

## Investigating Research Method in Persian Medicine: Insights from a Qualitative Study

Mojtaba Norouzi<sup>1</sup>, Ali Akbar Haghdoost<sup>2\*</sup>, Saba Barkhori<sup>3</sup>

<sup>1</sup>Department of Biostatistics and Epidemiology, Faculty of Public Health, Kerman University of Medical Sciences, Kerman, Iran

<sup>2</sup>HIV/STI Surveillance Research Center, and WHO Collaborating Center for HIV Surveillance, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman, Iran

<sup>3</sup>School of Persian Medicine, Shiraz University of Medical Sciences, Shiraz, Iran

Received: 18 Nov 2024

Revised: 17 Feb 2025

Accepted: 18 Feb 2025

### Abstract

Research is one of the most important cornerstones of success and always held a specific place in Persian medicine (PM). This study aims to investigate the basics of PM research method. In a qualitative study conducted between July and September 2024, we interviewed 19 experts in PM nationwide. During semi-structured interviews, they shared their perspectives on evidence-based medicine (EBM), research protocol standards, ethical codes, and using observational studies in PM. All participants agreed unanimously on four features of the research methodology: the potential for PM to evolve into EBM, the application of observational studies, adherence to strict product standards, and the similarity of research ethics in PM and contemporary medicine (CM). Over 89% agreed on the efficacy of blinding, the usefulness of current outcome assessment instruments, and the significance of assessing the patient-therapist relationship in clinical trial studies. Respondents (84%) believed the present randomization method was ineffective. Furthermore, 64% acknowledged the animal model's limitations. PM experts believed that the fundamental principles of medical practice should be implemented based on EBM. It is also vital to highlight that the philosophy of PM and CM differ, and this issue should serve as the foundation for creating PM's research methodology. Furthermore, the research methodology criteria for PM should be derived from the principles used in conventional medical sciences.

**Keywords:** Traditional Persian medicine; Evidence-based medicine; Complementary therapies; Integrative medicine; Research design

 <http://doi.org/10.18502/tim.v10i3.19761>

**Citation:** Norouzi M, Haghdoost AA, Barkhori S. Investigating Research Method in Persian Medicine: Insights from a Qualitative Study. Trad Integr Med 2025;10(3): 275-285. <http://doi.org/10.18502/tim.v10i3.19761>

\*Corresponding Author: Ali Akbar Haghdoost

HIV/STI Surveillance Research Center, and WHO Collaborating Center for HIV Surveillance, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman, Iran

Email: [ahaghdoost@gmail.com](mailto:ahaghdoost@gmail.com)

Copyright © 2025 Tehran University of Medical Sciences. Published by Tehran University of Medical Sciences. This work is licensed under a Creative Commons Attribution-NonCommercial 4.0 International license (<https://creativecommons.org/licenses/by-nc/4.0/>). Noncommercial uses of the work are permitted, provided the original work is properly cited.



## Introduction

Persian medicine (PM) has a holistic approach to healthcare that has been utilized for millennia. It covers a variety of medical approaches, including lifestyle changes, nutritional therapy, herbal remedies, and manual interventions (*Amal-e-yadavi*) [1]. PM, as an important branch of medicine, has contributed to the transfer of knowledge and medical practices in various parts of the world [2]. It is known as humoral medicine, which is founded on the four humors (*khelt*): yellow bile (*saфра*), blood, phlegm (*Balgham*), and black bile (*Sauda*) [3]. PM is gaining recognition in educational and medical systems [4].

The world health organization recommends integrating complementary medicine practitioners into healthcare systems to enhance patient safety and therapy efficacy [5]. Evidence-based medicine (EBM) is described as thoughtfully and prudently applying the most relevant scientific evidence to guide patient-specific medical decisions [6]. EBM integration into complementary and alternative medicine (CAM) is a transformative healthcare approach, aiming to empower patients by bridging traditional healing practices with modern scientific standards. Some Asian countries have successfully developed integrative medicine models that combine CAM and conventional treatments [7].

Research is a fundamental base of success and has consistently played an important role in PM [8]. Research has always been crucial for PM physicians, enabling them to demonstrate the therapeutic effects of drugs and evaluate their quality through various methods [9]. Due to inappropriate research methodology, researchers might present inaccurate, unreliable, or biased findings. Thus, the research method represents a critical component of the research process [10]. However, PM suffers from methodological shortcomings, and the quality of PM studies, particularly in the method section, is a cause for concern and this has not significantly improved over time [11,12]. This indicates a lack of sufficient development in the methodology, standards, and assessment methods of PM.

PM needs to use various research designs to address the existing questions. However, there is no need to create a new research methodology for PM, as the existing methods are sufficient for organizing studies and answering numerous PM inquiries. It is important to understand that merely having access to a research method does not guarantee obtaining trustworthy results from PM studies [13]. This is due to the philosophical differences between PM and contemporary medicine (CM), which means that research methods are not identical thoroughly, and fully adapting existing research methods will likely encounter challenges [14].

In recent decades, the practice of PM concepts has revived in Iran after a notable decline. However, its

research standards remain ambiguous. Clarifying the application of CM research standards to PM would be valuable. Consequently, PM should reassess and refine its research methods and approaches to bridge the existing gaps and address the shortcomings of current research methodologies. This study aims to explore the basics of the PM research method through a qualitative investigation and semi-structured interviews.

## Methods

A qualitative study was carried out to explore research methodologies in PM. We interviewed experts in the field to gain deeper insights through their perspectives. The interviews with participants and study commenced in July and concluded in September 2024. A qualitative approach was chosen as it facilitates a flexible exploration of the subject, capturing the attitudes and experiences from the respondents' viewpoints [15].

