

Assessment of the Need for Training in Clinical Pharmacology Research on Traditional Medicine among Modern Medicine Practitioners: A Questionnaire-based Study

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ABSTRACT

Introduction: Training young doctors is essential for carrying out need-based research. The field of Traditional Medicine (TM) has made significant contributions to modern medicine, and there is unlimited scope for exploring it further in search of improved treatment options. However, there is a lack of systematic research studies on traditional medicines. It was, therefore, considered necessary to assess the interest and awareness among modern medicine practitioners regarding Traditional Medicine Research (TMR).

Aim: To assess the need for training in TMR among modern medicine practitioners.

Materials and Methods: A cross-sectional questionnaire-based study was conducted in the Department of Pharmacology and Therapeutics at Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India, from March 2020 to September 2020 among modern medicine practitioners from the Western region of India. A validated questionnaire was used to collect data regarding the level of training in research methodology, research experience including TMR, areas for training, attitude towards

training in TMR, challenges in TMR, and therapeutic areas to focus TMR efforts. The data were analysed using descriptive statistics.

Results: Out of 109 participants, 96 (88.1%) were trained in research methodology. At least one research project was undertaken by 91 (83.5%) participants. Ninety-seven percent of participants felt that TMR was necessary. TMR was conducted by 19 (17.4%) participants. Approximately 65 (59.6%) participants felt that conducting TMR poses challenges such as lack of funds, infrastructure, lack of belief in TM, unavailability of literature pertaining to TM, lack of expertise, and lack of corporate attention and marketing. Therapeutic areas identified to focus research efforts included lifestyle-related disorders, diabetes mellitus, cancer, ageing, allergic disorders, osteoarthritis, and obesity.

Conclusion: All the participants expressed the need to undergo training in TMR. However, the experience of conducting TMR was limited. Lack of funds, infrastructure, and expertise were mentioned as the main hurdles in undertaking TMR. It is essential to conduct systematic and need-based training programs for modern medicine practitioners in basic research methodology and TMR.

Keywords: Alternative medicine, Biomedical research, Herbal drugs

INTRODUCTION

Research is an essential component of healthcare [1]. The medical research output from India is not up to par, both in terms of volume and quality. This is particularly conspicuous when considering the extensive healthcare requirements of the large population [2]. Although researchers in India have recognised the importance of research, the majority of the work is carried out in isolated pockets, leading to repetition and a lack of an effective network. One study found that 57.3% of Indian medical institutes did not have a single biomedical research paper published in the Scopus database from 2005 to 2014 [2]. Investigator-driven studies need to be undertaken in India to advance knowledge, bridge gaps, and develop guidelines and policies [3,4].

It is the need of the hour to train young health professionals to provide the foundation for undertaking need-based and patient-centered research. The National Programme on Technology Enhanced Learning (NPTEL) has started an online training course since 2019 entitled 'Basic Course in Biomedical Research,' which has been made mandatory for postgraduates and academic institute faculty. However, the impact of this training is not systematically evaluated [5-7]. The scenario of research on traditional medicine (TMR) in India also leaves much to be desired. According to the World Health Organisation (WHO), Traditional Medicine (TM) is defined as the sum of the knowledge, skill, and practices based on the theories, beliefs,

and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement, or treatment of physical and mental illness [8]. WHO classifies TM into three main categories: Codified medical systems (medicine with a well-defined body of knowledge in the form of literature and taught formally like Ayurveda, Siddha, and Unani system in India, homeopathy in Europe, and Traditional Chinese Medicine and acupuncture in China); Folk medicine; and allied forms of health knowledge, such as yoga and home remedies that have been passed down for generations [9-11].

The traditional knowledge has been passed down over 3-4 millennia and is based on unique concepts related to physiology, pathogenesis, and treatment options, which differ from modern medicine. For the universal acceptability of TM, evidence for its safety and efficacy needs to be generated by using modern scientific methodologies [10]. This, in turn, requires formalising training programs for research in TM for practitioners of modern medicine. A literature search revealed a lack of training courses and programs to train young researchers (from modern medicine) to conduct clinical research on TM in India.

