

## Study Protocol

### **A Protocol on Comparative Evaluation of Efficacy of *Prakriti* Based *Pathya-Apathya* with routine diet in Healthy Children to assess its Future perception towards diseases to prevent and treat morbidities-A Randomized Clinical Trial**

#### **Abstract:**

**Background:** *Prakriti* is a term that refers to an individual's inherent behavioural tendency. *Acharyas* have outlined many dos and don'ts for maintaining a person's excellent immunity and health, such as *Ritucharya* (seasonal routine), *Dinacharya* (dietary regulations), and so on. *Pathya* (healthy) and *Apathya* (unhealthy) are two ideas that are equally essential in the treatment of illnesses. **Objectives:** To Study *Prakriti* analysis as per systematic protocol (C-DAC) and its perception towards different diseases. To assess the impact of *Pathya-Apathya* concept to prevent morbidity status in adolescent. **Materials and Methods:** 12-16 years age group adolescent of nearby CBSE schools from MGAC will be selected *Pathyapathya* intervention will be given and study its perception towards different diseases prevention. **Result:** To summarise categorical variables such as gender, religion, education, *Ahara*, *Vihara*, and various participant complaints, frequency and percentages will be utilised. Subjective and objective criteria will be used to calculate the percentage of alleviation. The difference in results before and after intervention in this group will be observed, and the results will be presented using statistical data. **Conclusion:** If this *prakriti* wise *pathya* concept will be significantly efficacious then so many diseases can be prevented which is a need of the hour.

**Keywords:** *Pathyapathya*, *Prakriti*, *Ritucharya*, *Dinacharya*, *Ahara*, *Vihara*, disease/morbidity prevention

#### **BACKGROUND& RATIONALE-**

*Prakriti* is a term that refers to an individual's inherent behavioural tendency. *Ayurveda* is an ancient health discipline that explains the notion of **Tridosha** and *Prakriti*, as

well as dealing with numerous body metabolic pathways and chronic illnesses.<sup>1</sup> The *Tridosha* is a way of comprehending health and sickness that is central to *Ayurveda's* fundamental beliefs.<sup>2</sup> According to *Charaka Samhita*, the idea of *Tridosha* is a key premise of *Ayurveda*.<sup>3</sup> With the participation of external circumstances, **Prakriti is determined at the moment of conception and remains constant throughout life, as well as the mother's eating habits and lifestyle**(reframe the sentence) According to the realm of each *dosha*, different combinations of *Vata*, *Pitta*, and *Kapha*, *Prakriti* is categorised and will be unique to each. The sort of *Prakriti* (unique constitution) that an individual possesses determines susceptibility to certain illnesses.<sup>4</sup> As a result, evaluating the *Prakriti* analysis not only aids in understanding the patient's physical and mental condition, but it also plays a key role in the prognosis, diagnosis, treatment, and prevention of many complicated disorders<sup>5,6</sup>.

### **Concept of Pathya-Apathya: -**

The **ancientseers** detailed many do's and **don'ts** in order to preserve a person's immunity and health, such as *Ritucharya*, *Dinacharya*, and so on. One of the ideas that is equally essential in the treatment of illnesses is *Pathya* (healthy diet) and *Apathaya* (unhealthy food).<sup>4,5</sup> The *Ayurvedic* notion of *Pathya* (wholesome diet) and *Apathaya* (unwholesome diet) is unique. The name *Pathya* comes from the root word "*Patha*," which means "way or channel" in English. *Pathya* and *Apathaya* are described as drugs or regimens that do not have a detrimental impact on the body and psyche (healthy) *Apathaya* is the term for people who have a negative impact on them.<sup>5</sup> As can be seen from the definition mentioned above, *Pathya* and *Apathaya* refer to both material items and precise routines, but in *Ayurvedic* literature, these terms have come to refer specifically to meals.<sup>7</sup>

[reframe the complete paragraph, the words pathya and apathaya are appearing multiple times disturbing the flow of the reader]