### *The studied community and sampling*

Participants in this study were recruited using purposeful and snowball sampling methods, guided by specific criteria relevant to the research question. This method is useful when it is challenging to reach individuals with the desired characteristics, guiding researchers to participants who can provide rich information to complete the required sample [16]. The inclusion criteria for participants were based on their expertise in PM, interest in the subject, and understanding of the research method. The interviews continued until the saturation of the findings was ensured. Thematic saturation occurs when the analysis of new interviews reveals no additional information and repeating themes are recognized [17]. Efforts were made to achieve diversity in terms of professional experiences and geographical representation, which enriches the data and offers a broader perspective on the research topic.

### *Collecting data and conducting interviews*

The interviews were gathered using a semi-structured questionnaire divided into two components: (1) a 6-question demographic section about participants; and (2) a 14-question segment exploring the foundational elements of the research methodology, which includes questions such as the possibility of EBM, the application of observational studies, the efficiency of animal models, standardize treatment versus personal treatment concept, evaluating the therapeutic effects of the patient-therapist relationship in clinical trials, the necessity of strict standards to evaluate the safety and effectiveness of products and treatments, the efficiency of tools available for measuring the outcomes, the efficiency of standards of clinical trials such as randomization and blinding, selection methods and

the number of outcome measures, statistical methods for analyzing data, sampling, and determination of sample size, research errors and how to control them, methods for measuring variables, and research ethics. The interviews began with a briefing for the participants about the research's purpose, the interview process, and the confidentiality of their information. We obtained informed consent from each participant to ensure their willingness to participate in the study and to record the interviews. Each interview lasted between 30 and 55 minutes, during which probing questions were asked to explore the topic in greater depth. Additionally, after analyzing their responses, participants were encouraged to share further insights and opinions to enrich the discussion. Interviews continued until data saturation was achieved after the 15th interview, as no new topics emerged in the subsequent four interviews. In total, 19 people were interviewed. Our research encompassed participants from 9 cities, predominantly featuring professionals with over 20 years of experience. The geographic and experiential diversity provides comprehensive perspective representation and strengthens research findings. This strategic recruitment enabled a methodologically rigorous approach that captures insights while mitigating sampling bias.

### Data analysis

After each interview, the recorded audio was promptly transcribed using Microsoft word 2016. The data analysis process involved several sequential steps: becoming familiar with the data, coding, generating themes, reviewing themes, defining and naming them, and finally writing the results. A content analysis approach was employed, utilizing MAXQDA 2020 software to analyze the data. We selected MAXQDA 2020 for its comprehensive qualitative data analysis capabilities, which provide robust tools for systematic coding, quote organization, and mixed-methods research. The software's advanced capabilities facilitated efficient interview analysis and strengthened our methodological approach. MAXQDA's specialized functions allowed us to manage complex qualitative data effectively, ensuring a structured and thorough analytical approach. Initially, the text was read to gain a general understanding of its content, which led to determining preliminary codes. Similar initial codes were then grouped into broader categories (themes) and subcategories. Following coding all texts and extracting key issues, categories, and conceptual framework was created to uncover content within the data.

To ensure the accuracy and reliability of the data, the following criteria were used: credibility, transferability, dependability, and confirmability [18]. To enhance the credibility of the findings prolonged engagement with the subject was utilized. To ensure dependability,

the classification of codes and the conceptual framework were evaluated by an external researcher with expertise in qualitative studies. An external expert reviewed our coding framework, systematically analyzing code implementation, pinpointing potential inconsistencies, and proposing strategic improvements. This collaborative approach strengthened our theoretical framework's integrity and scientific rigor. Experts provided their insights on coding, and the structural framework to validate the confirmability of the findings. All recorded comments were thoroughly archived to allow for follow-up at each stage to support transferability.

### Results

Nineteen PM experts were interviewed for the study. The participants, aged between 30 and 55, were recruited from various cities (Table 1). A conceptual framework was derived from content analysis (Table 2). The thematic analysis of the interviews revealed that participants showed a strong consensus on seven aspects; while opinions varied on other ones (Figure 1).

### *Evidence-based medicine can be implemented in PM*

All participants believed that PM can be implemented in EBM, despite facing challenges related to philosophical issues, individual temperament (*Mizaj*), and

**Table 1.** Demographic information of the participants for investigating the basics of research method in Persian medicine

Variable	No. (%)
Gender	
Female	10 (53)
Male	9 (47)
Age	
30-35	2 (11)
36-46	8 (42)
47-55	9 (47)
Work experience (year)	
10>	3 (16)
10-20	6 (31)
20<	10 (53)
Location	
Large cities (Shiraz, Tehran, Mashhad)	10 (52.6)
Mid-size cities (Kerman, Yazd, Arak, Zahedan)	7 (36.8)
Small size cities (Babol, Sabzevar)	2 (10.6)

**Table 2.** Thematic analysis of the data obtained from interviews with experts about research method in Persian medicine

