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Survey Study

How knowledgeable are investigators studying therapies of traditional medicines?

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Abstract

Context: Research methodology in traditional Indian system of medicine. **Aim:** To determine the knowledge level of investigators conducting clinical trials in traditional medicines (TMs) including Ayurveda. **Materials and Methods:** This was a questionnaire survey conducted for selected researchers trained in any specialty and working in TM. 2087 researchers were selected based on selection criteria. A validated and pretested questionnaire containing the questions regarding regulatory issues, literature search, evidence-based medicine, clinical trial design, patient selection, and study reporting were sent either through E-mail or post. The answered questionnaires were analyzed. The parameters were analyzed based on median and interquartile range (IQR). **Results:** Forty two responses were received through E-mail and 21 researchers responded through post. Out of 63, six researchers sent incomplete responses. Among the remaining 57 respondents; 34 (59.6%) investigators had postdoctoral degree, 43 investigators (75.4%) did not receive any structured training on research methodology, 23 (40.4%) had two decades of research experience. Thirty three (74%) of investigators who received government funding didn't have any training on research methodology. Ayurveda experts group had better knowledge compared to pharmaceutical sciences and basic science group although they had a dilemma about conducting clinical evaluation of TM within the specific framework of rigorous clinical pharmacological principles without ignoring the Ayurvedic concepts such as *Dosha*, *Prakruti* etc., Investigators below 30 years possessed higher knowledge of research methodology when analyzed based on the age. The respondents working in research organizations, government organizations, and academic institutions had lower knowledge compared to those who were in private organizations/practice. **Conclusions:** It is recommend that investigators, peer reviewers, and fund managers involved in traditional medicine research need training especially in research methodology.

Key words: Ayurveda, evidence-based medicine, Integrative Medicine, knowledge level analysis, research design, research funding agencies, research policy, training support

Introduction

Traditional medicines (TMs), including Ayurveda, have not been officially recognized in many countries due to the lack of research evidence.[1] Some of the challenges on working in these nonbiomedical systems are the patient selection, regulatory issues, quality, and purity of the medicines.[2] A systematic search on vitiligo[3] for research papers and thesis on Ayurveda topics showed heterogeneous studies deficient in many basic issues concerning clinical trials. In this background, a study has been conducted to determine the knowledge level of investigators on conducting clinical trials in Ayurveda.

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Methods

Respondents

The study was conducted during 2010-2011, among researchers trained in any specialty and selected on the basis of their participation in TM research. A list of E-mails and postal address of investigators (authors and subscribers) were obtained from Indian journal editors publishing on TM, E-mail forums and websites of Indian health research grant making agencies.

A total of 2087 researchers were thus listed initially for inclusion in the study and were contacted for a response through E-mail (1631 nos.) and by post (456) along with self-addressed envelope. The nonrespondents were reminded after 1 month. However, 336 (20.6%) mail IDs bounced back stating incorrect mail address, and only 42 responses were received through E-mail. Similarly, 10 (2.2%) researchers could not be contacted since the letters were returned by post stating incorrect address and only 21 researchers responded through post. Thus, the total number of researchers who could be included in the study was 63. Again, out of the total of 63 researchers included in the study, six researchers sent incomplete responses. Hence, the final number of respondents in the study was only 57 [Figure 1].

Tools of data collection

Data was collected from the respondents using a pretested questionnaire [Annexure - 1]. The questionnaire inquired on regulatory issues to conduct clinical studies, literature search, concepts of evidence-based medicine, clinical trial design, patient selection in TMs, and study reporting. The information such as age, educational qualification, occupation, and research experiences were included in general information section. Questionnaire consisted of three sections to assess the knowledge level of researchers in TM. It contained closed- and open-ended questions. First section had 15 open ended questions, asking the opinion about principles of patient treatment in Ayurveda. Second section contained multiple choice questions about current methods of evidence-based research, with the right answer and three wrong answers. The option "don't know" was also added. There were 20 closed type questions on research methodology. The publication on evidence-based approaches for Ayurveda was used as standard.[4] Prepared questionnaire were edited by four referees comprising an allopathic researcher working in Ayurveda, two Ayurvedic academicians and, a questionnaire expert. The edited questionnaire were pretested on 57 postgraduate students and nine undergraduate teachers in two Ayurvedic Medical Colleges.

