

# The Research Protocol of SENIOR Project— Psychiatric Services and Support System for Serious Mental Illness in Old Age, Kerala, India

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## ABSTRACT

**Background:** India has the second-largest population of elderly in the world. Serious mental illness (SMI) is a subset of the mental disorders that result in significant functional impairment and is usually long term. Persons with SMI face several challenges in their old age that are different from the issues faced by younger people with SMI. Understanding the problems faced by elderly individuals suffering from SMI is fundamental for planning programs to address them. The SENIOR (Support Systems Evaluation of Neuropsychiatric Illness in Old age) project is a study aimed at evaluating the problems faced in obtaining mental health care by elderly persons having SMI in the Kerala state of India.

**Aim:** To describe the scientific methodology of the SENIOR project.

**Methods:** This study employs mixed-methods cross-sectional design among a minimum sample of 768 SMI patients identified through cluster sampling from

three districts, and Focus Group Discussion among mental health program officials.

**Discussion:** This paper presents a methodological model to assist researchers in future field epidemiological studies on mental illness. Assessing service needs and barriers to access for the most vulnerable among the mentally ill will help the policymakers make evidence-based decisions to improve their quality of life.

**Keywords:** Mental health, elderly, India, cross-sectional study, mixed-methods, research protocol, severe mental illness, serious mental illness, SMI, severe mental disorders, SMD, SPMI, dementia

**Key Messages:** Persons with Serious Mental Illness (SMI) face several challenges in their old age. The SENIOR research project employs a mixed-method study design in three districts of Kerala state in India to assess the psychiatric services and barriers to access of care for the SMI in their old age. This article describes the methodology and innovations of this community based study.

The world's population is aging rapidly. Between 2015 and 2050, the proportion of older adults in the world is estimated to almost double from about 12% to 22%.<sup>1</sup> One of the most significant social transformations in the present century is going to be this population aging, with implications for nearly all sectors of society including labor, services, transportation, housing, etc.<sup>2</sup> In 1951, life expectancy at birth was 36.7 years and by 2010–2014, it became 67.9 years.<sup>3</sup> As a result, the proportion of the elderly population in India has risen from 5.6% in 1961 to 8.2% in 2011.<sup>4</sup> This is projected to increase to 19% in 2050.<sup>5</sup>

Mental disorders include a broad range of conditions with different symptoms. These disorders generally have a combination of abnormal thoughts, emotions, behavior, and relationships with others.<sup>6</sup> Serious mental illness (SMI) is a smaller and more severe subset of all mental illnesses. National Institute of Mental Health (NIMH) USA defines SMI as a

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**HOW TO CITE THIS ARTICLE:** Thavody J, Kumar TMS, Sujina CM, Tharayil HM, Chandran P, George B, Mohan VMN, Prabakaran A. The Research Protocol of SENIOR Project—Psychiatric Services and Support System for Serious Mental Illness in Old Age, Kerala, India. *Indian J Psychol Med.* 2020;42(6S):87S–93S.

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**Submitted:** 7 Oct. 2020  
**Accepted:** 9 Oct. 2020  
**Published Online:** 14 Dec. 2020



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DOI: 10.1177/0253717620971196

“mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities.”<sup>7</sup> The disease conditions causing maximum disability under SMI are “schizophrenia-spectrum disorders,” “bipolar disorder,” and “severe major depression.”<sup>7</sup> “Dementia is a syndrome usually chronic, characterized by a progressive, global deterioration in intellect including memory, learning, orientation, language, comprehension and judgment due to disease of the brain.”<sup>6</sup> Dementia is one of the most common neuropsychiatric causes of disability in the elderly and its prevalence is likely to increase with the aging of the population.

A consensus has emerged in many countries that mental health services should be especially targeted at those suffering from SMI<sup>8</sup> and the need for identifying the vulnerable and tailoring special strategies for them.<sup>9</sup> Providing psychiatric care to the mentally ill elderly is a challenge globally. As per the WHO estimates, only 15% to 24% of people with SMI from low and middle-income countries (LMIC) receive treatment for mental illness and even in developed countries it is only 50%.<sup>10</sup> The Government of India launched the National Mental Health Programme (NMHP) in 1986 to address the burden of mental illness. The District Mental Health Programme (DMHP) was added as a component to it in 1996 and envisages the provision of basic mental health care services at the community level.<sup>11</sup> Many among the elderly SMI would have lost their parents or spouses who were their caregivers. Old age and debility prevent them from accessing health care and psychiatric services. It is also known that people with SMI die 10–20 years earlier than the general population.<sup>12</sup> Though one of the objectives of NMHP is to provide priority care to the most vulnerable sections of society, at present it has no specific strategy to address the needs of the elderly SMI.