Evidence-based medicine (EBM) can be implemented in PM	Supporters perspective	Previous research documented in PM literature has been based on expert consensus, which is considered the lowest level of EBM PM can be implemented based on EBM, provided it employs an accurate diagnostic approach Certain aspects, such as philosophical discussions, temperament ( <i>Mizaj</i> ), and psychological and mental reactions ( <i>Araz-e-nafsani</i> ), cannot be classified as EBM
Application of observational studies in PM	Supporters perspective	The viewpoint of PM can be integrated into cohort designs originally established for different objectives Cross-sectional studies can be designed by creating questionnaires based on the disease criteria specified in the literature on PM Case reports and case series can be utilized frequently
Efficiency of animal models in PM	Supporters perspective	PM can more effectively utilize animal models due to the ability to recognize differences PM categorizes various temperaments for both animals and humans PM allows for the selection of animals that closely resemble humans Temperament can sometimes be overlooked, which poses a limitation
	Opponents perspective	The findings from current animal studies do not benefit PM Using guinea pigs and rats in these studies is inappropriate Assessing the temperament of animals is challenging Without taking temperament into account, animal studies are incorrect for evaluating drug effects on human
Standardize treatment versus personal treatment concept in PM	Supporters perspective	Even with standardized treatments, individuals can receive personalized treatment In the interventional framework of PM, it is feasible to adjust the dosage of medications or manual interventions ( <i>Amal-e-yadavi</i> ) based on a person's specific condition While we should pursue scientific standardization, we must also take into account varying conditions for personalized treatment It is essential to establish a protocol that outlines these different conditions and provides personalized treatments, allowing individuals to receive care that is specific to their needs
	Opponents perspective	Standardization involves adjusting treatments without considering the personalized treatment approach of PM Undermines the significance of individual and temperamental differences If standardization is interpreted as a one-size-fits-all approach, it fundamentally contradicts the principles of PM Standardization can only be applied to the general guidelines of PM
Evaluation of therapeutic effects of patient-therapist relationship in clinical trials of PM	Supporters perspective	Evaluating these effects would be both valuable and ideal The current research designs of clinical trials are not ideal for PM, resulting in a methodological gap In clinical trials, the package of interventions is not assessed, neglecting the therapeutic impact of the patient-therapist relationship This is a challenge in clinical trials. If a method to measure this relationship could be developed, it would likely produce intriguing results
	Opponents perspective	This factor is unlikely to have a significant impact. Measuring it poses some challenges, and evaluating it is not essential
The necessity of strict standards to evaluate the safety and effectiveness of PM products and treatments	Supporters perspective	Adhering to rigorous standards is crucial for acceptance of PM within the scientific community We can apply varying standards to different products Strict standardization is not required for herbal supplements and plants that are commonly consumed and have demonstrated safety and efficacy In certain countries, numerous herbal supplements are launched in the market without having been subjected to clinical trials
Effectiveness of existing tools to measure outcomes of PM	Supporters perspective	Undoubtedly, the current tools are effective in facilitating a common scientific language with contemporary medicine (CM) It is crucial to develop tools aligned with the principles of PM There is a need for instruments that can evaluate outcomes related to lifestyle, spiritual relationships, and member temperament
	Opponents perspective	Utilizing CM tools for PM is similar to using a meter to measure weight
Effectiveness of standards of clinical trials such as randomization and blinding	Supporters perspective	Existing blinding and randomization methods can be effective in PM
	Opponents perspective	This manner of randomization is not effective for PM Randomization should be aligned with the principles of PM, considering individual temperaments The challenges do not stem from blinding and randomization, but rather from the trials, which often fail to incorporate the concepts of PM due to a reductionist approach Alternative study designs, such as before-and-after studies, test-retest designs, and preference trials, are more effective in demonstrating the impacts of PM interventions

Similarities in the selection methods and the number of outcome measures between PM and CM	Supporters perspective	The selection process and the number of outcome measures are similar in both medical systems Outcome measures in both medical systems are categorized into primary and secondary, with PM having a greater number of secondary outcomes compared to CM
	Opponents perspective	PM typically having a greater number of secondary outcomes The selection process and the range of outcome measures in PM are more diverse compared to CM In PM secondary outcomes related to sleep quality, digestive health, anxiety, weight management, and condition of chief organs ( <i>Aza-e-raieish</i> ) are important to assess
Are the statistical methods, sampling techniques, sample size, research errors, and variable measurements similar between PM and CM?	Supporters perspective	While the statistical methods are the same, they may not be sufficient for PM The processes for sampling and determining sample size, the types of research errors, and their control methods, and the approach to measuring variables are similar in both medical systems
	Without viewpoint	Addressing this issue falls outside the expertise of PM experts Those PM experts who lack knowledge in statistics and epidemiology should refrain from commenting on this topic
	Opponents perspective	Conducting studies in PM with a large sample size presents challenges The research errors and confounding factors in PM are significantly greater than in CM Some specific variables in PM require different measurement approaches
The comparability of ethics of research between PM and CM	Supporters perspective	All principles of research ethics in CM are also applicable to PM In addition to the ethical standards of CM, PM emphasizes additional aspects, including spirituality

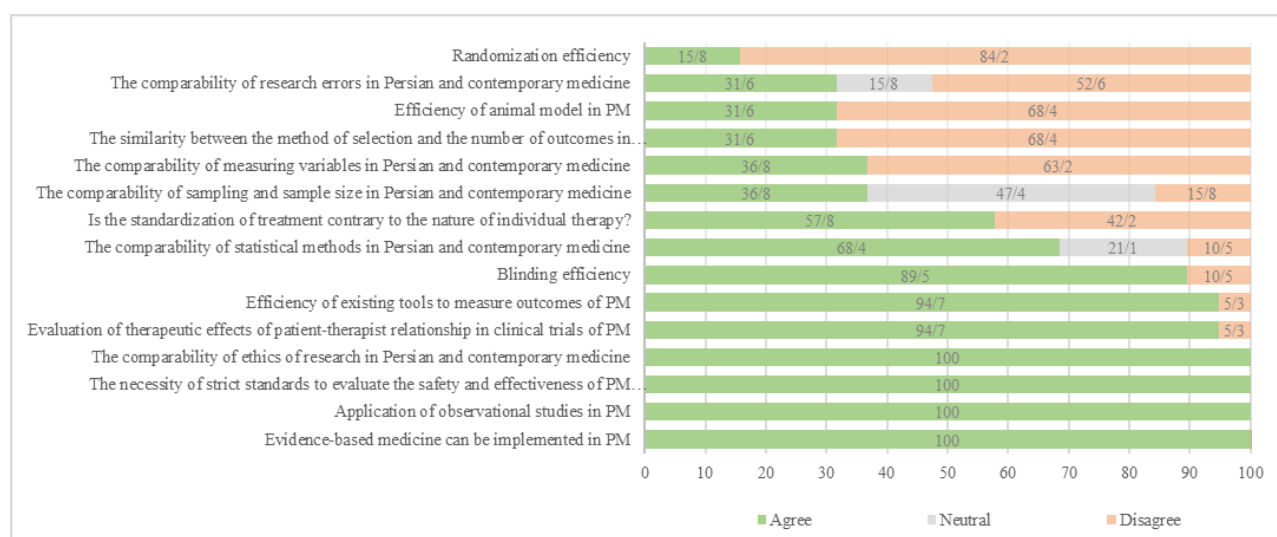


Figure 1. Participants' perspectives on appropriate research methodology in Persian medicine

