# Exploring the Research Evidence Approach and Application of Research Ethics Concepts in Ayurveda Research; A Qualitative Study Based on Researcher's Perception

#### Dr. Skanthesh Lakshmanan<sup>1</sup> and Dr. Vina Vaswani<sup>2</sup>

- 1. MSc Research Ethics Scholar, Yenepoya University-Fogarty International Centre Research Ethics.
- 2. Professor, Department of Medicine and Toxicology, Director, Centre For Ethics, Yenepoya (Deemed to be University) Mangalore.

#### Short Bio Profile



Dr Skanthesh Lakshmanan BAMS, PGDCR

Research Ethicist, Clinical Researcher, Traditional Indian Medicine doctor

Native of the southern state of India-Kerala[1] and explored State of Tamilnadu[2] for Graduation

Currently Research Ethics Scholar at centre for Ethics, Yenepoya university-Fogarty international centre, Mangalore [3] India

Director member at Non for Profit scientific research organization-PPHS Foundation, Bangalore, India

interested in exploring Research Ethics, Ethics assessment of Health technology, Research Evidence models Appraisal, Global Traditional medicine Research



# **Acknowledgement/**Conflict of Interest Declaration

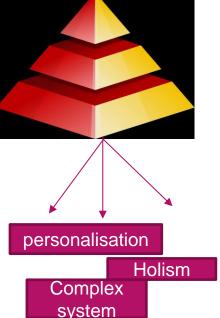
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- We declare no conflict of interest either financial or social or any other elements related with this presentations
- A Presentation based on this study has done in FERCICON Conference 2024 at Kolkata, India

#### Introduction

- ► Evidence-Based Medicine (EBM) has shifted the focus of clinical practice from expert opinion to systematically conducted research (Masic et al., 2008)
- ► The Hierarchical evidence model (HEM) in EBM, which ranks research designs based on strength in establishing cause-effect.
- ➤ The HEM has significant limitation when assessing Systems involving multiple interventions like complex systems, Real world practices and holistic care.

#### Introduction-continue

- Scholars have highlighted the limitations of the HEM in assessing traditional medicine, surgery, psychology, and nursing care (Walach et al., 2006).
- In this context, it is vital to examine Ayurveda, an Indian Traditional medicine system integral to healthcare in the Indian subcontinent
  - Despite of With thousands of years of history, it faces criticism due to a
    perceived lack of high-quality research evidence.





#### Introduction-continue

- The lack of quality evidence in Ayurveda is often attributed to the incompatibility of current HEM for validating research in Ayurveda
- Applied ethics and research ethics play a crucial role in designing research frameworks and guiding the conduct of studies
- Researchers' perceptions of their respective scientific paradigms significantly influence their choice of research methodologies
- Exploring the approach to research evidence and the ethical concepts in Ayurveda research, through the researchers' perceptions, is a critical scientific and ethical question.

#### Objectives

- ► To evaluate the research evidence approaches perceived by Researchers working in Ayurveda from several South Indian states.
- ► To evaluate the application of research ethics concepts in Ayurveda research, perceived by Researchers working in Ayurveda from several South Indian states.



#### Methodology











In Depth Interview(7) Thematic Analysis

- ▶ Inclusion criteria: worked on Ayurveda research, or affiliated with research institutions, or Independent researchers and having 3 or more than 3 year of experience.
- ► Exclusion criteria: Researchers without experience in human participant involved research.
- ► Yenepoya university Ethics committee-1 approval: 8/11/2023

#### Results

- There were four male and three female participants.
- > The age of the participants ranged between 34-49 years.

> Research experience in Ayurveda ranged between 4 years to 18 years

Participant No	Age/Sex	Qualification
A01	43/M	MBBS MD PHD-Modern medicine
A02	49/M	BAMS MD PHD- Ayurveda
A03	46/F	BAMS MD PHD- Ayurveda
A04	43/M	BAMS, MD
A05	46/M	BAMS, MD, PHD
A06	34/F	BAMS MD
A07	36/F	BAMS

