



RESEARCH PROTOCOL

Strategies for the management of Type 2 Diabetes Mellitus among the Ayurveda practitioners of Kerala: Study Protocol for a Grounded Theory Approach

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Abstract

Ayurvedic clinical practice, generally follow a pattern which is difficult to standardize and basically relying upon some intuitions and weekly framed conceptualizations. The first step towards an evidence based clinical practice is to identify the existing practices and to categorize them according to the evidences and rationale. This qualitative study is planned to identify such practices and their rationale in the management of Type 2 Diabetes Mellitus (T2DM) in the setting of Kerala. A grounded theory approach incorporating a survey using a semi-structured questionnaire followed by Focus Group Discussion is followed here. This methodology fits well to find out the existing strategies and their rationale by theoretical sampling and iterative data collection cycles. This will be useful to find out how far these practices are in accordance with the currently available evidences and what can be done to standardize such practices.

Introduction

Diabetes mellitus has become a threat to the quality of life and global economic growth, impacting physical, psychological, emotional, and social levels. The worldwide prevalence of Type 2 Diabetes Mellitus (T2DM) is on the rise and has increased from 200 million in 1990 to 830 million in 2022 (1). In developing countries, particularly Asian countries, the gravity of the problem is more and hence need special attention (2). India, being not an exception, is one of the most affected countries by this non-communicable disease, housing 14% of this global burden (3). Govt has taken many grass root level measures for the containment of this outburst and the associated complications (4). There arises the importance of alternative options to tackle the multifactorial nature of the clinical scenario. The evidence based form of Traditional, Complementary and Integrative Medicine can offer a great deal to the holistic management of the condition (5) (6) (7).

Due to the genetic and lifestyle factors, the prevalence in Kerala is so high to be called as the Diabetic capital (8). Hence, it is the need of the hour to find out a solution for this problem in the setting of Kerala. Being the front runner among the alternative and complementary medicines, Ayurveda offers enormously to the different levels of prevention and treatment of lifestyle disorders. This is particularly important regarding the usage of principles and practice of Ayurveda in T2DM (9)(10).

The clinical strategies used in the management of T2DM and their outcomes needs to be thoroughly studied to have a comprehensive view. This can be compared with existing protocols and guidelines (11) unravelling the gaps, ground realities as well as areas for improvement or areas needs to be focussed upon. A purely qualitative approach is best suited to explore into this area since the topics being dealt with are of fundamental and qualitative in nature. To achieve the long-term goal of developing an evidence-based protocol for managing Type 2 Diabetes Mellitus (T2DM) in Ayurveda, the preliminary step requires an unbiased exploration of the diverse clinical practices used by the practitioners and searching for their underlying philosophical principles. (12 -16)

● Rationale

Even though many Ayurveda practitioners face success as well as failure in the management of different stages of T2DM, there have been less efforts to document them in order to proceed towards a standardized Ayurvedic management protocol. Again, only a systematic approach grounded in the theoretical background can uncover the truth behind ideas, principles and practices. Neglecting these ground realities and always searching for quantitative results leads to nowhere, but a chaos of theory and practice as evident in many studies which neither updates Ayurvedic literature nor do any contribution to the existing practices. The basic issue related to researches in Ayurveda and the implementation of results lies in the lack of background works in the form of qualitative research. Literally, qualitative research is the basement for all further research works. Still, there are very less such studies available to throw light on the why and how of the principles behind practices. A PubMed search using keywords 'Ayurveda' and 'Qualitative Research' rendered 7 studies and all of them were systematic reviews. This shows the lack of effort from a qualitative point of view.

Hence, this study has been planned to collect the details regarding the commonly used antidiabetic medicines, treatment plans and therapeutic procedures in Ayurveda and to explore the rationale behind their usage, so that the real world connection between theory and practice can be showcased. Since this study focuses on existing practices and their rationale in accordance with the theoretical background of Ayurveda, a grounded theory approach has been selected. The uniqueness of this approach is that the focus is on the realities and their perceptions rechecked by the perceptions and their realities. This iterative cycles can help in collecting the 'genuine', 'real world' data which can further be used in building theories and finding solutions. As always in the case of qualitative studies, the role of researcher is crucial in deciding the fate of the study. Here, the background works and aptitude of the researcher helps in designing the study and being an active participant, can act as the driving force in the progress of the study, but with due attention given to possible bias and misinterpretations.