psychological and mental reactions (*Araz-e-nafsani*). Among the comments regarding the feasibility of implementing EBM, one participant stated: "EBM... its definition is broader than what is often known by doctors in CM; it ultimately starts from the base of the pyramid and moves to the top, with various levels of evidence. Previous research documented in PM literature has been based on expert consensus, which is considered the lowest level of EBM..." Pt. 19

#### Application of observational studies in PM

All participants expressed that various types of observational studies are valuable in PM. They noted that cohort studies can also be applicable in addition to case reports, case series, cross-sectional, and case-control studies. They proposed that cohorts originally designed for other purposes could be utilized while incorporating the PM perspective. One partic-

ipant stated, "Observational studies are highly beneficial... cohorts created for different objectives can still integrate the PM perspective without being exclusively designed for it." Pt. 1

#### Efficiency of animal models in PM

The majority of participants believed that animal models are ineffective for assessing the effects of drugs. They argued that these studies are valuable for safety assessments and for evaluating certain cases referenced in PM, such as examining the connection between cold water and conditions like fatty liver or infertility. Conversely, some participants believe that animal models are entirely effective in PM and that there are no limitations. The following comments were noted in this context:

"... Animal studies do not help PM... but if we could use animals that are close to humans, such as chim-



panzees and monkeys, it would be good... Currently, the methods employed in animal studies involving guinea pigs and rats are inaccurate to validate the theories of PM..." Pt. 14

"We can make extensive use of animal models... Incorporating temperament into animal models is challenging, but we do recognize that animals also have their temperaments, with some being hotter and others colder. While this knowledge can be beneficial, it is truly difficult to find an animal that closely resembles human temperament..." Pt. 11

### *Standardize treatment versus personal treatment concept in PM*

The majority of participants believed that standardizing intervention in PM is essential. They did not think that intervention standardization conflicted with the individualized treatment concept promoted by PM. Instead, they believed that alongside standardization, various intervention protocols could be developed based on individual temperament to facilitate personalized treatment. However, some participants opposed the idea of standardization, arguing that it contradicts the principles of PM. The following comments were noted in this context:

"While standardization of intervention is essential in PM, it does not imply that the same intervention plan is applied to everyone. For instance, in a pack of interventions, changes based on personal condition can be made, such as reducing or eliminating a specific medication for one person, or altering the level of manual interventions (*Amal-e-yadavi*). This approach allows for personalized treatments, meaning that alongside protocols, individuals can still receive personalized treatment." Pt. 5

"Standardization is neglecting the traditional and philosophical approach, rendering individual and temperamental differences insignificant." Pt. 10

### *Evaluation of therapeutic effects of patient-therapist relationship in clinical trials of PM*

The majority of participants agreed on the importance of employing a method to assess the therapeutic impact of the patient-therapist relationship. They believed that evaluating this relationship in clinical trials would be beneficial and would enhance the impact of PM interventions. However, a few believed that assessing this relationship would not be effective. The following comments were noted in this context:

"Certainly, in my opinion, it would be ideal if this could be possible.... We should develop approaches that cover the entire pack of PM interventions, rather than just focusing on one intervention. For instance, while we often assess dry cupping (*Badkesh*), it is important to recognize that dry cupping is only one aspect of the overall treatment we provide to the pa-

tient..." Pt. 1

"If it is feasible, that would be fantastic. This is currently a challenge we face in RCTs. If we can find a way to measure this, it will certainly produce valuable results." Pt. 11

"...It acts as an effective confounding variable; however, it is essential to recognize that randomization helps control this confounder to some extent. Although this factor could affect the outcomes, its influence is probably not high. Assessing this can be difficult and does not require evaluation." Pt. 3

### *The necessity of strict standards to evaluate the safety and effectiveness of PM products and treatments*

All participants agree that adhering to strict standards is essential for assessing the safety and efficacy of PM products. They believe that while it is important to comply with these standards for the scientific community, such strict standards are not necessary for herbal supplements or food products.

"Consider the application of standards for various products globally... Cosmetic products adhere to one set of standards; while pharmaceutical products follow another. This does not indicate a dual standard. For instance, the standards for chemical drugs are not applied to herbal products, they have their specific standards. This distinction is explained because herbal products do not make medicinal claims and are classified as supplements. Consequently, their regulation is easier.... I believe that international regulations could be applicable in Iran." Pt. 2

### *Effectiveness of existing tools to measure outcomes of PM*

The majority of participants felt that the current tools for assessing PM outcomes are effective but inadequate. Consequently, there is a need to design tools based on the principles of PM to complement the existing ones. However, one participant expressed that these tools are effective and sufficient for PM. The following comments were noted in this context:

"I am not proposing that we ignore the current measurement tools; instead, I think they should be employed to develop a common scientific language with CM. Therefore, it is important to design tools specifically for PM while utilizing the existing tools." Pt. 5

"Current tools are insufficient to show the benefits of PM interventions. What tool is available for assessing the impact of a plant on uterine temperament? While current tools can be utilized, they do not provide a comprehensive solution. Creating new tools is necessary, as PM principles indicate that existing tools are limited. However, it is important to note that it would be incorrect to dismiss existing tools." Pt. 17

"Utilizing CM tools for PM is similar to employing

unit of length to assess weight, as it overlooks the fundamental principles of PM..." Pt. 10

### *Effectiveness of standards of clinical trials such as randomization and blinding*

Randomization is a statistical process where a random mechanism is used to select a sample from a population or assign subjects to different groups. It involves creating a haphazard arrangement to simulate chance, ensuring that selection occurs without a predictable pattern.