The south Indian state of Kerala with a population of 33.4 million is the location for this study. The elderly constitutes 13% of Kerala's population, compared to 8.2% in India.<sup>13</sup> The National Mental Health Survey 2016 reported a prevalence of 1.1% for schizophrenia and other psychotic disorders in those above 60 years

in Kerala.<sup>14</sup> The DMHP in Kerala was launched in 1999.<sup>15</sup> Kerala state is ranked the top performer in the health sector in India.<sup>16</sup> The health-related indicators for many other states of India show improvement, and it can be expected that most of the states will catch up with the present status of Kerala. The results of the SENIOR project in Kerala will provide insights on what the remaining states of India can expect in a few years.

## Objectives of the Study

The objectives of the SENIOR (Support Systems Evaluation of Neuropsychiatric Illness in Old age) project are as follows:

1. To assess the psychiatric services reaching the seriously mentally ill in their old age in Kerala.
2. To identify barriers to the access of psychiatric services to the seriously mentally ill in their old age in Kerala.

## Materials and Methods

### Study Design, Setting, and Period

The study uses a mixed-method study design employing cross-sectional design & Focus Group Discussions (FGDs). It is planned to be conducted in three districts (Thiruvananthapuram, Malappuram, and Kannur) of Kerala state in India. The project will be for 2 years (2019–2020). Participant recruitment and data collection are to be completed over 12 months.

### Operational Definition

**Elderly with SMI:** Those aged 60 years or older, identified with SMI and/or moderate to severe dementia through screening using a tool administered to Accredited Social Health Activist (ASHA) workers after training them in a single day workshop, and confirmed through interviews of the SMI participants by the project research fellows. Schizophrenia-spectrum disorders, bipolar disorder, and severe depression are the SMIs expected to be captured through the study. Patients with a current or previous illness will be included.

**Caregiver:** Those adults who are in a caregiving relationship for 3 months or more with the SMI participant during the previous 12 months.

## Eligibility Criteria for Elderly SMI

Elderly SMI in this study will be those meeting the following criteria

1. Aged 60 years and above
2. Residing in one of the 60 sample panchayats
3. Identified by ASHA worker through a standard screening procedure
4. Interviewed and confirmed by a trained research fellow in the project

## Sample Selection and Sample Size

Study participants will be selected by a multistage cluster sampling technique (see figure 2). The State of Kerala has 14 districts. One district each from three regions of Kerala will be randomly selected. A total of 20 panchayats each from these three districts will be randomly chosen to select a total of 60 sample panchayats. From the list of the severely mentally ill population identified through screening by ASHA workers,  $15 \pm 2$  participants from each panchayat will be selected using MS Excel generated random numbers.<sup>17</sup> Based on 20% service access rate (average of WHO estimate),<sup>10</sup> 95% confidence level, 20% relative allowable error, and using the formula  $Z^2pq/d^2$ , the minimum sample size of 384 was calculated. Considering the design effect of 2.0 for cluster sampling, the final minimum sample size requirement of 768 was computed.

## Ethics Approval

The study was approved by the Institutional Ethics Committee of Government Medical College Manjeri (IEC/GMCM/10/17). The protocol was reviewed by the ICMR experts and experienced international researchers before approval for funding. Permission will be obtained from all the Government Health Centers in the study areas for the involvement of ASHA workers in the workshops and data collection by project staff. Informed consent will be obtained from the participants including the ASHA workers, competent SMI patients, caregivers, and FGD participants.