In light of the above, a training program was designed by the Department of Pharmacology and Therapeutics, Seth GS Medical College and KEM Hospital, Mumbai, under the aegis of the Indian Council of Medical Research Advanced Centre for Capacity Building of Young Investigators in Clinical Pharmacology Research

in Traditional Medicine. The objectives of this programme were to develop standardised modules for training in TMR, validate these modules by experts, conduct workshops using these modules across the country to identify their strengths and deficiencies, and further strengthen the modules for wider dissemination. It also proposed to encourage partnerships among clinicians, pharmacologists, and public health professionals during and after the workshop.

This program required formulating training modules on basic research methodology and clinical pharmacology research in TM and pilot testing of these modules in a workshop [12]. The present questionnaire-based survey is a first-of-its-kind survey, which was carried out as a prelude to this training program. The objectives were to find out the opinions of modern medicine practitioners about the need to undergo training in research methodology and the necessity to undertake TMR.

MATERIALS AND METHODS

The present study was a cross-sectional study conducted in the Department of Pharmacology and Therapeutics at Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India for a period of seven months (March-September 2020). The study was approved by the Institutional Ethics Committee (EC/OA-146-2019) and was registered with the Clinical Trials registry of India (CTRI/2020/05/025280). Informed consent was obtained from participants before administering the questionnaire. Anonymity and confidentiality of their responses were maintained. A convenience sampling technique was followed, and participants were approached either in person or were sent a link to the online questionnaire after seeking their willingness verbally. They were contacted in person, by email, or by an instant messaging system.

Inclusion criteria: Third-year residents, post-MD senior residents, faculty members, and clinicians belonging to different specialties at teaching hospitals and private practice who were currently studying or practicing modern medicine in the Western region of India were included in the study.

Exclusion criteria: Those participants not willing to give consent were excluded from the study.

Sample size: The authors approached approximately 1400 potential participants, of which 115 responded (estimated response rate 8.21%). Out of the 115 responses, six were incomplete and hence not included in the analysis, thus comprising 109 as the sample size.

Potential participants were given a hard copy of the questionnaire or sent an online questionnaire with an inbuilt informed consent document. A semistructured and multiple-response type questionnaire was designed by the authors after a comprehensive literature review. The questionnaire consisted of two separate domains, A and B, pertaining to basic research methodology and TMR (Therapeutic Medical Research), respectively. Domain A included questions on training related to research methodology, experience in research projects, and interests, as well as desired research methodology training topics. Domain B included questions on training related to TMR, such as the essentiality of TM and its research, knowledge of TMR methods, expertise with them, interests, preferred training topics for TMR, and challenges in the conduct of TMR.

The questionnaire was validated by 10 experts from the Departments of Pharmacology and Therapeutics and the Department of Clinical Pharmacology of the institute. Only those questions with an Item level-Content Validity Index (I-CVI) >0.78 were included [13]. The scale level content validity index (S-CVI) for domain A and domain B of the questionnaire was 0.92 and 0.91, respectively.

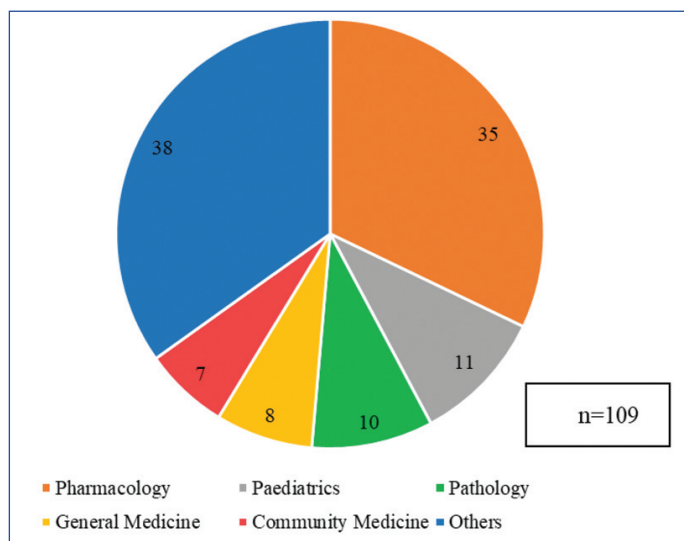
STATISTICAL ANALYSIS

The responses of participants were entered into MS-Excel 2013. The closed-ended questions were analysed by descriptive statistics ('countif' function). Analysis of open-ended questions was done

by grouping their responses on the basis of common themes. (Thematic analysis).