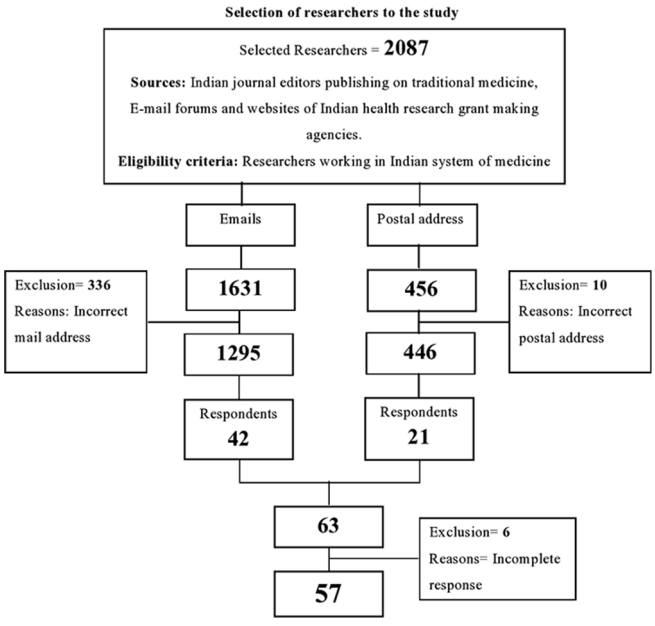

Figure 1: Flow chart showing the selection of researchers in different levels of inclusion

Analysis of data

The parameters were analyzed based on median and interquartile range (IQR). All the data were analyzed through SPSS 16 (SPSS Inc., Chicago, IL, USA).

Results

Profile characteristics of researchers

Among 57 respondents, 23 (40.4%) had >21 years and 15 (26.3%) <7 years of experience in their specialty. 45 (78.9%) were currently undertaking a research program. 4 (7%) were in private practice, 23 (40.4%) in research organization, and 17 (29.8%) working in academic institutions. Among the respondents, 27 (73%) were second degree holders in Ayurveda. 34 (59.6%) investigators had postdoctoral degree. All have conducted clinical studies in the past. Table 1 shows the basic details of the investigators. Table 2 shows their sources of funding.

Table 1: Profile characteristics of respondents

Details	Number of respondents	Percentage
Education qualification		
Ayurveda	37	64.9
Biomedicine	2	3.5
Pharmaceutical sciences	3	5.3
Unani medicine	1	1.8
Veterinary	2	3.5
Sciences (BSc)	11	19.3
Arts (BA)	1	1.8
Postgraduate education		
MD (Ayurveda)	27	
MD (allopathy)	2	
M Pharma	3	
Master (veterinary)	2	
Master of Science	11	
Master of Arts	1	
Employment status		
Private practice and hospital	4	7
Government	13	22.8
Research organization	23	40.4
Academic institution	17	29.8
Age		
<30 years	6	10.5
31-40 years	18	31.6
41-50 years	13	22.8
51-60 years	13	22.8
>60 years	7	12.3
Professional experience		
<7 years	15	26.3
7-14 years	10	17.5
14-21 years	9	15.8
>21 years	23	40.4
Doing research project		
Yes	45	78.9
No	12	21.1

Table 2: Source of support for Ayurveda related studies

Funding agencies	Ayurveda	Unani	Biomedicine	Pharmaceutical science	M Phil	Science	Arts
Department of Science and Technology	3					9	
Council of Scientific and Industrial Research	3		2		1	3	
The Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy	3	1					1
Central Council for Research in Ayurveda and Siddha	4						
Department of Biotechnology			3		1	6	
Indian Council for Medical Research	2			1	1	6	
University Grants Commission					1	3	1
Kerala Government	4					1	
Ayurveda Seva Sangh Nasik*	1						
Central Council for Research in Unani Medicine		2					
World Health Organization			1			1	
Rural Development Trust	1						
Western Ghats Development Programme						1	
Defence Research and Development Organization					1	1	
Mahatma Gandhi Institute for Rural industrialization	1						
Ministry of Environment and Forests	1					1	
Madras Diabetes Research Foundation*	1						
Dabur India*	1			1			
World Noni Research Foundation*				1			
National Institutes of Health						1	
New Millennium Indian Technology Leadership Initiative						1	
Wellcome Trust*						1	
National Medicinal Plant Board, New Delhi						1	
Indian Institute of Integrative Medicine, Jammu	1			1			
Department of Information Technology	3						
Centre for Development of Advanced Computing	2						
All India Council For Technical Education							1
Department of Health and Family Welfare	1						