#### Results-continue

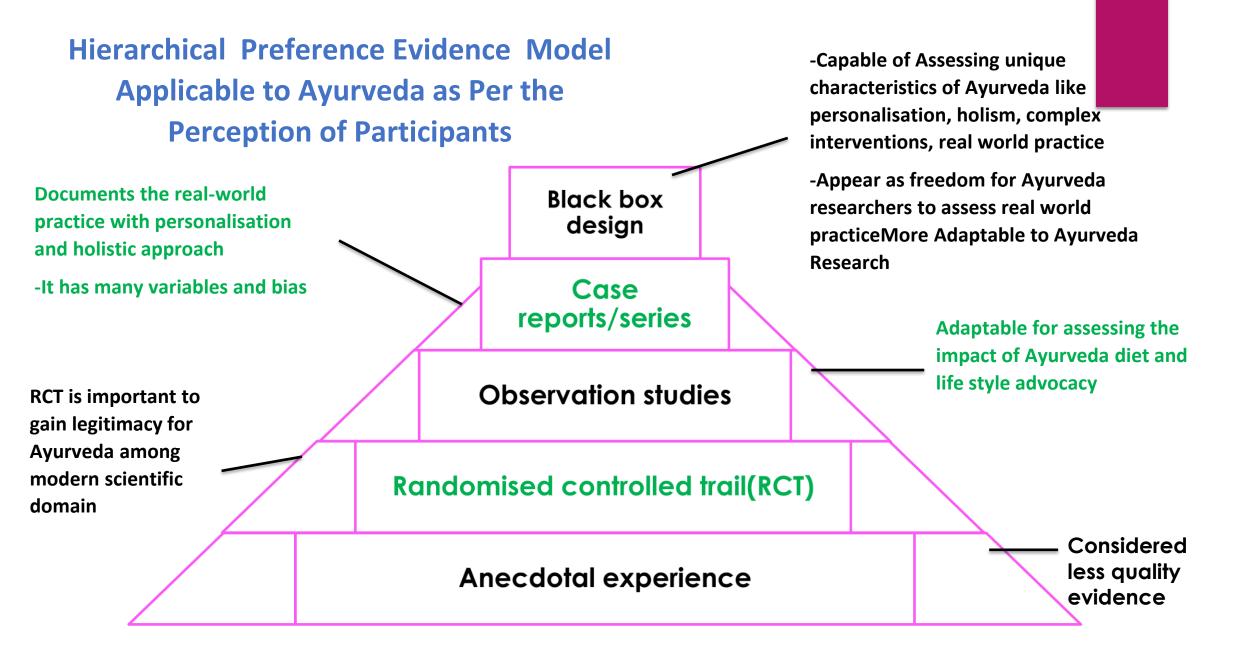
- Three core themes and five secondary themes, 11 categories and 1024 codes.
- The core themes include: what counts as evidence in Ayurveda research; evidence through whose lens, Research ethics in Ayurveda research
- The Secondary-themes included: EBM perception and application;
  Ayurveda evidence approaches; status of Ayurveda research;
  comparisons with modern medicine; and the application of research ethics.

#### Results-continue

- ▶ 7- Participants perceived the major characteristics of Ayurveda practice as personalized approach, holistic understanding and real world practice.
- ► There were a strong demand for using research designs which could accommodate characteristics of Ayurveda practice for assessment (Ao1, Ao3, Ao6 & Ao7).
- ▶ 2- participants with experience in working with more adaptable research models had greater clarity in designing appropriate research methods and applying ethics concepts (Ao3 Ao6).

#### Analysis and Discussion

- The perception analysis showcases the compulsion for the Ayurveda researchers to follow HEM to gain legitimacy in the scientific domain.
- ► The perception towards RCT reflects with Bourdieu's Theory of Symbolic Power, wherein Ayurveda research seeks legitimacy within the dominant biomedical paradigm.
- Bourdieu's symbolic power is the ability to shape perceptions and social reality through accepted meanings and norms, reinforcing dominance without overt force





#### **Quotes:-**

"So, of course, we hypothetically know that these RCTs are not golden standards to assess a complex system like Ayurveda" (A02)

"..with personalisation and so in this sense only case report can be done almost or this type of approach "(A01)

"The only possible method is the, what I feel is the better method will be the black box design.

Especially nothing else"(A04)

- Six participants perceives RCT to be incapable in assessing characteristics of Ayurveda practices like personalisation, complex nature and holistic care (Ao1, Ao2, Ao4, Ao5, Ao6 & Ao7).
- Four participants reflects the importance of case reports/case series as it can accommodate real world practices and personalisation in treatment (Ao1, Ao2, Ao4, & Ao6).
- Black box design perceived to be ideal research design by five participants considering its ability for the assessment of characteristics of Ayurveda practices (Ao1, Ao3, Ao5, Ao6 & Ao7)

What counts as Evidence?

