



RESEARCH ARTICLE

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# Is the Iranian Traditional Medicine warm and cold temperament related to Basal Metabolic Rate and activity of the sympathetic-parasympathetic system? Study protocol

Gholamreza Mohammadi Farsani<sup>1</sup>, Mina Movahhed<sup>2</sup>, Ahmadreza Dorosty Motlagh<sup>1\*</sup>, Saeed Hosseini<sup>1</sup>, Masoud Yunesian<sup>3</sup>, Taiebeh Mohammadi Farsani<sup>4</sup>, Ali Akbar Saboor-Yaraghi<sup>5</sup>, Mohammad Kamalinejad<sup>6</sup>, Kurosh Djafarian<sup>1,7</sup> and Mohsen Naseri<sup>8</sup>

## Abstract

**Background:** Our body's energy demand consists one of the most essential pillars of medicine. Basically, human beings consume energy to maintain life's vital processes and the expenditure of this total energy is affected by several factors. From the Iranian Traditional Medicine point of view, temperament is a basic concept that helps in the maintenance of health and treatment of disease. It could be assumed that there is a relationship between the factors affecting temperament and metabolism. In this study, this relationship is investigated by assaying the effect of Thyme and Sumac on the metabolic rate, activity of sympathetic-parasympathetic system and will also compare this effect between warm and cold temperamental people.

**Methods:** The present study will be conducted in two stages. 1. Based on the standardized questionnaire, the subjects will be divided into two groups including warm and cold temperament. Accordingly, basal metabolic rate, sympathetic-parasympathetic function, thyroid function, body composition and nutritional status of them will be compared. 2. Thermic effect of Thyme and Sumac will be measured by designing a double blind randomized crossover trial study. The subjects in each of the groups will be divided into two subgroups randomly and they will be given a single dose of Thyme or Sumac. They will be monitored for 4 hours at rest. At the beginning and end of the study blood samples will be taken and indirect calorimetry, body temperature, heart rate and blood pressure will be measured in half hour intervals. After a six day wash out period, the crossover investigations will be initiated. The data will be analyzed using the SPSS statistical software and using the equations for crossover clinical study.

**Results:** After doing study, results will be given.

**Conclusion:** This study is the first study that evaluates the relationship between human temperament and the metabolic rate, and also the effect of food temperament on some of the chemical, hormonal and functional factors of the body. We believe that the result of our study may create a new window in nutritional science that can be a step forward in improving health.

**Trial registration:** ClinicalTrials.gov NCT01643096.

**Keyword:** Temperament, Iranian traditional medicine, Basal metabolic rate, Thermic effect of food

\* Correspondence: dorostim@sina.tums.ac.ir

<sup>1</sup>School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Tehran, Iran

Full list of author information is available at the end of the article

## Background

Our need for energy is one of the most essential principles used in the science of nutrition and medicine. The total consumed energy consists of Basal or Resting Metabolic Rate (BMR), Thermic effect of Food (TEF) and Activity Thermogenesis (AT). BMR is the energy needed to sustain the metabolic activities of cells and tissues and comprises approximately 60-70% of the energy utilized by the individual himself. BMR is affected by several factors, such as body composition, size, age, sex, heredity, hormones and environmental conditions [1]. TEF, which consumes approximately 10% of the total energy, includes energy for digestion, absorption and metabolism of nutrients. The amount of the energy consumption by the TEF differs individually too and is affected by several factors such as type of food, insulin resistance, physical activity, age, order of meals and time of consumption of food [1]. For example; when compared to food without spices, food with spices have higher and longer TEF, i.e. meals with chili or mustard can increase metabolism by 33% more than of the food without them and their effects can continue for up to 3 hours [2].

Although energy is vital for the sustenance of life, the correct nutrition that delivers that required energy is as vital, and plays a role in improving health, prevent and treat diseases.

Iranian Traditional Medicine (ITM, which is also known as Unani medicine or Humors medicine) is one of the oldest schools of traditional medicine [3]. The ITM system tries to provide the best possible way for a person to lead a life with minimal sickness and disease [4]. In this school, prevention is more important than treatment [5]. In this regard, nutrition is one of the essential factors in the prevention of diseases and improvement of the nutritional status is the first step in the treatment of diseases. From an ITM point of view, temperament is one of the basic concepts of health and disease. Temperament in individuals varies and many factors such as age, sex, environment and body composition affect it. Initial investigations show that warm and cold temperament is associated with BMR. Some of these relationships are discussed in Table 1.