*Private funding agencies

Training in research methodology

Among 43 investigators (75.4%) who had not received any structured training on research methodology, 27 (73%) were Ayurvedic doctors. 14 (24.6%) investigators received research methodology training from leading institutions of India like South Asian Cochrane Network and Department of Biostatistics, Christian Medical College located in Vellore, Indian Council for Medical Research in Delhi, Tata Institute of Social Sciences in Mumbai, Central Council for Research in Ayurvedic Sciences in Delhi, KEM Hospital in Mumbai, and Institute of Clinical Research (India). One among two researchers from biomedicine had official training in research methods whereas 6 (54.5%) from basic science, 2 (66.7%) respondents from pharmaceutical science, all respondents from Unani and veterinary medicine did not receive any research methodology training.

Perception about clinical trials

Thirteen respondents opined that clinical trials on Ayurvedic medicine should be done based on Ayurvedic diagnosis. Ten respondents' preferred biomedical diagnosis and 26 felt both diagnostic criteria are essential for conducting Ayurvedic clinical trials. Fifty respondents perceived that the modern laboratory investigations could help in disease diagnosis and assessment of results in Ayurveda and two respondents disagreed.

Knowledge on research methodology

Knowledge level of researchers on research methodologies is summarized in Table 3.

Figure 2 shows the differences in knowledge level of respondents based on their expertise. Ayurveda experts showed median score 10 with an interquartile range (IQR) range of 9–14. Biomedicine and Unani experts had no IQR and median score was 17 and 13, respectively. Pharmaceutical science experts had median score 9 with an IQR range of 6–12.5. Basic sciences investigators had median score 4 with an IQR range of 4–11.5, whereas Veterinary experts had a median score 4 with an IQR range of 2–5. Analysis of variance test reveals that the mean score of all groups is significant at 5% level ($P = 0.016$).

Figure 3 shows the differences in knowledge level of respondents based on the age. Respondents below 30 years had 13.5 median score with an IQR range of 11–15.25. Age group of 31–40 years had 10 median score with an IQR range of 7.75–14.25. Respondents who were in private practice,

Table 3: Knowledge level of researchers on clinical research methodology

Steps of evidence-based medicine	Number of respondents (percentage)
Regulatory issues	
Institutional ethics committee	38 (66.7)
Informed consent	49 (86)
Causality analysis	32 (56.1)
CTRI	34 (59.6)
Literature search	
Publication bias (E search)	37 (64.9)
Hand searching	26 (45.6)
Evidence levels	
Lowest level of evidence in evidence-based medicine	33 (57.9)
Highest level of evidence in evidence-based medicine	31 (54.4)
Clinical trial design	
Developing a clinical question as first step before conducting a clinical trial	47 (82.5)
Contents of a well-built clinical question	8 (14)
Historical controlled trial	22 (38.6)
Outcome measures of clinical trial	31 (54.4)
External validity (generalisability)	21 (36.8)
Patient selection	
Blinding/masking	36 (63.2)
Randomization	36 (63.2)
Patient allocation	12 (21.1)
Allocation concealment	32 (56.1)
Study reporting	
Components of study title	13 (22.8)
Reporting system for randomized controlled trial-CONSORT statement	27 (47.4)
Reporting system for nonrandomized trials-STROBE statement	11 (19.3)

CTRI: Clinical Trial Registry of India, CONSORT: Consolidated Standards of Reporting Trials, STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

Government Organization and Research Organization had 10 median score with an IQR range of 9–12 in Private practice group, 6–12 in Government Organization group and 4–13 in Research Organization group. Respondents working in private hospital and Academic Institution had 9 median score with an IQR range of 8–13 [Figure 4].