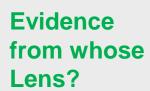
The perception of Participants regarding RCT align with Patwardhan (2011) argument that Ayurveda needs research design other RCT which could assess the whole system approach of Ayurveda

"So, our research is not to appease our own understanding. It's more actually to satisfy somebody else" (A03)

"Our basic evidence is our textbooks only and so that is the base evidence or foundation we can see"(A04)

"If you have to publish in a mainstream and modern journal, your paper should fit into their criteria" (A06)

- The participants (Ao1, Ao2, Ao4, & Ao6) perceives modern scientific domain, Ayurveda classical text, scientific journals as major agencies which influence their choose of research methodology.
- The modern medicine domain is perceived to be a power Agency which dominates over the selection of research methodology in Ayurveda.



Observation of Jackson and Scambler (2007) align with perception of Participants on Modern medicine domain as power Agency but here instead of Active resistance as in Jackson and Scambler (2007) there is aspect of seeking legitamacy from modern medicine

"Every aspect of the study was designed and done completely by the Ayurveda team" (A03)

"The benefit, what is the risk then no one will have the same judgment of it because it is our experience and we don't have the same experience...... at the end patient has to be in the centre "(A01)

" Main issue is the lack of funding" (A04)

Ayurveda being the science which has a lot of potential in those areas i think we should venture into those vulnerable population"(A06)

- Three participants consider informed consent as entire aspect for autonomy.
- ➤ Participants (A03 & A06) who worked on black box design express aspect of autonomy also as freedom Ayurveda researchers getting with designing such models.
- Participants (A01 & A06) reflected R-B Analysis to be done in personalised-patient centric and with real world practice of Ayurveda
- ➤ All the participants opined on lack of funding for Ayurveda research.
- Participants (A01, A04 & A06) consider the funding disparity of Ayurveda with modern medicine as injustice.

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Research Ethics Application Adams et al. (2005) discusses the challenges in conducting clinical trail in cross cultural settings and raises the importance of Democratic negotiation of applying research ethics into cultural context. Similarly the participant perception indicates applying ethics based on specific context of medical practice

#### |Conclusion|

- The Researchers working in Ayurveda from the selected South Indian states perceive the need for designing research methods which can Accommodate the characteristics of Ayurveda like Personalized approach, real world practice, holistic care
- ► The Researchers from Ayurveda seek legitimacy with modern medicine through aligning with RCT of HEM in Ayurveda research.
- ► The Research Ethics paradigm needs cultural context understanding of Ayurveda practice for better application of research ethics principals in Ayurveda research

### Limitation of the study

The Study has only explored the participants from south India and other than one all other participants were academically trained in Ayurveda, It would have caused Limitations in gathering diversified perception

#### Reference

- Masic I, Miokovic M, Muhamedagic B. Evidence based medicine-new approaches and challenges. Acta informatica medica: AIM: journal of the Society for Medical Informatics of Bosnia & Herzegovina: casopis Drustva za medicinsku informatiku BiH. 2008 Jan 1;16(4):219-25
- ▶ Walach H, Falkenberg T, Fønnebø V, Lewith G, Jonas WB. Circular instead of hierarchical: methodological principles for the evaluation of complex interventions. BMC medical research methodology. 2006 Dec;6(1):1-9.
- ▶ Patwardhan B. Ayurveda GCP Guidelines: Need for freedom from RCT ascendancy in favor of whole system approach. J Ayurveda Integr Med. 2011 Jan;2(1):1-4. doi: 10.4103/0975-9476.78175. PMID: 21731379; PMCID: PMC3121247
- ▶ Jackson, S., & Scambler, G. (2007). Perceptions of evidence-based medicine: traditional acupuncturists in the UK and resistance to biomedical modes of evaluation. *Sociology of Health & Illness*, 29(3), 412-429.
- Adams, V., Miller, S., Craig, S., NYIMA, SONAM, DROYOUNG, ... & Varner, M. (2005). The challenge of cross-cultural clinical trials research: case report from the Tibetan autonomous region, People's Republic of China. Medical Anthropology Quarterly, 19(3), 267-289
- ► Gale, N. (2014). The sociology of traditional, complementary and alternative medicine. *Sociology Compass*, 8(6), 805–822. https://doi.org/10.1111/soc4.12182



## Thanks