (Thomson Reuters-2018)	UGC Listed Yes/No If yes provide the details/link
1	Yoga module development and validation: A systematic review with methodological guidelines	https://doi.org/10.4103/ijoy.ijoy_59_22	IJOY	Pubmed	1.2	Yes
2	A protocol of development, content validation and feasibility of a Tele-Yoga module for Post-Traumatic Stress Disorder	https://doi.org/10.1016/j.ai.med.2023.10.005	Advanced in Integrative Medicine	Scopus	1.3	Yes
3	Development, validation, and feasibility testing of Tele-Yoga module for PTSD	https://doi.org/10.1016/j.ai.med.2025.100562	Advanced in Integrative Medicine	Scopus	1.3	Yes



Development, validation, and feasibility testing of Tele-Yoga Module for PTSD

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ARTICLE INFO

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Module development
Feasibility
Stigma

ABSTRACT

Introduction: Post-traumatic stress disorder (PTSD) is a growing concern worldwide. The increasing incidence of PTSD, compounded by the social stigma associated with it, often prevents individuals from seeking professional help. The objective of this study was to develop, validate, and test the feasibility of Tele-Yoga Module (TYM) for managing PTSD, within a community setting in India.

Methods: The TYM was developed and validated following the procedure presented in the protocol study [1]. The feasibility of the module was then tested in a 12-week study with sixty participants diagnosed with PTSD as per DSM-V criteria. Participants were split evenly between the TYM and a treatment-as-usual (TAU) group. We measured variables such as PTSD symptoms, social functioning, resilience, anxiety, depression, and yoga-based personality traits.

Results: Participants in the TYM group showed significant improvements in PTSD symptoms, anxiety, and depression, compared to the TAU group ($p < 0.001$ for all). No significant between-group differences were observed in resilience and psycho-social functions ($p = 0.11$). The feasibility aspects of the TYM have been discussed under seven dimensions, including safety and acceptability. These findings suggest that the TYM can serve as a potentially useful add-on intervention in managing PTSD. This study contributes to the emerging field of tele-yoga and highlights the importance of culturally and contextually adapted mental health interventions. Such approaches are crucial for addressing the global burden of PTSD.

1. Introduction

Post-traumatic stress disorder (PTSD) remains a hidden epidemic in India. Despite a seemingly low prevalence rate of 0.2% reported in India, compared to a global average of 3.9%–5.6%, studies indicate that many cases might go undetected due to numerous social barriers [2,3]. These include societal indifference, fear of being stigmatized, and a pervasive distrust of mental health professionals [4,5], which collectively hinder seeking effective care and treatment for PTSD [6]. Studies

show retention rates ranging from 60% to 72%, suggesting dropout rates range from 28% to 40% [7]. Given these obstacles, a critical question arises: if the full extent of the problem is hidden and ignored, how can it be adequately addressed in public health policies and interventions? What are the implications for those suffering from PTSD in the meantime? We propose to bridge the stigma-associated gap in PTSD-specific intervention by systematically developing and validating a Tele-Yoga Module (TYM) within a community setting. Designed for home-based, self-paced practice, TYM minimizes the fear of judgment

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Yoga Module Development and Validation: A Systematic Review with Methodological Guidelines

Abstract

In the past decades, more than fifty different yoga styles have been implemented in the therapeutic context to manage various diseases. Yet, not all of these yoga styles have been validated or standardized as a program. The aim of this article is to review the different methodologies used for yoga module development and to assess their quality. Three databases (PubMed, Web of Science, and Scopus) were searched using the following keywords and Boolean operators: (validation OR development OR design) AND (yoga OR mind-body) AND (module OR protocol OR program). Three thousand six hundred and seventy-one articles were enlisted, and based on the inclusion and exclusion criteria, 37 articles were narrowed down for review. Since no checklist exists to assess the quality of yoga modules, the authors designed a 23-item checklist to categorize each having low, medium, or high quality. As per the yoga module quality checklist, only 21.6% of the studies had high quality, while 75.3% of the articles had medium quality and 8.11% had low quality. A commonly used development method was literature review, while for validation, experts' scoring of the Likert scale was the preferred means. The feasibility of the module was carried out only by half of the studies. Few diseases such as cardiovascular disease, diabetes mellitus, obesity, Parkinson's disease, and obesity had more than one yoga module developed. The findings of this systematic review have shed some light on the growing need for standardized methods of yoga module development. The 23-item checklist can guide researchers in the homogeneous development strategies when designing yoga interventions in the future.