Discussion

This study determined the knowledge level of investigators conducting clinical trials in Ayurveda. Evidence-based approach for the Ayurvedic traditional herbal formulations was used as standard.[4] Ayurveda experts group had higher knowledge level compared to pharmaceutical sciences, basic sciences and veterinary sciences groups, with a median score 10 and IQR range of 9–14 [Figure 2]. Knowledge level analysis included queries on regulatory issues, literature search, evidence-based medicine,

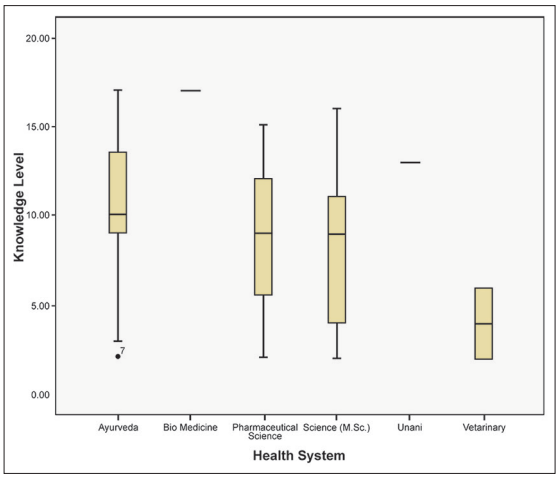

Figure 2: Knowledge level on research methodology according to specialization/qualification/category of researchers

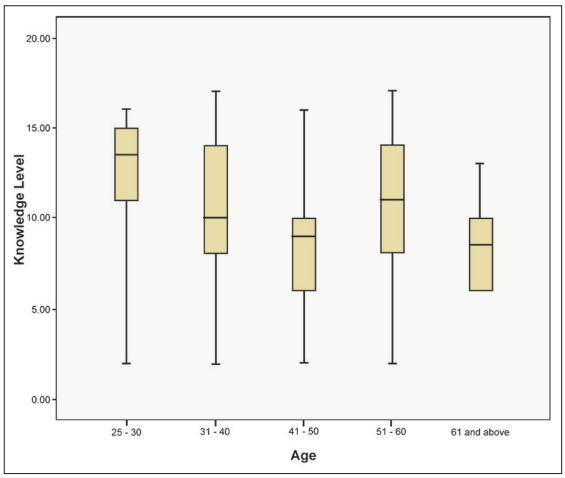

Figure 3: Knowledge level according to age of researchers

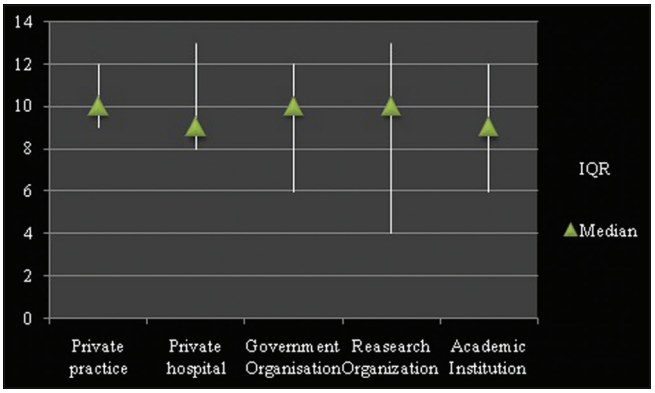

Figure 4: Knowledge level according to occupation of researchers

clinical trial design, patient selection and study reporting. 23 (40.4%) respondents were >21 years of professional experience and 45 (78.9%) had ongoing research projects. Investigators below 30 years possessed higher knowledge level [Figure 3]. The respondents working in research organizations, Government Organization and academic institutions had lower IQR compared to those who were in private practice [Figure 4].

The target population for the study was the researchers investigating TM. The questionnaire was designed as "user friendly" as possible and allowed maximum involvement of the respondents to answer the questions. Pretest showed that participants required 45 min to complete all the three sections, and respondents were able to answer easily. Prepared questionnaire was fine-tuned by experts and pretested using a representative population. This improved the clarity of the questions and avoided ambiguity posed to target population. The questionnaire was sent through mail as well as by post with self-addressed envelope. A covering letter was attached to allow the researcher to understand the objectives of the study.