On the other hand, from an ITM view point, criterion for the determination of food temperament was its effect on temperament. This means that foods can have a warm or cold effect on the temperament and cause the related signs and symptoms. The speed of the body's reaction after eating warm and cold food is differs and depends on each individual's temperament.

From the above discussion it is clear that warm temperamental people have a higher BMR while the cold temperamental people have a lower BMR. Also warm temperamental people have a greater amount of Thermic effect of food than cold temperamental persons. In order to investigate this relationship, we need to compare the

BMRs of both cold and warm temperamental people. To examine the differences in thermal effects of food on people with warm and cold-Temperaments, we will give both warm and cold temperamental foods to the two groups.

Based on indicators such as the amount of macronutrients, toxicity, characteristics of the warmth and coldness of temperament from a traditional medicine point of view, Thyme (with warm temperament) and Sumac (with cold temperament) were chosen. The sympathetic-parasympathetic system activity and thyroid function will be controlled to investigate the potential mechanisms affecting BMR and TEF and matching them with the symptoms of cold and warm temperament.

It is hoped that by explaining the relationships of food temperaments with the perspective of traditional medicine and modern medicine, there could be a new window created in nutrition science and public health.

## Methods

In order to compare the BMR, the sympathetic-parasympathetic system activity, thyroid function and thermic effect of Thyme and Sumac on warm and cold temperament persons, this study will be designed in two stages. In the first stage, a validated questionnaire will be used for a descriptive study; the subjects will be divided into two groups with warm and cold temperament for comparing the BMR, the sympathetic-parasympathetic system activity and thyroid function between people with warm and cold temperament.

Demographic characteristics such as measurement of height, weight, vital signs, BMR, body composition and biochemical assays (measurement of serum levels of adrenaline, noradrenalin, cortisol, T3, T4, TSH, insulin, FBS and CBC-diff, and the blood group) will also be included in the study. Nutrient intake will be assessed by using a food frequency questionnaire and two 24-hour dietary recalls.

In the second stage, a study of a randomized double blind cross over trial will be designed to measure the Thermic effect of Thyme and Sumac. The cold and warm-tempered individuals in each group will be randomly divided into two sub groups and they will each receive Thyme or Sumac. After giving a single dose of Sumac or Thyme, within half-hour intervals for 4 hours, the resting metabolic rate, peripheral and central body temperature, heart rate and blood pressure will be measured. For measuring the biochemical variables such as adrenaline, noradrenalin and cortisol, blood samples were taken at the beginning and at the end of the study. After the first phase in the cross over design, a six day wash out period will be observed. After the wash out period, Thyme and Sumac will be given to the other sub groups (see Figure 1).

**Table 1 The probable relationship between BMR & warm and cold temperament**

Variable	Basal metabolic rate	Temperament
Muscle mass or fat-free mass	Muscle mass is the most significant determinant of energy consumption at rest and it Increase BMR [1,6].	high muscle mass indicate the warm temperament & High fat mass indicate the cold temperament [7].
Age	BMR in the first and second year of life span is high and after it is reduced approximately 2 to 3% in each decade of life [1,6]	warm temperament in children and young people are more than the aged ones [7] & Heat of temperament start decreasing after the age of 35 to 40 years [8].
Body surface	Those who have more body surface, have higher BMR [1]	In view of ITM having extended chest, large hand and foot and prominent joints indicate temperament [7].
Sex	In women, BMR is 5 to 10% less than the men with the same weight and height [1,6].	The women temperament is colder than the men [8].
The sympathetic_parasympathetic nervous system	Stimulating the sympathetic nervous system (e.g. stress) raises the basal metabolism [1].	Some emotions can increase warm (warm degree or heat) of body temperament [9,10].
Thyroid function	Hypothyroidism reduced the BMR while in hyperthyroidism increase the BMR [1,11].	Individuals with cold temperament feel cold more than others and tolerate heat better than the cold in normal conditions. While in the warm temperament persons is reversed [7,9,10]. *

\*They are cold temperamental persons with characteristics such as cold fingers, high weakness and malaise, low vitality, low thirst and sweating, softened speech and deeds. While, warm temperamental persons have characteristics such as warm fingers, feeling of more heat, energy, thirst and sweating, more and faster speech and activity and tolerate cold better than heat [7,9,10]. Some of these symptoms are matched with thyroid dysfunction.