RESULTS

The number of analysable responses was 109, obtained from 37 (33.94%) junior residents, 33 (30.28%) senior residents, 23 (21.10%) faculty members, and 16 (14.68%) consultants. The specialty-wise distribution of the respondents has been depicted in [Table/Fig-1]. Eighty-six (78.90%) respondents were from a teaching hospital, 12 (11.01%) worked at a non teaching hospital, and the remaining 11 (10.09%) were from private clinics.

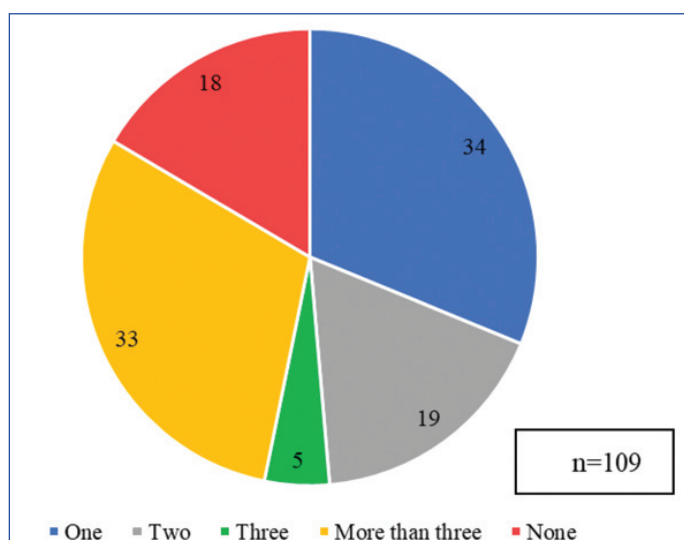


[Table/Fig-1]: Subject specialty of respondents.

Domain A: Questions on training related to Basic Research Methodology

Ninety-six (88.1%) participants had received training in research methodology. The topics of their training included literature search 75 (68.8%), clinical research 82 (75.2%), good clinical practices 81 (74.3%), ethics in research 78 (71.6%), biostatistics 72 (66.1%) and critical appraisal of evidence 51 (46.8%).

Ninety-one (83.5%) participants stated that they had carried out at least one research project. [Table/Fig-2] illustrates the number of research projects carried out by the respondents. Fifty-six (51.4%) participants had published at least one research paper. Original research papers made up 47 (56.63%) of the 83 published research papers, followed by review articles 19 (22.89%), case reports 16 (19.28%), and letters to the editor 1 (1.2%).



[Table/Fig-2]: Number of research projects carried out.

The participants were part of 37 interventional studies (randomised controlled studies and surgical interventional studies) and 74 non

interventional studies (observational studies, drug utilisation studies, adverse drug reaction monitoring studies, pharmaco-economic analyses, pharmacogenomic studies, etc.). Among the 109 participants, 39 (35.8%) had been a part of interventional/investigator-initiated studies other than dissertations. Of these 39 respondents, 3 (2.8%) had participated as principal investigators, 28 (25.7%) as co-investigators, 13 (11.9%) as study coordinators, and 3 (2.8%) as research assistants in various studies conducted at their respective centres. Two participants had worked in all three roles.

Eighty-nine (81.7%) participants expressed interest in receiving training in research methodology. When asked about the topics they would like to be covered, the suggested topics were related to planning and conducting research studies. [Table/Fig-3]. Eighty-four (77.1%) participants stated that they would prefer a workshop of short duration (1-2 days).