According to a Gazette notification of Government of India any organization conducting a clinical trial should have an ethics committee registered with drugs controller general of India.[5] Indian Council for Medical Research has issued ethical guidelines[6] for studies involving human subjects. The research involving human participants required autonomy or respect for participant, beneficence, nonmalfeasance and justice. The ethics committee has to approve the clinical trial prior to patient recruitment. The questions on regulatory issues covered all these areas. 49 (86%) knew about informed consent and 32 (56.1%) had the knowledge about causality analysis. 34 (59.6%) respondents knew about Clinical Trial Registry of India (CTRI) [Table 3]. It is mandatory to register clinical trials before recruitment of patients. Previous study showed that, out of 588 clinical trials registered in CTRI, 3.57% trials were investigating Ayurvedic medicines.[7] We searched CTRI using keyword "Ayurveda" and found 102 (2.86%) trials out of 3567 registered trials.

Constructing a well-built research question is an important step to conduct trials[8] and systematic reviews.[9] Forty seven (82.5%) of respondents were aware of developing a clinical question as the first step before conducting a clinical trial, but only 8 (14%) had knowledge on building a structured clinical question based on patient, intervention, comparison and outcome[10] [Table 3]. This indicated the inexplicit research planning in TM.

There are no comprehensive electronic databases similar to PubMed, for Ayurvedic publications.[11] Most of the publications are only retrievable via hand-search of references and interviews of experts. Survey revealed 44.8% respondents knew about "hand searching" [Table 3]. It is clear from the analysis that most of the researchers don't use a search strategy combining electronic and hand searching. This meant that most investigators' literature search was only partial. This emphasized the need for separate search engine for Ayurveda and importance of work of Baghel[12] and Narahari *et al.*[3] Although in developmental stage bibliographic databases, AYUSH Research Portal,[13] Digital Helpline for Ayurveda Research Articles[14] contain maximum citations of Ayurveda studies. PubMed has 11 journals related to Ayurveda. All three databases must be included during literature search.

Patient selection is an important step during clinical trials to reduce the selection bias. Narahari *et al.*[3] discussed 12 of 16 parameters to evaluate patient selection in Ayurvedic studies.[4] 50% of respondents identified the method of patient selection. More than half of our respondents were not able to identify different steps of clinical trial. Only 31 (54.4%) identified systematic review of randomized controlled trials (RCTs) as the highest level of evidence in evidence-based medicine [Table 3].

Forty three investigators (74.1%) did not receive any training on research methodology. Out of this, 24 (55.8%) respondents had basic qualification on Ayurveda. The research methodology was the part of their second degree and postdoctoral curriculum. Very minimal current research topics were included in older syllabus of Ayurvedic curriculum. However, the newer syllabus has some details about research methodology[15] without assigning any teaching faculty. Patwardhan *et al.* suggested reconstruction of Ayurveda study curriculum and include proper training in standard methods of research.[16] World Health Organization has also recommended proper training on research methodology, for TM investigators.[17,18] However, poor attention in this regard by CCIM, led to researchers in Ayurveda institutions having less than optimum level of knowledge to conduct evidence-based studies.[19] Forty five (78.9%) respondents were executing research projects funded by government funding agencies as well as nongovernmental agencies [Table 2]. Thirty three (74%) of them didn't have any training on research methodology. Our respondents were from multiple systems and focused on pharmacological approach. A survey revealed the dilemma among Ayurveda teaching community about conducting clinical evaluation of TM within the specific framework of rigorous clinical pharmacological principles without ignoring the Ayurvedic concepts such as *Dosha*, *Prakruti* etc.[20]

Twenty six (45.6%) respondents opined Ayurveda clinical trials should be conducted using both Ayurveda and biomedical diagnosis. This should be achieved by forming multi-system-doctors[21,22] and helps to generate a sufficient evidence base for wider global acceptance like success achieved through the integration with modern science in lymphedema treatment.[4] A literature review revealed that no studies used the Ayurvedic diagnostic criteria completely or never specified any diagnostic criteria.[23] However, 26 (44.82%) investigators opined that both biomedical and Ayurvedic diagnoses are needed for clinical studies and 50 (86.2%) opined that modern laboratory investigations could help in disease diagnosis and assessment of results in Ayurveda.