PMID	Title	Authors	Citation	First Author	Journal/Book	Publication Year	DOI
40201705	Ayurveda for Managing Noncommunicable Diseases in Organisation for Economic Cooperation and Development Nations: A Qualitative Systematic Review	Egwumba P, Wang H, Nellums L, Bains M, Chattopadhyay K.	Health Sci Rep. 2025 Apr 8;8(4):e70624. doi: 10.1002/hsr2.70624. eCollection 2025 Apr.	Egwumba P	Health Sci Rep	2025	10.1002/hsr2.70624
39085970	Adverse events in India's Ayush interventions for cervical and lumbar spondylosis: a systematic review	Ponnaiah M, Elumalai R, Muthappan S, Jaisankar S, Bagepally BS, Sivaprakasam S, Parasuraman G.	Eur J Med Res. 2024 Jul 31;29(1):396. doi: 10.1186/s40001-024-01985-3.	Ponnaiah M	Eur J Med Res	2024	10.1186/s40001-024-01985-3
42088561	Impact of integrative therapies on glycemic control in type 1 diabetes: a systematic review and global research landscape	Balkrishna A, Upreti J, Chauhan M, Chauhan M, Katiyar P, Dabas A, Arya V.	Front Clin Diabetes Healthc. 2026 Apr 20;7:1739023. doi: 10.3389/fcdhc.2026.1739023. eCollection 2026.	Balkrishna A	Front Clin Diabetes Healthc	2026	10.3389/fcdhc.2026.1739023
39763345	A Systematic Review on Safety and Efficacy of Ayurvedic Interventions in Hemiplegia (Pakshaghata)	M A, Nair PP, Nair DR, Ahmad A, Chandrasekhararao B, Sudhakar D, Narayanam S, Acharya R.	J Evid Based Integr Med. 2025 Jan-Dec;30:2515690X241304523. doi: 10.1177/2515690X241304523.	M A	J Evid Based Integr Med	2025	10.1177/2515690X241304523
33551339	Effectiveness of polyherbal formulations for the treatment of type 2 Diabetes mellitus - A systematic review and meta-analysis	Suvarna R, Shenoy RP, Hadapad BS, Nayak AV.	J Ayurveda Integr Med. 2021 Jan-Mar;12(1):213-222. doi: 10.1016/j.jaim.2020.11.002. Epub 2021 Feb 5.	Suvarna R	J Ayurveda Integr Med	2021	10.1016/j.jaim.2020.11.002

34513860	PRAGmatic Clinical Trial Design of Integrative MediCinE (PRACTICE): A Focus Group Series and Systematic Review on Trials of Diabetes and Kidney Disease	Chan KW, Lee PW, Leung CP, Law YK, Gao L, Chan GC, Yiu WH, Lam TP, Tang SC.	Front Med (Lausanne). 2021 Aug 27;8:668913. doi: 10.3389/fmed.2021.668913. eCollection 2021.	Chan KW	Front Med (Lausanne)	2021	10.3389/fmed.2021.668913
41658735	New-Onset and Flare Episodes of Adult-Onset Still's Disease Following COVID-19 Vaccination: A Systematic Review of Published Case Reports	Lakhani HA, Baidya OP, Alex A, Binorkar SV, Das D, Hazra A.	Cureus. 2026 Jan 6;18(1):e100889. doi: 10.7759/cureus.100889. eCollection 2026 Jan.	Lakhani HA	Cureus	2026	10.7759/cureus.100889

3. Research question

Which are the Ayurvedic management strategies for T2DM among the Ayurveda practitioners of Kerala and how far they can be streamlined?

4. Primary Objective

- To identify the different Ayurvedic management strategies for T2DM among the practitioners of Kerala

Secondary Objective

- To find out the rationale for different management strategies for T2DM and to update the principles accordingly.