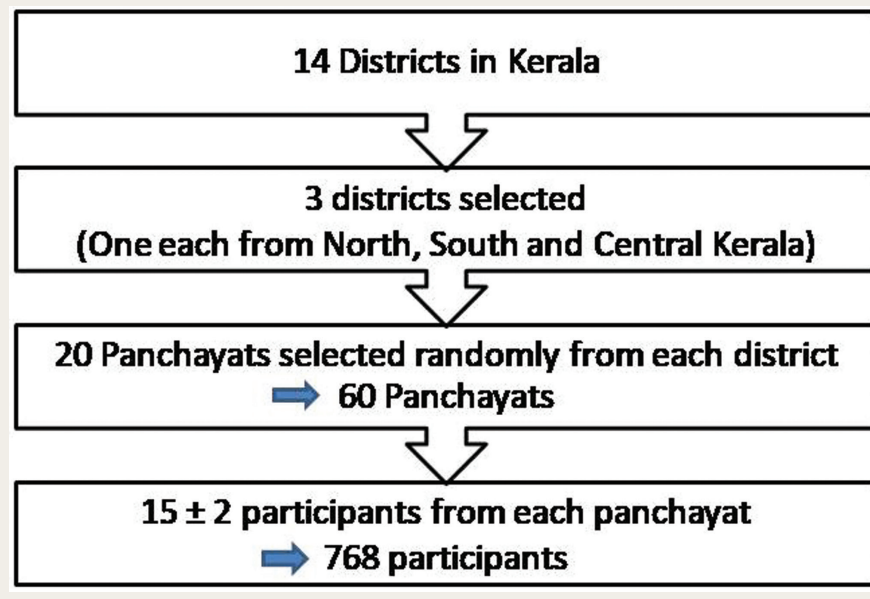
## Project Team and Training

The team of investigators in the project includes two psychiatrists and three

FIGURE 1.

**Study location – Three sample districts in Kerala state**

FIGURE 2.

**Sampling Strategy**

community medicine faculty—all having training and research experience in quantitative and qualitative study methods. One senior research fellow and five junior research fellows with postgraduation in public health (MPH) and graduate

degrees in medicine or allied subjects will form the field team. The field team will be provided a 1-month training in three modes: classroom sessions, practice interviews of patients, and caregivers in hospital settings and practice data

collection in field settings. The team will be trained to collect data on both paper formats and tablet computers. They will then be allotted one panchayat each for conducting data collection as a training exercise.

**Study Tools**

The study uses seven different tools for assessment. This includes standard tools and two tools developed by the investigators for assessing the sociodemographic details and access to care. All the study instruments have been extensively pilot tested and validated. The tools in English were translated into the local language: Malayalam by two language experts, adopting standard procedures of translation, back translation, and cultural adaptation.

**SMI screening tool for use by ASHA worker:** This tool is a symptom-based screening tool developed from “Symptoms in Others Questionnaire.”<sup>18,19</sup> Symptoms in Others Questionnaire is a set of 15 questions that was developed as part of the Indian Psychiatric Survey Schedule.<sup>18</sup> The questionnaire is used for identifying possible cases of mental illness in the community. It is administered to an informant from the household or the community. The questionnaire gives information about the presence of easily identifiable features of mental illness among people who are well known to the interviewee. The Malayalam version of the Symptoms in Others Questionnaire was used in one large-scale psychiatric epidemiological survey in Kerala.<sup>20</sup>

**SMI verifying tool for the interview by research fellows:** This interview tool for verification of SMI reported through ASHA screening was based on the Symptoms in Others Questionnaire which has already been described.

**PHQ-9:** PHQ-9 is the nine-item depression module Patient Health Questionnaire which itself is a self-administered version of PRIME-MD (Primary Care Evaluation of Mental Disorders). PRIME-MD was an instrument developed and validated in the early 1990s to efficiently diagnose five of the most common types of mental disorders presenting in medical populations: depressive, anxiety, somatoform, alcohol, and eating disorders. The PHQ-9 is a multipurpose instrument for screening, diagnosing, monitoring, and measuring



the severity of depression.<sup>21</sup> The reliability and validity of the Malayalam translation of PHQ-9 has already been established.<sup>22</sup>

**Everyday Abilities Scale for India (EASI):** Dementias have been included along with SMI in this study as dementia is very common in old age. EASI is a tool developed as a measure of activities of daily living appropriate for use in assessing the presence of dementia in illiterate rural elderly people in India.<sup>23</sup> It is a brief, reliable, and valid “activities of daily living” measure, with norms appropriate for use in assessing dementia in illiterate rural elderly people in India.<sup>24</sup> The Malayalam translation of EASI was used earlier in large-scale epidemiological survey in Kerala.<sup>20</sup>