### **Need of Study:**

The purpose of this study is to determine the morbidity status of adolescent aged 12 to 16. Childhood disease morbidity and mortality have been a serious problem across the world. Dengue, Malaria, respiratory infections, and diarrheal illnesses are the most common causes of morbidity and death in adolescent. In *Ayurveda*, there is a concept of *Pathya* and *Apathaya* in relation to *Ahara* and *Vihara*. According to *Acharya Charka*, eating wholesome food is one of the causes of human growth and wellness, whereas eating unwholesome food is the source of all illnesses<sup>7-8</sup>. As a result, in order to avoid early morbidity in infants, this idea

required to intervene in order to establish Ayurveda as an evidence-based medicine concept. So, with the intervention of *Pathya* and *Apathya*, attempt will be made to find out the association of *Prakriti* based morbidity as well as determine the efficacy of trial group intervention as modified prakriti opposite diet (ahar) and routine actions (Vihar) in prevention of diseases within short duration of three months.

### **Research gap Analysis:**

1. In Kashyap Samhita it is given that Ahar is the great medicine- '*Mahaushadh*'<sup>9</sup>.
2. Children are more prone to any infections due to less immunity.
3. Ayurved focuses on prevention than cure of any disease.
4. Prakriti focuses on their possibility of probable diseases and hence prakriti based Ahar is undertaken as an intervention.
5. As children do not like to take medicine so to maintain the *ahar* as opposite to their prakriti will enhance their immunity.
6. Pathyapathya as an intervention has the ability to prevent and treat their common problems in day today life<sup>7-9</sup>.
7. No such study has been carried out till date with *Prakriti based Pathyapathya* kind of intervention in children.

### **Research Question:**

1. Is there significant association of *Prakriti* and *Pathya-Apathyato* prevent and treat morbidities in children?

### **Aim: -**

Comparative Evaluation of Efficacy of *Prakriti* Based *Pathya-Apathya* with routine diet in Healthy adolescent to assess its Future perception towards diseases to prevent and treat morbidities-A Randomized Clinical Trial.

### **Objectives:**

1. To Study *Prakriti* analysis tool as per systematic protocol (C-DAC<sup>10</sup>) and its perception towards different diseases.
2. To assess the impact of *Pathya-Apathya* concept to prevent morbidity status in adolescent by different scales such as Musculoskeletal Health Questionnaire (MSK-HQ)<sup>11</sup>, Gastrointestinal (GI) Health Assessment,<sup>12</sup> Questionnaire on Respiratory

Symptoms<sup>13</sup> as a subjective parameters CBC, RBS & Sr.calcium, Sr.protein as objective criteria.

3. To determine the efficacy of *Pathya-Apathya* to treat common ailments of adolescent seen during study period in participants of 12-16 years as per above mentioned subjective and objective criteria.
4. To aware and educate adolescent of 12-16 years age regarding their *Prakriti* based probable morbidities in future to prevent in advance by adopting the general guideline related to diet which will be **remained same** for all groups of the study.

### **Hypothesis**

**Null Hypothesis:** There is no significant difference ( $p>0.05$ ) in *Prakriti* and *Pathya-Apathyain* order to prevent and treat morbidities in children.

### **Alternative Hypothesis:**

There is significant difference ( $p<0.05$ ) in *Prakriti* and *Pathya-Apathyato* prevent and treat morbidities in children.

### **METHODOLOGY:**

**Data collection methods-**12-16 years age adolescent of nearby CBSE schools from MGAC, General materials *Pathyapathya* will remain as intervention instead of drug to check its efficacy.

**Source of Data & place of study:** Nearby CBSE schools from Mahatma Gandhi Ayurvedic College

### **Statistical Methods:**

The information will be entered into a Microsoft Excel spreadsheet. STAT, Version 10.1, 2011 statistics software will be used to analyse the data. Gender, *Ahara*, *Vihara*, various participant complaints, and other categorical data will be summarised using frequency and percentages based on subjective and objective criteria. Chi Square test, ANOVA test, student t test, and co relation will be used to evaluate whether there is a positive or negative co connection between variables. The level of significance will be set at 5%.