The Consolidated Standards of Reporting Trials (CONSORT) statement is endorsed by 50% of Biomedical journals and a few major Ayurveda journals. Only 27 (47.4%) respondents were aware of CONSORT statement. The present curriculum of post graduate programs in Ayurveda has CONSORT statement as one of the topics in the research methodology.[15] There are only a few RCTs conducted in Ayurveda due to its complexity of treatment delivery and personalized approach.[24]

The major limitation of this study was very low rate of response from the researchers. Despite reminders, we were unable to get good response rate. However, no incentives were offered for their response which is regarded as essential to get response in most questionnaire studies.[8] Other reasons may be that most TM investigators who publish occasionally may not be internet savvy. We have not categorized the investigators on the basis of frequency of their publications. We received only 4.9% replies through post. There is no organized portfolio for researchers in ISM.

Implications of the study

Healthcare is undoubtedly a complex interaction of challenges and intellectual exercises which result in mostly the advancement of a chosen domain of health science. Research is no different in this field. Seeking to understand the knowledge level of research investigators in an area like Ayurveda by itself is a challenging step that has been taken. The results gave a different insight for further research to be conducted, especially in the area of education system, challenges in understanding the knowledge level, need for continued education in research, research literacy and the importance of evidences in Ayurveda research. Policy makers should now be looking into the role of governmental organizations, economy, and innovations in comprehensive care and evidence-based practices to upgrade the quality of treatment delivery in health care institutions/industries. To improve on these areas which will influence an effective research, there should be optimum governance which recommends the knowledge of investigators, time frame, financial planning and management. It should also reflect a clear framework of accountability, responsibilities and quality requirements. A research audit similar to clinical audit may form a key stone for research governance and management. An efficient management of research process should keep unnecessary delays and irresponsibilities at bay. A good cross system team would be effective in solving the draw backs of uni-system analysis. Organizations and groups involved in research investigations should interact and approach a situation uniformly. Therefore, a regular study on knowledge level analysis will help in understanding the need at that point in time to achieve good advancement in TM.

Results of the present study suggest the need of research methodology training for investigators in TM especially on constructing a structured research question and conducting a comprehensive literature search. We recommend the second degree/post doctoral curriculum should include proper training on current research methodologies by faculty specialized in the same. Proper training is needed for investigators, authors and peer reviewers to ensure high quality of publications. PubMed listing of Ayurveda journals gives an opportunity for international scientific groups to critically review the quality of ISM studies and ability of complementary and alternative medicine (CAM) peer groups to filter those studies devoid of minimal standards. Globally there is an increased demand for CAM, albeit it would consolidate this gain only through evidence-based studies. Especially it is important for agencies granting public money to understand the expertise of investigators to conduct studies using sound scientific methods.

Acknowledgment

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ANNEXURE - 1

QUESTIONNAIRE ON RESEARCH METHODOLOGY FOR STUDIES IN AYURVEDA

PART-I

1. Name and address :
2. Email :
3. Age :
4. Educational Qualification :
   Name of the AcademicCourse completed Year of passing
   Institution
5. Professional experience:
   Name of the hospital/institute/organisation Years of service
   1.
   2.
   3.
6. Present employment :
   Private practice/Private hospital/Government service
   Research organisation/Academic Institutions
   Post held Organisation
7. Whether any research projects have been handled so far? Yes/No
   If yes, please give the details as follows
   Title of the project Funding agency Status of the project. (Ongoing/completed)

PART – II

Please give your response to all the items below

1. Did you receive any training for conducting clinical trials? Yes/No
2. If yes, please indicate the method of training received (through research institution/self learning/through literature/any other method (pl. specify)
3. In your opinion what are the parameters to be considered while conducting clinical trials in Ayurveda?
4. What Ayurveda-based parameters you would like to use generically in any clinical study in Ayurveda?
5. What Ayurveda based specific parameters should be used in Studies related to Samanyaj vyadhis/Nanatmaja vyadhis?
6. Do you think it is possible to arrive at one to one correlations between disease nomenclature in Ayurveda and Modern Medicine?
7. In your opinion how modern laboratory investigations could help in disease diagnosis and assessment of results in Ayurveda?
8. Do you think clinical trials in Ayurveda should be based on Ayurvedic diagnosis of the disease or biomedical diagnosis?
9. In your opinion, what should be the criteria to be considered for selecting patients for Ayurvedic clinical trials?
10. How and where you are searching for literature?
11. Is it possible to conduct RCT in Ayurveda? Yes/No (give reasons thereof)
12. In your opinion can epidemiological studies be conducted in Ayurveda? Yes/No
13. Are you aware of any epidemiological studies be conducted in Ayurveda? Yes/No
    If yes, please mention the same –
14. Do you think the drug and cosmetic act is important in Ayurvedic studies? Yes/No
    Please elaborate on the reasons for the same.
15. In your opinion what is the evidence base for the ongoing practice of Ayurvedic medicine in India.