**WHO burden assessment tool for caregivers (BAS):** Caregivers are all persons who support and help a person who needs regular care because of personal—not professional—reasons. The caregiver burden is the strain or load borne by a person who cares for a chronically ill, disabled, or elderly family member. This burden is an important predictor for negative outcomes of the care situation for the caregivers as well as the one who is cared for. BAS was developed by the Schizophrenia Research Foundation (SCARF) in collaboration with the World Health Organization (WHO). It assesses caregiver’s feelings about their caregiving role. There are 20 questions in BAS that can be scored between a range of 1 and 3.<sup>25</sup>

**Sociodemographic data tool:** A range of socioeconomic factors affect mental health. This tool captures details like religion, social group, marital status, education, occupation, income, type of family, family size, and housing standards of the participants. This tool was based on the relevant components of “National Family Health Survey 4 (NFHS-4)” — a large-scale, multiround survey conducted in a representative sample of households throughout India<sup>26</sup> and The Census of India 2021.<sup>27</sup>

**Access and barriers to care tool:** This questionnaire was developed by the investigators to meet the specific objectives of the project by assessing treatment-seeking, comorbidities, access to services, DMHP care, social support, medication, financial barriers, social

security, insurance, addictions, self-care, etc. Two FGDs—one among psychiatric professionals and the other one among ASHA workers—were conducted initially to help develop this tool. The questionnaire was modified after pilot testing and sent to 10 psychiatrists and 10 public health professionals for content validation. The modified questionnaire based on peer feedback was pilot tested again, and test–retest reliability was assessed before final use in the study.

## Data Collection

House to house survey to screen for mental illness in the community is time consuming and expensive. This study employs an alternate strategy. ASHA is a trained female community health activist. They work as an interface between the community and the public health system. At present, there are over 0.9 million ASHAs in India.<sup>28</sup> The study’s innovative strategy involving ASHA to screen for SMI based on two presumptions.

1. It will be easier to identify the elderly SMI patients from the community than the elderly with milder mental illnesses due to the functional impairment and long-standing nature of SMIs.
  2. The ASHAs with their familiarity of the community will be able to list the elderly SMI from their area through a workshop arranged for this purpose.
- The ASHAs, drawn from a local community and who make regular house visits among a rural population of 1000 as a part of their duty, are expected to personally know all the individuals in their area. The definition of SMI by NIMH USA focuses on the serious functional impairment and substantial interference in major life activities rather than on the specific diagnosis of the mental disorder to consider those with mental, behavioral, or emotional disorders as SMI.<sup>7</sup> As the aged people who meet the above criteria will be most often well recognized in the community, the ASHA workers should be able to identify and list those from their area through memory recall. In general, each Primary Health Center (PHC) in Kerala is meant for a population of around 30,000 and each panchayat in Kerala has one PHC. Considering the proportion of the elderly population in Kerala and the prevalence of severe

mental illness among the elderly, the average number of elderly SMI in a panchayat in Kerala was estimated. Pilot testing of the innovative screening strategy in two panchayats before the actual survey produced a list that matched the expected prevalence.

To further pilot test the screening strategy, the list of SMI prepared by ASHAs in the above two panchayats was compared with the list produced by another group of grass root level workers: anganwadi workers (AWW). AWW is involved in providing preschool education, nutritional improvement, etc. As they are also familiar with the community, meetings of these workers in the same two panchayats were held and the same listing exercise for SMI was undertaken. Triangulation of the data in the above two panchayats during the pilot phase showed that there was a good match between the list generated independently by ASHA and AWW.