Keywords: Development, feasibility, guidelines, module, validation, yoga

Introduction

The word yoga originates from “युग” meaning to yoke, referring to the discipline of aligning the mind and body for spiritual goals.^[1] Yoga practices aim at calming down the agitations of the mind through physical postures with awareness (*asanas*), breath regulation (*pranayama*), meditation (*dhyana*), chantings (*mantras*), lifestyle changes, and spiritual beliefs.^[2] Yoga has metamorphosed as yoga therapy inculcating different yogic techniques for alleviating a spectrum of physical and psychological complaints.^[3]

Contemporary yoga has undergone a significant evolution from the traditional style by trying to fit in the various needs of practitioners. Transition in terms of quality of research in yoga has become the need of the hour. The earliest scientific literature from PubMed databases is from 1948.^[4,5] From 1948 to 2021, a total of

6628 articles were published in PubMed with the term “yoga,” and 75.9% of these researches have been published in the last decade. There are multiple reasons to substantiate this recent exponential increase in yoga publications: (1) its popularity as a low-cost, non-pharmacological health promotion and stress management tool, (2) global shift toward integrative approaches in medicine and focus on prevention, (3) global interest in using yoga as a tool to connect people, and (4) rising support from international and national research agencies and scholarly interest.^[3,6]

Considering the spurt of yoga research in the past decade, the need to tread cautiously in the selection of intervention is imperative. According to a PubMed search conducted by the researchers, 52 yoga styles were practiced in 306 randomized controlled trials (RCTs), out of which the most commonly used yoga

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A protocol of development, content validation and feasibility of a Tele-Yoga module for Post-Traumatic Stress Disorder[☆]

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ABSTRACT

Background and objectives: Globally, the incidence of Post-Traumatic Stress Depression (PTSD) is 6.1 %. Different therapeutic approaches are adopted for PTSD amongst which Yoga has the potential to manage symptoms of PTSD. However, a set module for PTSD is not available. The present study aims at developing, validating, and testing the feasibility of the Tele-Yoga (TY) module for patients diagnosed with PTSD.

Material and methods: The proposed study is planned to be conducted in three phases. Phase-1: a review of literature involving published studies along with ancient and contemporary books related to yoga, PTSD and TY. The focus will be on designing the TY module after understanding the conceptual basis of yoga practices for patients with PTSD. Phase 2: the developed module will be sent to the experts for quantitative and qualitative validation. Phase 3: the feasibility testing of the module will be done with sixty participants diagnosed with PTSD. The participants will be divided into two groups (TY group and waitlist control group) based on choice based allocation.

Statistical analyses: Experts' responses will be analysed using Lawshe's Content Validity Ratio (CVR) and the Delphi technique of iteration will be adopted. The feasibility data will be tested for normality and appropriate tests will be used to assess the difference between both groups.

Expected outcomes: The outcome of this study is to have a validated module for PTSD with the support of experts. The module's doability for patients suffering from PTSD will further be provided.

Lastly, the researchers will identify if the module has an effect on anxiety, depression, resilience, psychosocial functioning and vedic personality.

1. Introduction

Post-traumatic Stress Disorder (PTSD) is a debilitating and persistent result of traumatic events [1]. A traumatic incident might be a single occurrence or a series of occurrences. As a result, symptoms, and behaviors such as repeated re-experiencing of the trauma or flashbacks of the incident, avoidance of any reminders of the painful idea, talk, or location, numbing of happy feelings, social disengagement, and elevated autonomic arousal develop [2]. PTSD is a severe public health issue, with a global incidence of up to 6.1 % [3]. One in every five adult critical

care survivors may experience PTSD symptoms, with a high relapse rate of one year after discharge [4]. With continuing conflicts, natural disasters, interpersonal violence, and other traumatic occurrences, it is estimated that over 70 % of the world's population has been exposed to at least one traumatic experience in their lifetime [5].

Previous research showed that many cases of PTSD are not diagnosed [6] and even in those diagnosed, not all seek treatment [7,8] as avoidance is one of the core symptoms of PTSD. Concerns about stigmatization, lack of social acknowledgment, poor health care infrastructure, the lack of training institutions, shame, rejection, low mental health

[☆] Trial Registration: The registration number for trail is CTRI/2022/03/041356.

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