The majority of participants believed that blinding is effective for PM. However, a few expressed doubts about its effectiveness. They thought that randomization in this way would not be beneficial for PM. They suggested that randomization should be based on temperament. Additionally, some participants noted that clinical trials typically cannot demonstrate the impacts of PM interventions. They proposed alternative studies such as preference trials, before-after, and test-retest studies. The following comments were noted in this context:

"...To carry out research or clinical trials in a more rational and scientifically valid way according to PM principles, it is advisable to implement cluster randomization. Additionally, blinding can be utilized in PM in the same manner used in CM..." Pt. 12

"...It is advisable to conduct preference trials, where patients select between this treatment pack and another. This approach is not randomized, as it relies on the patient's choice. Consequently, this method allows for a more realistic observation of the effects of the PM interventions." Pt. 2

"PM study designs are not typically aligned with blinding and randomization. While blinding and randomization can be applied, the outcomes of such research may not align well with the concept of PM, leaning more towards a phytotherapy intervention." Pt. 16

### *Similarities in the selection methods and the number of outcome measures between PM and CM*

The majority of participants believed that the selection process and the number of outcome measures in PM differ from CM. They noted that PM examines not only the primary outcome but also several other significant outcomes. On the other hand, some participants believed that the selection method and the number of outcome measures in PM and CM can be similar and categorized into two groups: primary outcomes and secondary outcomes. The following comments were noted in this context:

"In PM, there is a greater number of interventions, which results in a more varied number of outcome measures. When a patient is being evaluated, we con-

sider various aspects of their health, including their sleep patterns, digestion, neurological function, and cardiac health..." Pt. 8

"In PM, similar to CM, the outcome measures are classified into two general categories: primary and secondary. This indicates that there are a set of primary and a set of secondary objectives..." Pt. 13

### *The comparability of statistical methods for analysis in PM and CM*

More than half of the participants believed that statistical methods used in the two medical systems are similar. However, they believed that the current statistical methods do not perform well as the number of parameters increases. On the other hand, some participants believed that specialists in statistics and epidemiology ought to comment on statistical methods.

"We must use other statistical methods in addition to existing ones. We learned to assess a single intervention and its corresponding effect. For instance, if you wish to evaluate the impact of a specific intervention on depression and subsequently decide to assess anxiety too, the sample size and statistical methods will differ..." Pt. 1

### *Comparability of the concepts of sampling and sample size in PM and CM*

Nearly 50% of the participants expressed no opinion regarding sampling and sample size determination, feeling that they should refrain from commenting on this issue. Some participants believed that there is no distinction between PM and CM concerning sampling and sample size determination. A small number of participants believed that sampling and sample size determination in PM should be different from CM.

"Statistics is a scientific issue, and we cannot assert that there is a distinction between PM and CM. We must provide our findings based on statistical science, which shows that statistics does not differentiate between PM and CM." Pt. 3

### *The comparability of research errors and how to control them in PM and CM*

The majority of participants believed that the research errors and their management in PM differ from CM. They considered a higher prevalence of errors and confounders in PM compared to CM. However, some participants believed that research errors and their control in both medical systems are similar. The following comments were noted in this context:

"If the studies in PM are approached from a holistic perspective, the design of the research will differ in terms of both errors and methods of control..." Pt. 16

"They are identical; I am merely pointing out that in PM we have a set of new variables. The only distinction lies in this aspect. Therefore, the statistical meth-

ods will remain unchanged." Pt. 13

### *The comparability of methods for measuring variables in PM and CM*

The majority of participants believed that the measurement of variables in PM differs from CM. They noted that certain variables in PM are unique and are measured differently. However, some participants believed the measurement methods in both medical systems are similar.

"Some variables in research, such as age, sex, height, and weight, are the same in two medical systems. However, the specific variables associated with PM differ. Unfortunately, we do not have a standard, scale, or specialized tool for assessing variables like temperaments, general temperaments, and dystemperament (*Su-e-Mizaj*). For any variable to be measured effectively, it must have a specific tool..." Pt. 5

"The approach to measuring the variables is similar in both PM and CM. However, there may be variables utilized in PM that are not found in CM." Pt. 6

### *The comparability of research ethics in PM and CM*

All participants believed that the research ethics in PM are similar to CM. One stated, "The ethical standards of research in CM align with PM, and the ethical principles of research in CM are acceptable for PM." Pt. 7

## **Discussion**

This study compared key research concepts in PM and CM, revealing a strong consensus among PM experts that CM research methodologies can also be applied in PM. Participants believed that PM has specific principles such as a holistic perspective, applying traditional sources, paying attention to individual temperaments, and the alignment of prevention and treatment with personalized medicine. It suggests that certain parts of the research methodology may need to be customized. In recent decades, alternative medicine, including PM, has experienced significant transformations. Historically, the principles of EBM were not widely embraced within alternative medicine, and therapeutic practices primarily relied on the experiences and viewpoints of practitioners [19, 20]. Alternative medicine has gradually begun to adopt EBM principles, leading to changes in research methodologies and the updating of research methods to identify the most effective treatment recommendations. This shift reflects an effort to enhance the credibility and efficacy of alternative therapies within medical community [21]. Perhaps an important motivation for creating specialized areas of PM in medical science universities was the transition to evidence-based approaches in PM. They seek to enhance the quality and efficacy of treatments provided through traditional methods.