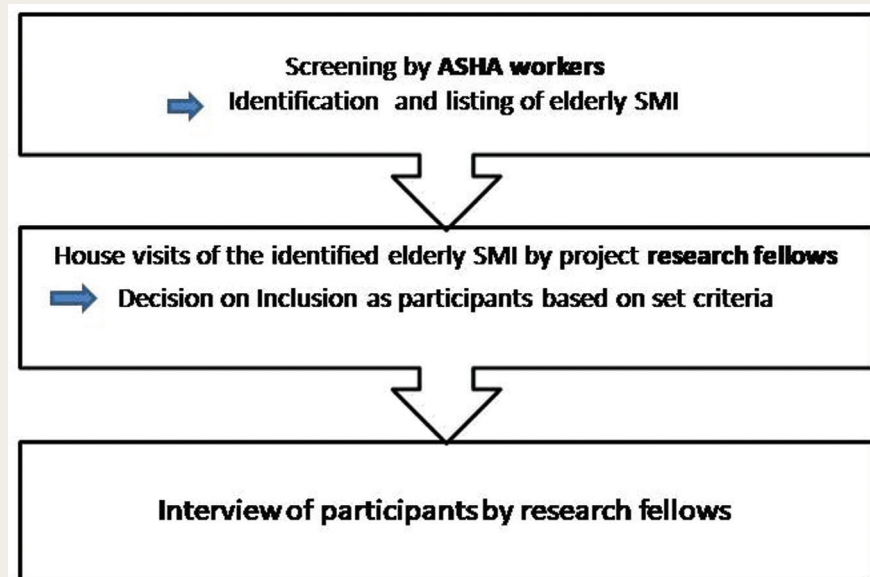
## Quantitative Component

The cross-sectional study part of the project will use a two-phase strategy for participant selection (see Figure 3).

1. In the first phase, screening for SMI will be done through specific ASHA worker workshops. For this, the project team will arrange a workshop for ASHA workers from the selected panchayats at the local PHC. A copy of the single page validated screening tool in the Malayalam language with instructions to help ASHA identify elderly SMI from their area will be shared with them through WhatsApp messaging application—an app that is quite popular among ASHAs. This will be done at least one week before the meeting so that the ASHAs come prepared with the required information on the day of the meeting. On the scheduled day of the ASHA meeting, training classes on identifying the SMI and completing the screening tool followed by a question and answer session will be conducted. The ASHAs will be then handed over paper copies of the screening tool to list and report the name and address of the elderly SMI from their area. Recognizing the possibility that the ASHA might not list the SMI whom they perceive as not likely to consent,

FIGURE 3.

### Procedure for Participant Selection



ASHA, Accredited Social Health Activist; SMI, serious mental illness.

they will be encouraged to list these patients too, but mark them as “unlikely to co-operate.” After ASHAs complete the forms and return it, the project team will verify the completeness of the collected pro formas and the workshop will conclude. After holding the workshops and listing the SMI in each district, the second phase will be planned and executed.

2. In the second phase, interviews of patients/caregivers (participants) will be conducted;  $15 \pm 2$  participants will be selected from each panchayat through simple random sampling from the compiled list of SMI and these participants will be approached for a detailed interview at the participant’s households. If the interviewers find it difficult to locate the participant’s houses on their own, they will seek the help of ASHA workers from these areas. Caregivers will be chosen as the primary respondent for interviews and competent patients will be interviewed only if there are no caregivers or other persons who could provide reliable information. After obtaining informed consent, the interview of participants will be conducted by trained research fellows on tablet computers. Digital versions of the study tools using the Open Data Kit (ODK) were developed for field data collection in this

study. ODK is a free, open-source software for data collection using Android-based devices.<sup>29</sup> The diagnosis of the participant’s mental illness by ASHA workers will be corroborated using the SMI verifying tool. The JRFs will be encouraged to call the psychiatrists among the investigators and clarify their doubts about the diagnosis at all stages during data collection. If the patient meets the inclusion criteria, he/she will be included as a participant and appropriate tools will be administered. To ensure confidentiality in the unlikely scenario of data loss from the ODK server, the participant name and address details will not be entered in the digital survey tool and will instead be entered manually in a printed register. The access and barriers to mental health care and caregiver burden will be assessed, and the name of the medication the participant is having will be noted. Geolocation will be added to the dataset for easy house identification during supervisory visits. When available, patient prescriptions and/or medicine strips will be photographed sans identifiers, and the photos automatically linked to the data set for later review purposes of the entered data. The interviewers will be trained to provide referral information to the participants who were not

taking treatment and willing to access professional assistance. If the participant agrees to be assisted, the ASHA will be informed.