S. No.	Topic for training	Number of participants who suggested the topics (N=109) n (%)
1	Statistical analysis and interpretation	89 (81.7)
2	Sample size calculation	80 (73.4)
3	Writing a protocol	74 (67.9)
4	Clinical trials in specific age-groups, special populations	73 (66.9)
5	Investigator and sponsor responsibilities	70 (64.2)
6	Regulatory considerations for trials on vaccines and devices	70 (64.2)
7	Good clinical practice	70 (64.2)
8	Phases and requirements for conduct of clinical trials	66 (60.6)
9	Writing a manuscript	63 (57.8)
10	Applying for a grant	63 (57.8)
11	Research question framing	61 (55.9)
12	Bioavailability and bioequivalence	60 (55.0)
13	Safety evaluation	59 (54.1)
14	Informed consent form and process	54 (49.5)
15	Ethical considerations (IEC submissions and Ethical issues)	53 (48.6)
16	Clinical trials on herbal drugs/phytopharmaceuticals	53 (48.6)
17	Literature search	51 (46.8)

[Table/Fig-3]: Topics desired to be covered in research methodology training and good clinical practices.

Domain B: Questions on training related to TMR

One hundred and six (97.2%) participants responded that TMR is necessary. The responses pertaining to the need for TMR were grouped under common themes and are presented in [Table/Fig-4].

S. No.	Common themes suggesting need for Traditional Medicine Research (TMR)	Number of responses pertaining to one or more themes
1	To generate evidence on traditional medicine	38
2	To learn about safety and efficacy of traditional medicine drugs	17
3	To understand the therapeutic utility of traditional medicine	15
4	To enhance our knowledge and understanding regarding traditional medicine	15
5	To understand how traditional medicine can be used as an alternative to modern medicine	12
6	To know more about pharmaceutical aspects of traditional medicine	7
7	To serve unmet medical needs	5
8	To increase the acceptance of use of traditional medicine in the society	3

[Table/Fig-4]: Analysis of responses on need for Traditional Medicine Research (TMR).

Ninety-eight participants (89.9%) had not attended any conference/workshop on TM. Only 6 (5.5%) participants read journals on TM.

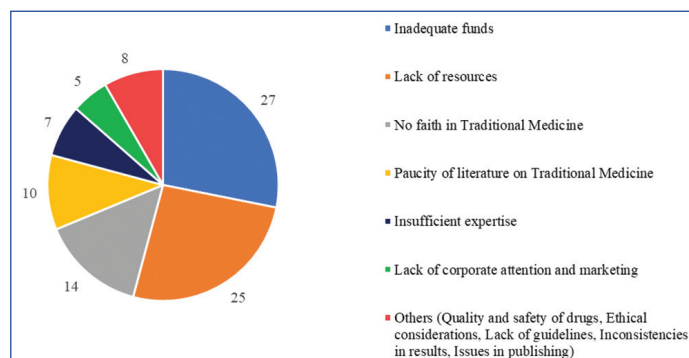
Nineteen (17.4%) had conducted research using formulations/therapies from TM.

Some of the topics suggested by participants for undergoing training in TMR were like those stated for undergoing training in basic research methodology, such as obtaining funding for research, study designs, literature search, and statistical analysis, as well as methods to procure resources, placebo effect, and safety analysis. Additional topics suggested by them that pertained to TMR are listed in [Table/Fig-5].

S. No.	Desired topic of training in a workshop on Traditional Medicine Research (TMR)	Number of responses pertaining to one or more themes
1	Therapeutic applications of traditional medicine	41
2	Establishing rationale for the use of traditional medicine	16
3	How to generate evidence on safety and efficacy of traditional medicine products	13
4	Conducting clinical trials in traditional medicine	12
5	Drug manufacturing process	11
6	Regulatory issues; Intellectual property rights and patent laws	9
7	Literature search on traditional medicine	6
8	Ethical considerations in carrying out Research in Traditional Medicine (TMR)	2
9	Others: (statistical analysis, chemical assays and analysis, ways to integrate traditional medicine with modern medicine, reverse pharmacology)	6

[Table/Fig-5]: Topics suggested for training in Traditional Medicine Research (TMR).