### **Study instrument / Data Collection tools**

**Trial design-** Randomized comparative study

**Type of Study:** Interventional study.

**Sampling procedure:** Stratified sampling method to have same *Prakriti* participants in each group.

**Trial duration - 18 months**

**Participant timeline: 3 months (90 Days)**

**Allocation (Sequence generation) - Computer-Generated Randomization**

**Data collection tools and process:**

A Survey will be conducted with prior permission from school authority and parents among school adolescents of age between 12 to 16 years. It will be pre discussed in parent teacher meet with power point presentation to aware about prevention of morbidity with the help of dietary modifications. *Prakriti* analysis will be done with the help of ‘C-DAC prakriti vichay’ AYU SOFT Software<sup>10</sup>. Accordingly, participants and parents are advised to follow this intervention.

**Intervention:** It will be advised to main and sub-groups for minimum three months.

**Primary Outcome-** *Prakriti* Based Pathya-Apathya with routine diet to assess its future perception towards diseases to prevent and treat morbidities.

**Secondary Outcome -** Awareness regarding future perception towards diseases to prevent and treat morbidities.

**Sample Size:** -Total 200 adolescents will be enrolled in this study including 10 % drop out rate which will be divided into 100 in each group with at least 30 in each three sub-groups dominating with Vata, Pitta & Kaphadwandwaj prakriti

**Grouping:** Group R-control-Routine diet & Group P-Trial group-pathya as prakriti opposite diet which will be sub-divided into 3 subgroups as shown in table no 1 & 2

**Table no 1 showing Group R: - Control group (dwandwaj prakriti healthy adolescents will be receiving routine diet as blank control intervention)**

Sr. no	Dosha	Control	Sample size in each sub-groups
1	Vata-pitta dominant- Musculo-skeletal scale	Routine diet	30
2	Pitta-kapha dominant- GI scale	Routine diet	30
3	Kapha-vata dominant- Respiratory scale	Routine diet	30

**Table no 2 showing Group P: - Trial group (Dwandwaj prakriti healthy adolescents will be receiving Prakriti opposite diet-Pathya as intervention)**

Sr. no	Dosha	Intervention	Sample size in each group
1	Vata-pitta dominant-Musculo-skeletal scale	Prakriti opposite diet	30
2	Pitta-kapha dominant-GI scale	Prakriti opposite diet	30
3	Kapha-vata dominant-Respiratory scale	Prakriti opposite diet	30

### Eligibility (Inclusion) criteria

1. Healthy adolescent of age between 12 to 16 years,
2. Recent common but **cured** illness like cough-cold
3. Parents who are willing to give consent for this study.

### Exclusion criteria

1. Parents who do not allow their adolescent to participate in the study and
2. Who are suffering with morbidity.

**Screening method-** History taking and Ayurvedic diagnostic methods with clinical Examination to confirm health status as screening tools for pre-intervention

### Subjective criteria

1. *Prakriti* Analysis tool Ayusoft-CDAC software
2. Musculoskeletal Health Questionnaire (MSK-HQ)
3. Gastrointestinal (GI) Health Assessment
4. Questionnaire on Respiratory Symptoms

### Objective criteria -

1. Morbidity Score will be calculated by using the following formula<sup>12</sup>  
Morbidity Score= Incidences (last 3 months) × Severity
2. CBC
3. RBS
4. Serum calcium
5. Serum protein

### Trial design Flow chart

School survey and counselling to parents in Parent-Teacher meeting about this interventional study



Duly signed & informed consent form will be taken from parents of adolescent who are ready



Subjects are screened based on their baseline evaluation and inclusion and exclusion criteria.



Grouping, randomizationallocation, during study and post study Follow up



Observation



Statistical analysis & Conclusion

**Investigations:**

CBC, RBS, Sr.Calcium, Sr protein (as objective criteria) will be done in 15% samples per group.