## Qualitative Component

Six key officials from the DMHP who includes the nodal officer, psychiatrists, medical officers, psychologist, and psychosocial workers from each district who are willing to participate and talk freely will be invited for each FGD to assess their felt needs and perceptions about the study area and DMHP services for the elderly SMI. One FGD each is planned in the three districts, and the discussions will be aided by FGD guides. There will be general questions, specific questions, and probe questions in the guides. The questions will be framed in an open-ended style to facilitate free discussion. The FGD facilitators will be one of the investigators trained in qualitative research. A note-taker will record the discussions. All the interviews are to be audiorecorded and after completion of interviews, the audio files will be transferred and stored in a computer as password-protected files.

## Data Management

The Principal Investigator of this project will be responsible for the management and sharing of the data. The name and address of the participants will not be collected electronically but will be noted down in the register for the purpose. This delinking will be done as an additional precaution for maintaining confidentiality. Data collected on tablet computers will be uploaded daily by the interviewers, and once this is done they cannot review or modify the data. Hard copies will be stored under lock and key and electronic data files will be downloaded and stored as password-protected files. Only designated project staff will have access to the confidential individually identifiable data thereafter, and all data will be aggregated or masked for publication. The raw data will be uploaded to the ICMR website maintained for the purpose.

To ensure data quality the following measures will be taken:

1. The team of interviewers will be provided intense training on data collection.

2. The electronic data entry module will have in-built validation and logic skips to prevent mistakes during data entry.
3. The start time and end time of the interviews will be automatically logged in the system.
4. The geolocation of the household, where the interviews are held will be attached to the data set.
5. Photographs of prescriptions and medications whenever available will be attached to the data set.
6. Regular supervisory visits during field data collection by the SRF and investigators will be undertaken.

## Data Analysis

Quantitative data will be analyzed using SPSS version 17.0 statistical package. Univariate and bivariate analyses will be done, and appropriate statistical tests will be used to draw valid conclusions from the data. Quantitative variables will be expressed as mean and standard deviation. Qualitative variables will be expressed as frequencies and percentages. Association of variables will be done using the chi-square test and the Student's t-test. The level of significance will be estimated with 95% confidence intervals and a p-value <0.05.

After listening to the voice recordings of the FGD, a verbatim translation of all data to English will be done. The sample of transcripts will be compared with the recorded digital files for accuracy. The FGDs will be manually coded and analyzed over 2 months. The content analysis will be done manually. The interpretation of the study findings is to be done according to the broad themes. Findings will be presented after consulting the field notes and the transcripts to create a comprehensive report.

## Expected Outcomes

The existing mental health services should be geared up for the increase in the elderly population, taking into account their special needs. The SMI form a particularly vulnerable group among the mentally ill elderly and face separate challenges in accessing care. The results of the study are expected to help policymakers at the state and the national levels understand some of these challenges and plan evidence-based

interventions. The innovative screening strategy used in this study with cost, effort, and time-saving benefits could have wider applications

### Acknowledgments

The work was supported by the Indian Council Medical Research (ICMR) under Capacity Building Projects for National Mental Health Programme, ICMR-NMHP. We thank Dr Soumya Swaminathan (then Secretary, Dept. of Health Research, DHR), Dr Balram Bhargav, current Secretary DHR, Professor V. L. Nimgaonkar, Professor Smita N. Deshpande, Dr Ravinder Singh, and Dr Harpreet Singh. We thank the faculty of "Cross-Fertilized Research Training for New Investigators in India and Egypt" (D43 TW009114, HMSC File No. In-do-Foreign/35/M/2012-NCD-1, funded by Fogarty International Centre, NIH). We are also thankful to National Coordinating Unit of ICMR for NMHP Projects for their constant support and guidance. The content of this manuscript is solely the responsibility of the authors and does not necessarily represent the official views of NIH or ICMR. NIH and ICMR had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

### Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### Funding

This protocol paper describes the methodology of a research project funded under 'Capacity Building Task Force for Mental Health Research in India' funded by the Indian Council of Medical Research vide file number 5/4-4/151/M/2017/NCD-1. International mentors were funded by the training program 'Cross Fertilized Research Training for New Investigators in India and Egypt' funded by FIC, NIH (No. D43 TW009114).

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