Approximately 65 (59.6%) participants felt that conducting TMR encompassed more challenges than carrying out research in modern medicine. The potential challenges listed by them are shown in [Table/Fig-6]. On further questioning about the challenges they had faced, 13 participants who had conducted TMR stated the challenges encountered by them as lack of funds (6), infrastructure (4), belief in TM (2), literature pertaining to TM (1).



[Table/Fig-6]: Potential challenges in Traditional Medicine Research (TMR) which were enlisted by participants.

The various therapeutic areas marked (5 or more than 5 responses per participant) by participants for directing research efforts to integrate TM with modern medicine are outlined in [Table/Fig-7].

S. No.	Therapeutic area	Number of responses by participants (5 or more than 5 responses per participant)
1	Lifestyle related disorders/chronic conditions	69
2	Prevention and health promotion: ageing	50
3	Allergic disorders	48
4	Osteoarthritis	46
5	Chronic bronchial asthma	43
6	Cancer	39
7	Obesity	35
8	Irritable bowel syndrome	35

9	Chronic ulcer/diabetic foot	31
10	Infertility and sexual disorder	26
11	Other therapeutic areas (alopecia, vascular dementia, piles, insomnia, acne, urticaria, backache, etc.,)	227

[Table/Fig-7]: Therapeutic areas for integration of TM with modern medicine.

DISCUSSION

Medical practitioners are required to keep themselves updated about the new developments in the medical field pertinent to their area of expertise. It is also the responsibility of practicing clinicians to equip themselves so that they can differentiate between scientifically good and bad research studies and make decisions about applying the inferences in clinical practice. Moreover, to design, carry out, and publish research studies, they need a basic understanding of research methodology and statistics. It has been reported that there is a lack of systematic training in research methodology and specific training workshops catering to diverse training needs in India [6,14]. It is hoped that the new National Programme on Technology Enhanced Learning (NPTEL) online training course will bridge the existing gap in the research training programs to a certain extent [7]. However, practitioners of modern medicine not affiliated with academic institutes also should undertake research activities and need to undergo such training periodically to practice evidence-based medicine.

The present study was undertaken to understand the gaps in training modern medicine practitioners in the areas of basic research methodology as well as in TMR. A total of 115 survey responses were recorded, out of which 109 were analysable, owing to their completeness in the responses. Of these, 23 responses were received from the participants belonging to non academic hospitals and private clinics, expressing the need to undertake basic as well as TMR. This is an encouraging finding.

Although 88% of participants had received training in basic research methodology, 81.7% were still desirous of getting trained in research methodology. This highlights the need for continued training and also gaps in the research training programs. The training should be customised as per the needs and previous knowledge of researchers. The current study also sheds light on the key areas related to basic research methodology which need to be focused upon, viz., statistical analysis and interpretation, sample size calculation, protocol writing, critical appraisal of evidence, and regulatory considerations for trials on vaccines and devices in the training sessions. Nearly all the participants affirmed that TMR and training to conduct TMR are both essential, and 48.6% of them also expressed their desire to be trained in clinical trials on herbal drugs and phytopharmaceuticals.

Even though 88% of the participants had received training in research methodology and 83% of the participants had carried out at least one research project, only 51% of these had published their studies. This high discordance wherein research is undertaken but not published can be attributed to various factors. Moreover, the scenario in India is that there is a requirement for the submission of a dissertation for obtaining a postgraduate medical degree. Hence, less importance is given to undertaking other academic studies out of interest and publications by postgraduate students. Previous studies have reported the possible reasons such as a shortage of time to write or submit, and inadequate support for carrying out the data analysis. Besides, researchers lack awareness about the current reporting guidelines, and do not have proficiency in writing, which further lead to poor quality of writing and high rejection rates from journals [15,16]. Rahman S et al., have cited barriers to participation of physicians in clinical research viz., lack of interest and expertise in research methodology, financial constraints, uncertainty of the study outcome and fear of adverse effect, increasing complexities in clinical trials, and have suggested regular training as one of

the remedial strategies [17]. In this survey, 77% of participants preferred a research methodology workshop of short duration. This is perhaps because most Indian doctors are already overworked due to a very low doctor-population ratio of 0.77:1000, and they cannot afford to spend time on research methodology workshops of longer duration [18].