Some individuals believe that PM is fundamentally different from CM, making it difficult to apply standard research principles in this field. In this study, we examined the fundamental concepts of research in medical sciences based on insights from PM's experts. Our findings indicate that key research principles such as application of observational studies, application of EBM, ethical guidelines in medical research, sampling techniques and sample size determination, data analysis approaches, application of existing tools, and even essential elements of interventional studies are applicable within PM with some modifications. Nevertheless, there are some differences as well.

The objective of the EBM concept is to reduce biases and to implement more effective treatments [7]. Participants believed that, to some extent, PM can be based on EBM. For example, specific treatments for PM which are not influenced by temperament can be based on EBM. Additionally, in PM the experiences and opinions of experts are important; whereas such factors are not typically acknowledged in EBM. The rationale behind these statements reflects that in PM, some treatments are influenced by individual temperament and personal experiences. Also, some treatments are guided by expert opinions. These approaches cannot align with EBM because EBM demands findings that can be universally applied and systematically replicated across diverse populations. The findings of this study align with the results of Moradi et al., who noted that while PM is consistent with EBM, it cannot be entirely incorporated into the EBM framework [22]. Furthermore, Bigdali et al. highlighted the importance of applying EBM within PM [4]. The integration of PM into EBM is an evolving area that continues to attract the interest of PM experts.

Animal models play a crucial role in experimental research of human diseases [23]. However, participants believed that existing animal models are not particularly effective for evaluating the efficacy of PM drugs. They argued that, under PM principles, it is difficult to accurately diagnose an animal's temperament, making it challenging to find an animal whose temperament closely resembles humans. As a result, the efficiency of animal models is limited. The rationale underlying these statements centers on the inherent limitations of animal models in PM, particularly in accurately representing human temperamental complexities. Diagnosing an animal's temperament is fundamentally challenging, making it difficult to find an animal model that mirrors human physiological and psychological variations. Consequently, the efficiency of such models is significantly constrained. When considering animal models in PM, the selection of an appropriate model is vital. In CM, it is essential to investigate which animal model suits the disease [24-26]. There-



fore, the PM should take into account the temperamental characteristics of animals. Furthermore, there are numerous cases where animal testing has failed to predict toxicity in humans [27]. This issue has led many experts to doubt the necessity of conducting animal studies for all drugs [28].

Randomization and blinding are crucial components of clinical trials [29], and improper implementation can lead to exaggerated results [30]. Participants agreed that blinding is effective for PM. They believed that randomization would be beneficial if it adhered to PM principles and considered individual temperament. Currently, the randomization methods used in PM clinical trials do not consider temperament [31-33]. For example, in a COVID-19 dietary intervention RCT neglecting temperamental differences, researchers might apply a uniform nutritional protocol that fails to account for individual physiological variations. The study could produce inconsistent results by overlooking each participant's unique temperament, potentially compromising treatment effectiveness and immune response. This approach demonstrates how ignoring traditional Persian medical principles of personalized intervention can reduce the overall efficacy of clinical research.

Participants believed that clinical trials test a piece of the PM intervention package. While in practice, in the PM specialist's office, patients receive the entire package, for example, in addition to medication, manual interventions (*Amal-e-yadavi*) practices are also applied. Therefore, clinical trial studies suffer from reductionism and cannot effectively demonstrate the effects of PM interventions. On the other hand, these studies do not focus on the patient's temperament, and randomization is not conducted based on temperament. These reasons led them to suggest alternative studies that do not have randomization problems and provide a comprehensive evaluation of PM interventions. Therefore, minimization and optimization methods can be proposed to enhance the efficacy of clinical trials in PM. Simulation studies indicate that minimization yields better-balanced groups compared to traditional randomization methods. Minimization approach allows for a balanced treatment allocation [34] that can consider individual characteristics, such as temperament, which are crucial in PM. Sometimes the number of variables is large, and their weight and importance are not the same. In addition, we do not want to reduce the effect of chance to zero; therefore, we use the optimization method [35]. Implementing these methods can improve study robustness and align with the individualized treatment principles of PM.

Nearly half of the participants believed that statistical methods were inadequate due to the numerous parameters involved in PM. They suggested to explore appropriate methodologies. When the number of desired

outcomes increases in the analysis of PM studies, it is essential to investigate suitable statistical techniques, such as multivariate analysis. Multivariate analysis specifically refers to statistical models and techniques that simultaneously analyze multiple dependent (outcome) variables. This statistical method analyzes multiple variables simultaneously to uncover relationships and patterns among them [36]. Utilizing this approach in PM appears necessary because it can effectively handle complex data sets where various factors influence the outcomes.

Herbal products may be classified as drugs, cosmetics, dietary supplements, or food, depending on the context [37]. All participants agreed that adhering to strict standards is essential for assessing the safety and efficacy of medicinal products in PM. However, they made exceptions for herbal supplements and items that existed in people's diets. As the market for herbal medicines expands, numerous countries have established regulations and guidelines to ensure their safe use by consumers [38]. Consequently, developing a regulatory framework for therapeutic products in PM is crucial. It is important to note that herbal products marketed as food supplements do not need strict standards. In many countries, herbal supplements are regulated differently from medicines [39,40]. For instance, in the United States, the food and drug administration does not assess dietary supplements or their labels before distribution in the market [37,41].

Participants acknowledge the current tools' effectiveness in establishing a common scientific language with contemporary medicine, yet deem them inadequate. For example, the Beck questionnaire fundamentally conflicts with PM principles by neglecting individual temperamental variations and applying a uniform diagnostic approach. Its standardized scoring system fails to capture the holistic, personalized health perspective central to Persian medical philosophy. By reducing complex mental health states to generic scores, the questionnaire overlooks the multidimensional nature of human health and interactions between physiological and psychological states that are essential in PM diagnostics. Therefore, creating an auxiliary questionnaire grounded in PM principles is imperative to complement existing diagnostic tools.