PART – III

Please indicate answers for the following by tick mark against the appropriate item from the choices.

1. Before conducting a trial on human subjects, it is important to take the approval of-
   A. Govt. of India, B. IEC/IRB
   C. CCIM D. CCRAS
   E. Don't know
2. Informed consent refers to-
   A. Seeking the consent of Govt to conduct the study
   B. Getting the consent by the program coordinator of sponsoring industry
   C. Getting the permission of head of the institution to conduct trial
   D. Written consent from the patient after informing complete details of the treatment/procedures
   E. Don't know.
3. Causality analysis used for-
   A. Patient safety B. Patient recruitment
   D. Disease diagnosis D. Differential diagnosis
   E. Don't know
4. First step before conducting a clinical trial—
   A. Allocating the patient in to clinical trial
   B. Blinding the patients to trial
   C. Structuring a well formulated research questions
   D. Blinding the investigator to the trial
   E. Don't know.
5. Contents of a well built clinical question—
   A. Population-Outcome-Study setting Intervention
   B. Population-Intervention-Comparison-Outcome-Study design
   C. Population-Intervention-Comparison- Outcome
   D. Disease- Intervention-Study design
   E. Don't know.
6. Please select one of the topics given below which is an important component while forming study title.
   A. Study settings B. Age group
   C. Outcome D. Drug dosage
   E. Don't know
7. Historical controlled trial is…
   A. Comparison of intervention group with similar group who did not receive treatment
   B. Comparison of intervention group with similar group who receive placebo treatment
   C. Comparison of intervention group with similar group from the past who did not receive treatment

D. Comparison of intervention group with similar group who received active control
E. Don't know.

8. Pick any one of the following which is not an outcome measure in clinical trial?
A. Quality of life
B. Death
C. Adverse drug reaction
D. Participants opt out from the study
E. Don't know

9. In a clinical trial, if patient, investigator and evaluator are blinded (masked), the study will be ---
A. Triple blind
B. Double blind
C. Single blind
D. Open trial
E. Don't know

10. Which procedure will be adopted to minimize bias while randomization?
A. Initially allocating the set of patients to one group and then rest of the patients to other group
B. Envelop method
C. Patient allocation according to severity of the disease
D. Allocation according to patient's willingness
E. Don't know.

11. Who will allocate the patients in RCT?
A. Investigator
B. Pharmacist
C. Statistician
D. Evaluator
E. Don't know

12. What is the proper method of allocation concealment?
A. By employing a responsible pharmacist at dispensing counter and using identical packs for medicines.
B. By instructing dispensing counter orally
C. By writing orders in case sheet E
D. By asking patients to come in different times
E. Don't know.

13. What is the external validity (generalisability)?
A. Description about how participants are allocated to the interventions
B. Application of results found in the study to other people or settings
C. Description of the budget required to conduct clinical trial
D. Application of the statistical tests for the data analyzed
E. Don't know.

14. Hand searching is…
A. Searching journal publications which is non electronic
B. Searching 'google' for appropriate articles
C. Searching electronic databases for relevant articles
D. By designing a 'search strategy' on the basis of PICO and searching in appropriate databases
E. Don't know.

15. Which of the following are considered as lowest level of evidence in evidence based medicine?
A. Properly designed randomized controlled trials
B. Systematic review of properly designed randomized controlled trials
C. Quazi randomized trials
D. Case series
E. Don't know.

16. Which of the following are considered as highest level of evidence in evidence based medicine?
A. Properly designed randomized controlled trials
B. Systematic review of properly designed randomized controlled trials
C. Quazi randomized trials
D. Case series
E. Don't know.