5. Hypothesis

NA

6. Methodology

- Study setting – South, Middle and North zone of Kerala
- Study design – Qualitative Study (Grounded theory approach)
- Study duration – 6 months
- Study population – Ayurveda practitioners from the south, middle and north zone of Kerala
- Inclusion criteria
 - Ayurveda practitioners with minimum 5 years of clinical experience
 - Ayurveda practitioners having expertise in treating T2DM
- Exclusion criteria
 - Ayurveda practitioners unwilling to share their clinical experience
- Sampling technique used – Purposive sampling for Focus Group Discussion (FGD) / in-depth Interview (IDI)

An initial online survey using a semi-structured questionnaire among different sectors of Ayurveda Practitioners namely Govt Ayurveda Medical Officers, Ayurveda College Faculties and Private practitioners will be done. This has been planned since there is expected

variations within and between these categories. The survey will be done using theoretical sampling and in the form of iterative cycles until data redundancy with respects to responses to open ended questions. (At least 30 practitioners (Minimum 10 from each strata) for initial qualitative survey). Based upon the responses to open ended questions, unique practices will be identified and they will be selected for FGD.

- Sample size - Based upon data redundancy.

Minimum 5 experts for 1 FGD. If more than 8 experts are identified from initial survey, a second FGD / IDI also will be conducted.

Operational definitions

- **Ayurvedic principles** – The concepts of *dosha*, *dhatu*, *srotas*, *agni*, *prakriti*, *ojas* etc. which are used for the diagnosis, assessment and treatment of the patient.
- **Data redundancy / Sampling saturation** – The stage in data collection when no new themes, information, or insights emerge (With respect to this study, saturation will be considered achieved in 2 phases. First while selecting the participants for FGD from the online survey, when there is no more different answers for the open ended questions. Second in the FGDs / IDIs when they yield no new codes or themes related to management strategies or their rationales)
- **Strategies and their rationale** – The treatment approach and their background reasons which are in alignment with the principles and practice of Ayurveda.
- **Unique practices** – Standalone practices or application of principles used by clinicians.
- **Practices that diverge from Ayurvedic principles** – The practices which are not in alignment with the principles of Ayurveda or against the contemporary scientific knowledge.

This study is intended to find out the different practices adopted by the clinicians to manage T2DM and their rationale evolved from the concepts and cross verified from the available evidences. The different practices can be related to

- the choice of medicine with the concerned principle followed
- dosage and their theoretical and practical implications

- duration of usage and the rationale (if any) for this duration
- *anupanas* (carriers or vehicles used) with the reasons and other implications
- *pathya* and *apathya* advised with the observations of following (and not following) them
- change in the medication according to chronicity and severity
- assessment and evaluation methods used in the diagnosis, prognosis and treatment
- criteria for opting or not opting for therapeutic procedures
- Absolute and relative contraindications of some food items and medications

These details will be collected as per the methodology of grounded theory, and using the qualitative insights of the PI, the data will be documented, scrutinized, cross-checked, compared with existing evidences and summarized using data triangulation and respondent validation.

Grounded Theory Approach

Theoretical Sampling will be followed in the methodology. The sampling here is based upon the theoretical variations in the background of practices. First of all, 3 strata of Ayurveda practitioners will be selected since substantial variations are expected between the Govt Medical Officers, Ayurveda College Faculties and Private practitioners. These strata will be identified from the 3 zones of Kerala from the records of registered organizations. Care will be taken to focus on practitioners with unique practices and theoretical understanding. An online survey will be conducted using a semi-structured questionnaire to explore the management strategies used by the practitioners. Details regarding the assessment approach towards T2DM, prognostic criteria used, commonly used antidiabetic medicines, diet and lifestyle corrections, treatment plans and therapeutic procedures in Ayurveda as well as the rationale behind all these approaches with supportive references will be collected. The responses will be regularly screened and tabulated. According to the responses for open ended questions seeking rationale for following an assessment method or a treatment approach and their algorithms, the different sections of the practitioners will be selected for the FGD.