Another fact highlighted by the present study is the meager involvement of participants in interventional studies, as compared to observational studies. Interventional studies are demanding in terms of infrastructure, resources, investigator responsibilities, time commitments, and risks involved apart from the training and expertise of the team conducting them. The topics which participants suggested to be covered in research methodology training hinted at their lack of preparedness to undertake interventional studies.

Nearly all the participants in this study affirmed that TMR and training to conduct TMR are both essential. However, their experience in the field of TMR was scarce, as evident from the small number of participants who had conducted research on TM. The number of participants attending conferences/workshops on TM and regularly reading journals on TM was also minimal. This brings forth speculations like perhaps the interested researchers did not have adequate opportunities, as well as an encouraging environment and infrastructure to conduct TMR. They probably did not have sufficient awareness and training in the field of TMR. "Another question that arises is why journal editors are not willing to publish more research papers on TMR?" Telles et al., have reported that the main reasons for TMR being less popular are inadequate sample sizes, variable outcomes, faulty research study designs, inconsistency of descriptions of the treatment or product, and lack of a control arm [10]. An attitude of apathy towards TMR may also stem from the numerous challenges faced while conducting research on TM. This is resonated in the potential challenges in TMR cited by researchers. Lack of funds and infrastructure has been cited as important barriers confronted by the participants while undertaking TMR.

Out of the 19 participants who conducted research using TM products, 17 were pharmacologists. Pharmacology professionals are more likely to take up herbal drugs from TM for preclinical studies and are more conversant with the drug development process. Apart from training at research methodology workshops, postgraduate students of internal medicine and other disciplines should also be sensitised to undertaking TMR in the pursuit of new drugs using modern research methodology. In a study conducted among medical postgraduate students from various specialties at a tertiary care hospital in Mumbai, 80% disagreed with compulsory training in Ayurveda medicine use during postgraduation; however, 68% felt that Ayurveda and modern medicine should be integrated [19].

The participants in the current survey have identified therapeutic areas where research efforts need to be directed to integrate TM with modern medicine. Most of them agreed on chronic illnesses and lifestyle diseases. The need for conducting TMR in areas of unmet need, like rheumatoid arthritis, other autoimmune disorders, and sensitising students about systems of alternative medicine, has also been emphasised in the literature [20-22].

To overcome the hurdles in carrying out TMR and to create awareness about this field, which has a huge untapped potential, concrete multidisciplinary efforts and backing by the central government are required. Some of the preliminary suggestions include increased funding opportunities from the public and private sectors specifically for TMR, training courses for advanced-level training in TMR, and certification offered through government programs. Evaluation of the long-term impact of the training program and a credit points system for academic promotions for research, as well as extra credits for TMR done as part of a government program, are also suggested. There is a need for multidisciplinary collaboration in TMR projects with a structured strategy, such as the identification of key areas, potential

formulations, and research teams at the national level to undertake multidisciplinary projects. Efforts are required by the stakeholders involved to foster the research and to train researchers.

The Government of India is taking steps to intensify research programs. The Indian Council of Medical Research has been at the forefront to identify the gaps and encourage funding for structured training programs in clinical pharmacology research. The team of authors had received funding, and the department was recognised by the Indian Council of Medical Research in 2018 as the 'Advanced Centre for Capacity Building of Young Investigators in Clinical Pharmacology Research' by the Indian Council of Medical Research.

Limitation(s)

The generalisability of the findings of this survey is limited due to the small sample size. However, the opinions of participants from diverse backgrounds, such as different specialties of modern medicine, public and private sectors, and levels of seniority, could be captured.

CONCLUSION(S)

The study highlights the need for conducting systematic and need-based training programs in both basic research methodology and TMR. TMR is not undertaken on a large scale, although its need and applications, especially in the areas of unmet medical need, are recognised by modern medicine physicians. The gaps in training and conducting TMR, such as the lack of expertise, adequate training, and infrastructure among practitioners of modern medicine to undertake TMR, were identified by the participants in this study. Availability of resources, a multidisciplinary approach, and support by policymakers will help researchers boost research on traditional medicines.

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