17. Pick up the reporting system used to report the randomized controlled trial
A. STROBE
B. MOOSE
C. CONSORT
D. MeSH
E. Don't know

18. Pick up the reporting system used to report the non randomized trials
A. STROBE
B. MOOSE
C. CONSORT
D. MeSH
E. Don't know

19. What is publication bias?
A. Publication of non relevant articles in a journal
B. Studies which show significant results are more likely to be reported than the studies show non-significant results.
C. The differences between reported and unreported findings
D. Rejecting case series studies
E. Don't know.

20. In India, It is mandatory that investigator should register the clinical trial in…. before subjecting the drugs to human subjects
A. Controller General of Patents designs and Trade Marks- Govt of India
B. Clinical Trials Registry of India (CTRI)
C. Indian council for medical research (ICMR)
D. Central council for Indian medicine (CCIM)
E. Don't know.

हिन्दी सारांश

पारंपारिक औषधियों का अध्ययन करनेवाले संशोधक कितने ज्ञानी है ?

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प्रस्तुत अध्ययन आयुर्वेदसहित अन्य चिकित्सापद्धतियों में चिकित्सीय परीक्षण संचालित करनेवाले संशोधकों के ज्ञान का स्तर निश्चित करने हेतु किया गया। किसी भी विशेषज्ञता में प्रशिक्षित एवं पारंपारिक चिकित्सापद्धतियों में काम करनेवाले चयनित संशोधकों के लिए एक प्रश्नावली के द्वारा सर्वेक्षण किया गया। इसके लिए विशिष्ट चयन कसौटी के आधार पर कुल २०८७ संशोधकों का चयन किया गया। नीति-नियमन विषयक, साहित्यशोध, प्रमाणसिद्ध औषधि, चिकित्सीय परीक्षण, रुग्ण चयन और अभ्यास विवरण सम्बन्धित एक पूर्वपरीक्षित और विधिमान्य प्रश्नावली ई-मेल अथवा डाक से भेजी गयी। उत्तरित प्रश्नावलियों का विश्लेषण किया गया। मीडियन और इन्टरक्वारटाईल रेन्ज के आधार पर मापदण्डों का विश्लेषण किया गया। ४२ अभिप्राय ई-मेल द्वारा और २१ अभिप्राय डाक द्वारा प्राप्त हुए। कुल ६३ में से, ६ संशोधकोंने अपूर्ण अभिप्राय दिया। शेष ५७ प्रतिभागियों में से ३४(५९.६%) संशोधकों के पास पदव्युत्तर उपाधि थी। ४३(७५.४%) संशोधकों ने अनुसंधान पद्धति का कोई विशेष प्रशिक्षण नही लिया था। २३ (४०.४%) संशोधकों को दो दशकों का संशोधन का अनुभव था। सरकार द्वारा आर्थिक अनुदान प्राप्त ३३(७४%) संशोधकोंने अनुसंधान पद्धति का कोई भी प्रशिक्षण नही लिया था। भेषज-रासायनिक एवं मूलभूत शास्त्रज्ञों के दल की तुलना में आयुर्वेद शास्त्रज्ञों के दल का ज्ञान बेहतर था, किन्तु वो दोष, प्रकृति आदि आयुर्वेद के मूलभूत सिद्धान्तों को नजरअंदाज किये बिना आधुनिक औषधशास्त्र के विशिष्ट सख्त मर्यादा में रहकर पारंपारिक औषधियों का चिकित्सकीय मूल्यांकन करने की दुविधा में थे। उम्र के आधारपर किये गय`विश्लेषण में, ३० वर्ष से कम उम्र के संशोधकों में अनुसंधान पद्धति का उच्च ज्ञान पाया गया। अनुसंधान संस्थाओं, सरकारी संस्थाओं और शैक्षणिक संस्थाओं में काम करनेवाले संशोधकों को निजी संस्थाओं अथवा निजी चिकित्सा व्यवसाय करनेवाले संशोधकों की अपेक्षा कम ज्ञान था। हम अनुरोध करते है कि, पारंपारिक औषधियों के अनुसंधान में कार्यरत संशोधक, तज्ञपरीक्षक और अनुदान नियोजकों को विशेषतः अनुसंधान पद्धति के प्रशिक्षण की आवश्यकता है।