**Consent/ Assent Form:** Informed consent will be obtained from the /parents/guardians prior to the start of clinical trial.

**Follow up** –3 follow up during intervention and 3 post on monthly basis.

**Observation and results:**

Data will be derived with the help of prakriti opposite dietary modifications as guided in group P whereas general *Pathya* and *Apathya* will remain same for both the groups adolescents.

**General Pathya and Apathya:**

Healthy people should constantly take certain food items, according to *Acharya Charka*. *Shashtika* (rice variety), *Shali* (rice variety), *Mudga* (*Phaseolus radiatus* Linn.), *Saindhav*, *Amalaka* (*Emblica officinalis* Gaertn.), rain water, *Ghee* (clarified butter), meat from arid-climate animals, and honey are among the foods mentioned<sup>14</sup>. In the same way, *Acharya Charka* has mentioned several foods that healthy people should avoid. dried meat, dried vegetables, lotus rhizome, and stalk are examples of such dietary items, and sick animal meat should never be consumed<sup>15</sup>.

**General guidelines regarding Ahara<sup>16,17</sup>:**

1. Quantity of food should be appropriate and as per one's hunger.
2. Participants will be advised about *Hitabhashi* (wholesome diet, with proper chewing, not to be very slow or fast or other task like watching TV, chatting etc), *Mitabhashi* (not to have water much (1 cup only) in the diet, should consume slightly less than actual

capacity for good digestion with proper chewing is not be very slow or fast engaged with other task etc like, chatting, tv watching).

3. All participant is advised to take *Ushapan* early in the morning and the water can be taken as per *rutu i.e., sheet, ushna* etc.
4. It is also advised to have a cup of buttermilk with cumin seed and milk at night.

**Table 3: Daily Pathya Advised Ahar(Diet) and Vihar<sup>15</sup>**

Particulars	Vataprakriti	Pittaprakriti	Kaphaprakriti
<b>Breakfast (Time 8.00 am)</b>	Upama, Paratha, Halawa Fruits includes Anjir, Awla, Banana, Apple, Barley oat, banana, Cow Milk, Camel milk, Curd, Butter mik, Egg, Papaya, Sweet potato, Carrot, Turnip, Goose berry jam, Date palm, Fig, Pomegranate, Mango, Orange juice, Coconut, Pear juice, Guava, Cherry plum, Mulberry, Watermelon, Musk melon, Wood apple, Current, Kasheu nut, Almond, Wallnut, Pea nut, Pistachio soft	Upama, Halawa, Goat milk, buffalo milk, cow milk, Multi grain as Paratha with less spicy, Fruits includes Angur, Anjir, Awla, Guava, Water chaste nut, Manuka, Barley oat, Milk, butter milk, Aloe vera juice, cucumber, Sweet potato, Turnip, Goose berry jam, Date palm, Fig, Pomegranate, Coconut, Coconut water, Pear juice, Guava, Blackberry, Mulberry, Custard Apple, Netted Custard Apple, Musk melon, Wood apple, Rasin, Current, Alomnd, Fox nut, Pistachio soft, Honey	Poha, jwar roti, Bajra roti, Camel milk, Finger millet, jamun, manuka, Aloe vera juice, Papaya, Carrot, Turnip, Goose berry jam, Date palm, Fig, Pomegranate, Pear juice, Blackberry, Water melon, Wood apple, Rasin, Kasheu nut, Pea nut, Honey
<b>Lunch (11.00 am)</b>	Chapati, Wheat Roti, Shastishali Rice, Mung Dal, Black gram, Sweet halwa, Sewai in Milk, less spicy chicken, Mutton, Fish, Soya been, Methi, Gobhi, Lemon pork meat, Pumpkin, Snake guard, cucumber, Dry Jujube,	Chapati, Wheat Roti, Shastishali Chawal, Mung Dal, masur dal, Sweet, mutton, Fish, Palak, Butter milk, Reddish, Choulai, Turai, Bhendi, karela, Bengal gram leaves, Pumpkin, bitter guard, ridge guard, Banana,	jwar roti, Bajra roti, Rice, masur dal, Eggs, Mutton, Palak, Gobhi, Choulai, Reddish, karela, Pumpkin, Gaurad, Whiregurad,