This Iterative data collection cycles will be continued until data redundancy regarding the strategies (minimum of 30 practitioners). The survey report will be consolidated and those who have reported unique methods and supportive findings / reasons (for example, A practitioner using a particular medicine in cases with a unique presentation should be able to substantiate it with a theoretical statement or observation). Also, the main parameter considered in treatment may vary between the practitioners. The parameters; *dosha*, *srotas*, *agni*, *prakriti* and *ojas* are listed to be identified as the main parameter and the selection of the most important one among these

will be compared with their treatment approach. This will be done using memo-writing process, constant comparison strategy, audit trail documentation and analytic triangulation; which render a subset of practitioners representative of existing strategies and with adequate theoretical and clinical background. They will be selected for the FGD.

FGD guide will be prepared and it will be followed in the conduction of FGD. The rationale, unique approaches of personalized Ayurveda and the comparison with contemporary treatments will be covered in the FGD. The probes to be used in FGD can be summarized as follows:

- General pattern of presentation and their Ayurvedic interpretation based on *dosha-dooshya*
- Common medications used and their rationale
- Contraindications of any medication or complications developed due to their usage
- *Doshavridhi* assessed and their relationship with *prakriti* of the individual
- Measures used to identify variations in *dosha* (*bahudosha*)
- Procedures commonly prescribed and their rationale
- Contraindications of any procedures or complications developed due to their usage
- Protocol based on *dosha* status

From the FGD findings, themes and subthemes will be identified and the various practices existing among the Ayurvedic practitioners of Kerala in the management of T2DM will be consolidated and basic details of the management plan will be derived. This will be subjected to respondent validation to increase the validity of the findings.

Finally, the management strategies and their rationale will be compared with the available evidence regarding these components and the data will be consolidated.

Reflexivity

- FGD / IDIs will be conducted by the Principal Investigator (PI)
- The Male PI with a qualification of MD (Ay), working as Asst Professor in Govt Ayurveda College of Kerala, with a research experience of Thirteen years, with an interest in carrying out Qualitative Research and Tool Development. He is not related to participants prior to this study.
- Being an Ayurveda faculty, the PI can better understand the feelings, intuitions and motives behind the strategies.
- Being a post graduate in physiology, the PI can take unbiased stand in conditions where the confidence of the practitioner regarding a particular strategy is questionable, overstated or understated.
- A reflexive research diary will be maintained to document the purpose, content and impact of each activity.

Outcomes expected

- Ayurvedic medicines, treatment plans and therapeutic procedures used in the Management of T2DM
- Presence of protocol / protocols and adherence to the protocols
- Rationale for the management strategies
- Comparison with the contemporary management plan for T2DM
- To identify irrational management strategies or practices for T2DM, which needs to be discouraged

Limitations of Grounded Theory Approach

A qualitative approach may render some results which are not quantifiable, but still they are more near to truth when compared to the results of a clinical trial. When this quantification aspects are stressed upon, the qualitative part gets weakened. Still, this grounded theory approach may have its limitations when it comes to comparing the logic and reasoning of practices in different levels. For example, the reasoning and practices of different clinicians may differ according to different factors.

The grounded theory approach can detect many of these differences. But when it comes to the behaviour change depending upon how far and how much they rely upon conditions like modern investigations; this approach have its limitations. Again, clarifications in the diagnostic and therapeutic areas, if they have some solid quantitative reasons, this approach may become inadequate.

Possible bias and their prevention

Table 1. Showing possible bias in this qualitative study and the measures taken to prevent them.

7. Ethical Considerations: Protocol has been approved by IEC, Govt Ayurveda College, Tripunithura. No. 04/PJ/ICMR/IEC/2025 dt 10-10-2025

Before participating in the study, participants will be explained about the study's goals, privacy, and their right to join or leave the study.

Informed consent – will be taken from the practitioners for Survey and FGD. Privacy and data confidentiality will be maintained.

FGD / IDI participants will be informed of the limits of confidentiality in a focus group / IDI setting and that all identifiable information will be removed from transcripts.