### Selection of participants

In order to select people to participate in the study, an informed consent will be published and distributed among the students in the dormitories of Tehran University of Medical Science. Furthermore we will inform those who wish to participate in the study and explain to them the theme of this study by means of cell phone and also by contacting the clinic coordinators.

With regard to the inclusion and exclusion criteria, those who will agree to participate in the study will sign the informed consent and those who will not agree to participate will be excluded from the study. According to a prepared questionnaire, the participants will be randomly divided into groups.

### Selection criteria

#### Inclusion criteria

- Within the age limit of 18 to 40 years
- Being in good health and not suffering from any disease, according to the history and physical examination.
- Willingness to cooperate

#### Exclusion criteria

- Having any disease.
- The use of specific dietary patterns such as vegetarianism.
- Having a body mass index outside the normal range (BMI  $\geq$  25, BMI  $<$ 18.5).
- The use of any medications or supplements in the past month.

### Criteria for withdrawal from the study

- Allergic or non-allergic reaction to Thyme or Sumac
- Noncompliance of participants
- Record of any adverse events

### Sample size

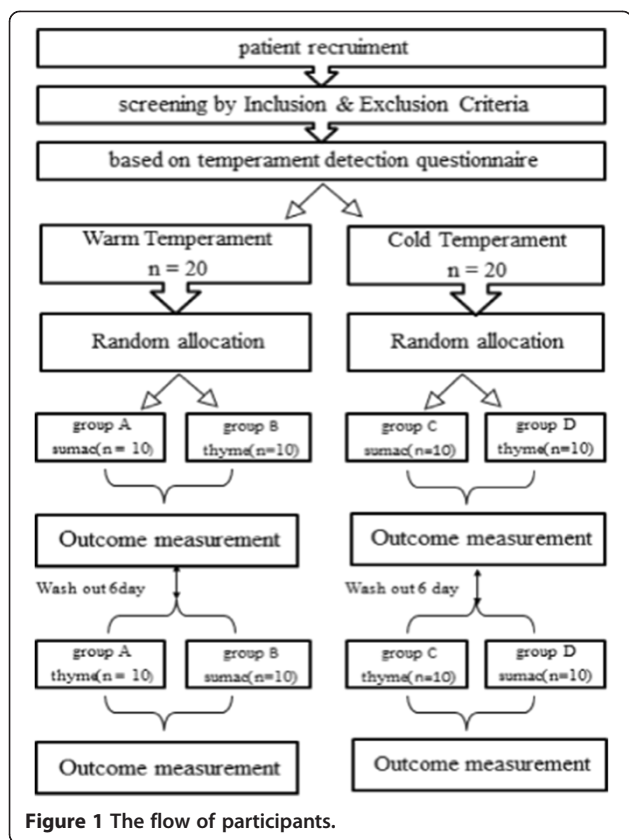
In order to calculate the sample size, we will assess many variables such as BMR, TEF, and sympathetic-parasympathetic activity between cold and warm temperament individuals. The maximum sample size will be calculated based on the base of BMR and determined the number of samples in each subgroup, so that the null hypothesis will be rejected if the average range of BMR after the intervention is 10% [12,13]. Calculations will be performed using 80% power, a 5% significance level, and a 25% dropout rate. The required sample size will be approximately 10 participants for each subgroup. We will plan to enroll 20 participants in each of the two groups, allowing a 25% withdrawal rate.

### Validity of questionnai

For detection of the temperament of participants, a questionnaire will be used that is reliable and validated by Mojahedi M et al. in a school of traditional medicine in Shahed University of medical science [14]. Then, by using this questionnaire the participants will be divided in to two groups of cold and warm temperament.

### Treatment protocol

In the first stage, participants were divided into two groups, i.e. warm and cold temperament. These two groups will be then further divided into two subgroups



**Figure 1** The flow of participants.

randomly. One category will receive Thyme while the other will receive Sumac. After this, they will be given a six-day wash out period, and then the food will be crossed over to the other group such that the receiver of Thyme will receive Sumac and the receiver of the Sumac will receive Thyme. At the end of the study a balanced and steady diet will be given.

### Interventions

For food substance selection, we consider some criteria such as components of food, toxicity, availability, price, history of previous studies, daily consumption, amount of macronutrients, low species diversity and consensus about its temperamental characteristics from a traditional medicine point of view.

According to the above criteria, in the first step some foods are selected including Thyme, Oregano, Cinnamon, Saffron, Ginger, Cumin, Fennel Flower, Psyllium, Barberry, Sumac, Chicory and Coriander, then in the second step Sumac and Thyme are selected.