The association between standardization and personalized treatment in PM is complex. In PM personal treatment is a priority [42]; whereas standardization aims to create uniform protocols and guidelines. Few participants argued that standardization does not account for PM's personalized approach. They believe that standardization introduces rigid processes that might not fully address the unique needs and requirements of each patient. Nevertheless, most of the participants expressed that standardizing treatment in PM is essential and does not conflict with personal treatment. They

thought it was possible to establish standardized treatment protocols while implementing personal treatment. So that the standard treatment within PM can be modified depending on the patient's condition. While standardization maintains consistency, the application of these protocols may vary based on the patient's condition [43,44]. As a result, adjusting standard treatment guidelines according to the patient's condition facilitates a personal treatment approach.

A synthesis of differing views regarding various domains such as the applicability of observational studies, standardization, and statistical methods could help identify actionable recommendations for PM research. For example, participants propose reimagining cohort studies to incorporate PM perspectives and developing cross-sectional studies using carefully constructed questionnaires that align with established PM disease criteria. This methodological approach enables researchers to utilize existing research infrastructure while introducing innovative analytical frameworks that reflect PM's distinctive holistic methodological principles.

### Limitations of the study

This study focused on the perspectives of Iranian PM experts, which may not fully represent the diverse experiences and viewpoints of PM professionals in other regions, such as central Asia and the broader middle east. Also, the findings of this study were derived from expert opinions and should not be interpreted as conclusive.

### Conclusion

While there was agreement on the importance of EBM, the definition and application of this concept in PM remained unclear among participants. Research in this field must be justifiable to both PM experts and external observers. This highlights the need for robust evaluation tools to address specific PM concepts. The holistic approach of PM is at risk because its incorporation with CM practices reduces the emphasis on prevention, lifestyle, health, and personal treatment. The application of animal models to evaluate the effectiveness of PM-products is restricted, which requires careful consideration in their use. Standardization of treatments can coexist with personal treatment approaches in PM. While blinding in PM research is advantageous, the existing randomization methods are not optimal. These highlight the need to adjust certain parts of the existing research methodology in accordance with the fundamental principles of PM.

### Suggestions

In this research, certain PM experts acknowledged limitations in their proficiency regarding sample size

determination, statistical methods, and research error assessment. Consequently, the study recommends integrating PM practitioners from various regions and statistical and epidemiological professionals in future research studies. A more thorough examination of the distinctions between the two branches of PM and CM is necessary, along with a detailed presentation of the research methodology of PM.

### Conflict of Interests

There is no conflict of interest between the authors.

### Acknowledgments

This article is derived from a doctoral thesis that received review and approval from Kerman University of Medical Sciences (ethical code: IR.KMU.REC.1401.569). The authors also express their gratitude to all participants involved in this study.

### References

- [1] Daneshfrad B, Irannejad S, Shams M, Shirzad M, Vaghasloo MA, et al. Persian medicine standard terminology. *Trad Integr Med* 2024;9:136-148
- [2] Shirafkan H, Taghavi M, Mirzapor M. Investigating the difference between principals of Iranian traditional medicine and modern medicine for providing a model for integrated medicine. *Islam Health J* 2014;1:10-15.
- [3] Pasalar M, Nimrouzi M, Choopani R, Mosaddegh M, Kamalinejad M, et al. Functional dyspepsia: A new approach from traditional Persian medicine. *Avicenna J Phytomed* 2016;6:165.
- [4] Bigdeli S, Kordafshari G, Soltani Arabshahi SK, Shams Ardakani MR, Mohammadi Kenari H. Evidence-based Iranian traditional medicine schemes and threats. *Educ Strategy Med Sci* 2013;6:17-23.
- [5] von Schoen-Angerer T, Manchanda RK, Lloyd I, Wardle J, Szöke J, et al. Traditional, complementary and integrative healthcare: global stakeholder perspective on WHO's current and future strategy. *BMJ Glob Health* 2023;8:e013150.
- [6] Solomon M. Just a paradigm: evidence-based medicine in epistemological context. *Eur J Philos Sci* 2011;1:451-466.
- [7] Mortada EM. Evidence-based complementary and alternative medicine in current medical practice. *Cureus*. 2024;16:e52041.
- [8] Javan R, Ghazanfari SM, Naqibi Z. The principles of the research method in the Iranian school of medicine and its comparison with new methods. Iranian traditional medicine conference and a decade of academic activity: review of the past, future horizon 2017. [In persian]
- [9] Suri H. Research method in wisdom-based medicine. *Nafs Quarterly*, 2023;10.[In persian]
- [10] Bahishti AA. The vital role of research methodology in addressing the research questions. *Int J Methodol* 2022;1:1-1.
- [11] Norouzi M, Haghdoost AA, Kkarimafshar M. The reporting quality and risk of bias of randomized controlled trials in traditional persian medicine: a systematic review. *Curr Trad Med* 2024;10:1-20.
- [12] Norouzi M, Haghdoost AA, Setayesh M. Quality assessment of traditional persian medicine observational studies. *Iran J Public Health* 2024;53:1469-1481.
- [13] Tamayo C, Boon H, Ghishan F, Trinh K. Research methodol-