8. Plan of Analysis

- Descriptive statistics regarding choice of medicine, diet plan and glycemic control will be generated from the survey report.
- Statistical methods for qualitative data – Open coding, Axial coding and Selective coding. Prevailing strategies and their theoretical background will be revealed through grounded theory approach. Further probing will be done in areas of uncertainty or contradictions. These findings will be cross-checked with the quantitative data obtained from the survey as well as with the available published evidences in these areas.
- Gantt Chart has been shown below

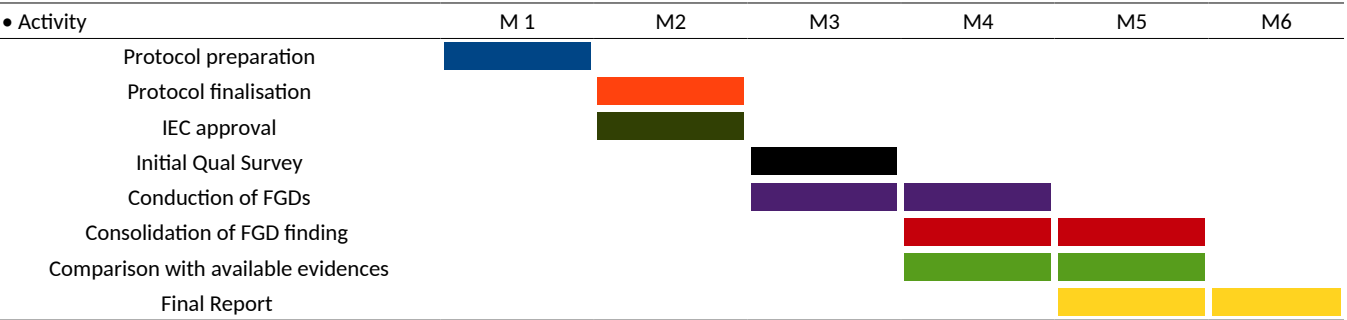
9. Expected Benefits

The Ayurvedic management strategies for T2DM can be classified based upon the clinical experiences and their preventive and therapeutic potentials can be compared with the standard dietetics and medications available.

10. Experience and Credits of the PI:

- Undergone hands-on training on Qualitative Research, Tool Development and Clinical Consensus under Kerala University of Health Sciences. Editor of the notes published as part of the training; “Notes on Qualitative Research and Tool Development in Ayurveda” by KUHS – School of Fundamental Research in Ayurveda. July 2019 and “Clinical Consensus for Research in Ayurveda - Spectrum Approach” by KUHS – School of Fundamental Research in Ayurveda, July 2020.
- Completed 2 research projects (mixed methods) as Investigator funded by Kerala University of Health Sciences and School of Fundamental Research in Ayurveda - namely “**Development of a clinically useful tool for Prakriti assessment**” and “**Role of Ayurveda in Emerging and Re-emerging Diseases – A Multiphase Multicentric Study – Phase 1**”

Possible Bias	Measures taken to prevent
Selection of practitioners who are related to the investigator or near to the investigator	From the initial survey, the answer to the open end questions will be the criteria for selection of practitioners until data redundancy.
Giving more importance to any group of clinicians like Govt Medical officers or Ayurveda College faculties	An initial online survey using a semi-structured questionnaire will be conducted uniformly among different sectors of Ayurveda Practitioners namely Govt Ayurveda Medical Officers, Ayurveda College Faculties and Private practitioners.
Some experts trying to dominate in the FGD and some others getting sidelined	While conducting the FGD, the principal investigator will serve the role of facilitator and he will be interfering whenever there is dominance or inertness of any expert. This can be cross-checked from the sociogram.
Highlighting some medications or procedures and ignoring some others while describing the treatment options	The medications or procedures recommended and not recommended revealed from the qualitative survey and further reconsidered in the FGDs will be finally cross-checked with available literature evidences.



● Principal investigator in the research project **“Evaluation of health interventions delivered through different public health care systems of Ayurveda in Kerala”**, shortlisted by **UGC- Scheme for Transdisciplinary Research for India’s Developing Economy (STRIDE) – Component 2** after primary screening.

11. Funding Sources

None.

12. Conflict of interest

The author declare that he has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

13. Declaration of generative AI in scientific writing

The author declare that he has not used any artificial intelligence (AI) tools for writing and editing the manuscript.

14. Author Contribution

The author is the sole contributor to this manuscript including visualization, conceptualization, writing draft, editing and all correspondence.

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