### Thyme (*Zataria multiflora* Boiss)

Thyme belongs to the laminaceae family that is grown in the Mediterranean areas and some parts of Asia such as Iran. Thymus is used in medical, food, health and cosmetics industries. Iranian Traditional Medicine (ITM)

thyme is considered a warm tempered food [15,16]. There are no studies concerning the dose of thyme for the evaluation of its thermic effect. But with regards to recommended doses of thyme in ITM sources, the amount of thyme in our study will be 5 grams [17,18]. It is an alcoholic extract in one capsule, and will be given to participants with 250 cc of water at per dose [15].

### Sumac (*Rhuscoriaria*)

Sumac belongs to the anacardiaceae family and it is consumed as a diet in Canary Islands, Atlantic Ocean, Persia and Afghanistan. Nowadays, Sumac is widely used as a spice, because many studies have reported the nutritional value of Sumac as an antioxidant and also food preservative [19-23]. There are no studies concerning Sumac's dose for the evaluation of its thermal effect. But with regard to its recommended doses in ITM sources, the amount of Sumac given in our study will be 1 gram [17,18], it is an alcoholic extract contained in one capsule, which will be given to participants with 250 cc water.

### Outcomes of measurement

In the first step, after dividing participants into two groups of warm and cold temperament, some variables including height, weight, central and peripheral body temperature, systolic and diastolic blood pressure and heart rate will also be measured. Further, BMR and body composition will be measured by indirect calorimetry and Bioelectrical Impedance Analyzer (BIA) respectively and biochemical assay (including measurement of serum levels of adrenaline, noradrenalin, cortisol, T3, T4, TSH, insulin, FBS and CBC-with differentiation and blood group) will also be tested. A food frequency questionnaire (FFQ) and 24 hour dietary recall will be completed in order to assess dietary intake and intake of warm or cold food temperament by both of groups.

In the second stage, subjects will receive intervention (including Thyme or Sumac). Pre-intervention and within 4 hours after intervention, at the half-hour intervals will be measured BMR, central and peripheral temperature, heart rate, and systolic and diastolic blood pressure.

In addition, before and at the end of the intervention, two blood samples will be taken from participants in order to measure levels of adrenaline, noradrenalin and cortisol.

### Method of measurement primary outcome

There are different methods for measuring energy expenditure at rest and the thermic effect of food. Indirect calorimetry is one of the most practical ways of measuring it.

In this method, the amount of energy consumed will be measured by measuring the utilization of oxygen and the production of carbon dioxide by the body at a specific time. Accordingly, BMR and the TEF will be measured using indirect calorimetry. The metabolic rate will



be measured at the baseline and then after every half hour up to four hours. In order to control the factors affecting a person's metabolic rate, the participants will be recommended to avoid any food especially coffee and cigarette 12 days before the test. Before performing indirect calorimetry, the participants will be made to rest for 10 and 20 minutes. Participants will be advised to avoid moderate and severe aerobic or anaerobic activity 2 and 14 hours before the test respectively. During this test the room temperature will be maintained at 20- 25°C. Each individual's physical state during and after the test will be maintained in a constant position.

#### **Method of measurement in the secondary outcome**

The demographic characteristics of the participants such as height, weight, vital signs (including central and peripheral body temperature, systolic and diastolic blood pressure and heart rate) and body composition (by BIA) will be measured. Vital signs of every person during the intervention will be measured after every half an hour up to four hours.

Serum levels of adrenaline, noradrenalin, cortisol, T3, T4, TSH, insulin, FBS and CBC-diff and blood group will be measured at the beginning and the end of the study. Amount of dietary intake of warm or cold temperamental food will be evaluated by the food frequency questionnaire where the 24-hour dietary recall will be also discussed.

#### **No risk for participants**

Physical examination of all participants will be conducted by a physician. Any participant suffering from any disease in the history taking or examination will be excluded and referred to the doctor for therapy. Furthermore, if the initial tests of the participants such as complete blood cell count (CBC), serum glucose, thyroid function tests and serum levels of adrenaline, noradrenalin and cortisol are abnormal, they will be excluded from our study. The Thyme and Sumac dose, that will be administered, will have no side effects and complications in healthy people [18]. However, the participants will be controlled during the intervention and if they have any changes in vital signs or any other problems, they will be referred for medical attention.