- ogy evaluating complementary and alternative therapies. *Drug Inform J* 2002;36:535-548.
- [14] Avijgan M, Nasab MM. The methodology of research in Traditional Medicine. *J Med Herbs* 2010;1:63.
- [15] Oranga J, Matere A. Qualitative research: essence, types and advantages. *Open Access Library J* 2023;10:1-9.
- [16] Nyimbili F, Nyimbili L. Types of purposive sampling techniques with their examples and application in qualitative research studies. *Br J Multidiscip Adv Stud* 2024;5:90-99.
- [17] Rahimi S, khatooni M. Saturation in qualitative research: An evolutionary concept analysis. *Int J Nurs Stud Adv* 2024;6:100174.
- [18] Nowell LS, Norris JM, White DE, Moules NJ. Thematic analysis: Striving to meet the trustworthiness criteria. *Int J Qual Methods* 2017;16.
- [19] Bigdeli S, Kordafshari G, Soltani Arabshahi SK, Shams Ardakani MR, Mohammadi Kenari H. Evidence-based Iranian traditional medicine schemes and threats. *Bimonth Educ Strategies Med Sci* 2013;6:17-23.
- [20] Abdipour Mehrian SR, Uddin S, Ghahramani Z, Moshfeghinia R, Shahabi S, et al. Evidence-based practice in traditional persian medicine (TPM): a stakeholder and social network analysis. *BMC Complement Med Ther* 2024;24:253.
- [21] Mortada EM. Evidence-based complementary and alternative medicine in current medical practice. *Cureus* 2024;16:e52041.
- [22] Moradi S, Hosseini A. Iranian traditional medicine and evidence based medicine: An overview of dialogue between two paradigms *BMJ Open* 2017;7.
- [23] Domínguez-Oliva A, Hernández-Ávalos I, Martínez-Burnes J, Olmos-Hernández A, Verduzco-Mendoza A, et al. The importance of animal models in biomedical research: current insights and applications. *Animals* 2023;13:1223.
- [24] Lama J, Buhidma Y, Fletcher EJ, Duty S. Animal models of Parkinson's disease: a guide to selecting the optimal model for your research. *Neuronal Signal* 2021;5:NS20210026.
- [25] Muñoz-Fontela C, Dowling WE, Funnell SG, Gsell P-S, RIVERS-Balta AX, et al. Animal models for COVID-19. *Nature* 2020;586:509-515.
- [26] Gisterá A, Ketelhuth DF, Malin SG, Hansson GK. Animal models of atherosclerosis—supportive notes and tricks of the trade. *Circ Res* 2022;130:1869-1887.
- [27] Van Norman GA. Limitations of animal studies for predicting toxicity in clinical trials: is it time to rethink our current approach? *JACC: Basic to Translational Science*. 2019;4:845-854.
- [28] Van Norman GA. Limitations of animal studies for predicting toxicity in clinical trials: Part 2: Potential alternatives to the use of animals in preclinical trials. *Basic Transl Sci* 2020;5:387-397.
- [29] Farrokhvar F, Karanicolas PJ, Thoma A, Simunovic M, Bhandari M, et al. Randomized controlled trials of surgical interventions. *Ann Surg* 2010;251:409-416.
- [30] Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *J Pharmacol Pharmacother* 2010;1:100-107.
- [31] Aghabeiglooei Z, Namazi N, Karimi M, Soleymani S, Ayati MH, Rezaeizadeh H. effects of komouni formulation (herbal product of persian medicine) with a low-calorie diet on cardiometabolic risk factors in overweight and obese women: a triple-blinded randomized clinical trial. *Iran J Pharm Res* 2023;22:e136114.
- [32] Molkara T, Akhlaghi F, Ramezani MA, Salari R, Vakili V, et al. Effects of a food product (based on *Daucus carota*) and education based on traditional Persian medicine on female sexual dysfunction: a randomized clinical trial. *Electron Phys* 2018;10:6577.
- [33] Adalat M, Khalili M, Ayromlou H, Haririan S, Fazljou SMB, et al. Antidepressant effects of a Persian medicine remedy on multiple sclerosis patients: a double-blinded randomized clinical trial. *Galen Med J* 2019;8:e1212.
- [34] Coart E, Bamps P, Quinaux E, Sturbois G, Saad ED, et al. Minimization in randomized clinical trials. *Stat Med* 2023;42:5285-5311.
- [35] Saghaei M. An overview of randomization and minimization programs for randomized clinical trials. *J Med Signals Sens* 2011;1:55-61.
- [36] Hazra A, Gogtay N. Biostatistics series module 10: Brief overview of multivariate methods. *Indian J Dermatol* 2017;62:358-366.
- [37] Complementary and Alternative Medicine Products and their Regulation by the Food and Drug Administration. [cited 2024]. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/complementary-and-alternative-medicine-products-and-their-regulation-food-and-drug-administration>.
- [38] Noviana E, Indrayanto G, Rohman A. Advances in fingerprint analysis for standardization and quality control of herbal medicines. *Front Pharmacol* 2022;13:853023.
- [39] Ventola CL. Current issues regarding complementary and alternative medicine (CAM) in the United States: part 1: the widespread use of CAM and the need for better-informed health care professionals to provide patient counseling. *P T* 2010;35:461-468.
- [40] Guo R, Canter P, Ernst E. A systematic review of randomised clinical trials of individualised herbal medicine in any indication. *Postgrad Med J* 2007;83:633-637.
- [41] FDA's Regulation of Dietary Supplements with Dr. Cara Welch. [cited 2024]. Available from: <https://www.fda.gov/drugs/news-events-human-drugs/fdas-regulation-dietary-supplements-dr-cara-welch>.
- [42] Mojahedi M, Naseri M, Majdzadeh R, Keshavarz M, Ebadini M, et al. Reliability and validity assessment of Mizaj questionnaire: a novel self-report scale in Iranian traditional medicine. *Iran Red Crescent Med J* 2014;16:e15924.
- [43] Holmes C, McDonald F, Jones M, Ozdemir V, Graham JE. Standardization and omics science: technical and social dimensions are inseparable and demand symmetrical study. *OMICS J Integr Biol* 2010;14:327-332.
- [44] Gopalakrishnan S, Udayshankar P, Rama R. Standard treatment guidelines in primary healthcare practice. *J Fam Med prim Care* 2014;3:424-429.