#### **Data collection and analysis**

In the first step of this study, basic information will be collected i.e. Personal & Demographic Information, by using a questionnaire and baseline body composition. Also we will complete the other information including temperament diagnosis, register food recall and FFQ, by questionnaire. Results of variables including the BMR and biochemical indicators will be recorded after intervention. All obtained information will be kept in separate files for statistical analysis.

#### **Ethical considerations**

- Thyme and Sumac administration within the prescribed dose in healthy subjects will not cause problems [18], however, participants will be regularly checked and if any problem occurs, it will be evaluated by the researcher.
- If anyone has problems due to the Thyme and Sumac dosage, they will be excluded from the study.
- All subjects will be informed through a written consent form and sufficient information about this study will be given to them.
- Participants will not pay any fee for Para clinical measures and their information will be kept confidential. If they do not want to continue co-operating in the study, they will be removed.
- This study was approved by the Tehran University of Medical Sciences ethics committee bearing code number 90-04-27-15366-55307.

#### **Discussion**

Need for energy is one of the most essential principles in the science of nutrition and medicine. It is established fact that energy is required for respiratory and circulatory activities, central nervous system, the synthesis of organic compounds, to maintain equilibrium of ions across the cell membrane, maintain body temperature, digestion, absorption, metabolism and physical activities. Since food plays a vital role in the sustenance of physiologic processes and in the prevention and treatment of diseases, thus a better understanding about better nutrition would help maintain and enhance health.

The use of traditional medicine and medicinal plants has been given attention to, as one of the objectives of the World Health Organization's (WHO) "global strategy of Health for All by 2000". Subsequently, the WHO has advised its member states to include traditional medicines and medicinal plants as part of their national drug policies [24].

Today, because of the side effects, high costs and low efficiency (in some cases) of modern medicine, there is a greater tendency to use traditional, complementary and alternative medicine among people. In Iranian Traditional Medicine (one of the oldest schools of traditional medicine) temperament is one of the basic concepts of health and disease. In this view, there is a strong relationship between nutrition and temperament, in a way that individuals can have various nutritional needs and these differences are related to differences in the type of food temperament. Furthermore, it is understood that improvement of the nutritional status is a basic step in the treatment of diseases. Therefore, by explaining the relationship between food temperaments from a traditional medicine perspective by using principles of modern medicine will enable a creation of a new window in nutrition science.

This study is the first study that evaluates the relationship between the individual temperament, the metabolic rate and the relationship between food temperament and some of the chemical, hormonal and functional factors of the body. We will discuss in detail the collection of data and appropriate methods for measuring body composition, BMR and biochemical variables, we will also provide an appropriate questionnaire to determine individual temperament.

We believe that the results of our study might be able to explain the relationship between food temperaments from the perspective of traditional medicine by using modern medicine principles; and would be creating a new window in nutrition science. In the event that a relationship could be demonstrated in this study, it could also be a step in the improvement of health.

#### Abbreviations

(TEF): Thermic Effect of Food; (AT): Activity Thermo genesis; (BMR): Basal Metabolic Rate; (ITM): Iranian Traditional Medicine; (BIA): Bioelectrical Impedance Analyzer; (FFQ): Food Frequency Questionnaire; (CBC): Complete Blood Cell count; (WHO): World Health Organization.

#### Competing interests

The authors declare that they have no competing interests.

#### Authors' contributions

GMF carried out the design of the study, performed the statistical analysis and drafted the manuscript. ADM conceived the study, participated in the design and statistical analysis of the study, and approved the final manuscript. SH, MN and MY participated in the study design. TMF participated in coordination of the study and assisted to draft the manuscript. MM also participated in its design, coordination and draft of the manuscript. AAS participated in the study design, and MKN participated in the study design and the statistical analysis. All authors approved the final manuscript.

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#### Author details

<sup>1</sup>School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Tehran, Iran. <sup>2</sup>School of Traditional Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran. <sup>3</sup>Department of Environmental Health Engineering, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran. <sup>4</sup>Student School of Advanced Technologies in Medicine, Tehran University of Medical Sciences, Tehran, Iran. <sup>5</sup>Associate Professor of Biochemistry, Department of cellular and molecular Nutrition, School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences, Tehran, Iran. <sup>6</sup>Department of Pharmacognosy, School of Pharmacy, Shahid Beheshti University of Medical Sciences, Tehran, Iran. <sup>7</sup>Noorafshar Rehabilitation and Sports Medicine Hospital, Tehran, Iran. <sup>8</sup>Iranian Traditional Medicine Clinical trial Research Center, Shahed University, Tehran, Iran.

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