	Monkey fruit, old ghee, Jaggery, Old jaggery, Sugar, Sesame oil, Mustard oil, Linseed oil, Peanut Coconut oil, Rock salt, Black salt, Common salt	Drumstick, Monkey fruit, Lemon Old ghee, Old jaggery, Sugar, Coconut oil, Rock salt	cucumber, Drumstick, Lemon, Old ghee, Sesame oil, Mustard oil, Rock salt
<b>Dinner (7.00 pm)</b>	Chapati, Wheat Roti, Shastishali Chawal, Mung Dal, gajar, Black gram, Sweet Shira, Mutton, Fish, Soya been, Methi, Pointed gourd, Garlic, Onion, Khichadi with smooth ghee	Chapati, Wheat Roti, Shastishali Chawal, Mung Dal, masur dal, Sweet, Fish, Mutton, Bitter guard, Pointed gourd, Brinjal, Round melon, Cluster bean, Khichdi with ghee	jwar roti, Bajra roti, Rice, Masur dal, Gajar, Eggs, Mutton, Bitter guard, Pointed gourd, Brinjal, Round melon, Yam, Garlic, Khichadi

**Table 4: Daily Apathya Advised Ahar(Diet) and Vihar**

Particulars	Vataprakriti	Pittaprakriti	Kaphaprakriti
<b>Breakfast (Time 8.00 am)</b>	Poha, fast food, Burger, pizza, noodles, Packed junk food, besan, maida oily food	Salty food, sour, pickle, chutney, colored beverages, packed fast food pizza, chinese, Spicy oily, fried food	Ice cream, cold drinks, halwa, sweets, diary food, stuff.
<b>Lunch (11.00 am)</b>	Bread, pav, bhaji, biscuits	Bread pav, Noodles, chicken spicy, fried	Cheese, cold items, sweet, santarpakGuruahar,
<b>Vihar</b>	Diwaswap, Hurry, exertion	Stress, strain, hurry, worry	Laziness, diwaswap, sedentary lifestyle

**Table 5: Pathya-Apathya<sup>18</sup>**

**A) Vata dominant Prakriti**

	Varga	Pathya	Apathya
<b>Ahaar</b>	<i>Shuka Dhanya</i>	<i>Raktashali, ShastikaGodhuma, Jwar</i>	<i>Yavaka</i>
	<i>ShamiDhanya</i>	<i>Mudga, Masura, Mangalya, Aadhaki, Soyabeen</i>	<i>Masha</i>
	<i>MansVarga</i>	<i>Rohit Matsya, Mutton</i>	<i>Chicken</i>

<b>PhalaVarga</b>	Seasonal fruits like Anjir, Angur, Khajur, Guava, Apple, Narikel	Nikucha (Atrocarpuslakoocha)
<b>Gorasavarga</b>	Go dugdha, Aja dugha, MahishaDugdha, Go-Ghee, Takra, Navneeta, Paneer, Cheese	Avi(sheep) Dugdha, Aavika

**B) Pitta dominant Prakriti ahara:**

	<b>Varga</b>	<b>Pathya</b>	<b>Apathya</b>
<b>Ahara</b>	<b>ShukaDhanya</b>	Raktashali, ShastikaGodhuma,	Yavaka
	<b>ShamiDhanya</b>	Mudga, Masura, Mangalya, Aadhaki,	Masha, Tuwar dal
	<b>Mansa Varga</b>	Rohit Matshya,	Go mansa, Chilchim fish, Chicken, Eggs
	<b>PhalaVarga</b>	Seasonal fruits like Dry plum(ber), Khajur, Musk melon, Apple, Jujube, rasin, Fig, pomegranate	Nikucha (Atrocarpuslakoocha), banana, coconut citrus, fruits.
	<b>Go rasa varga</b>	Go dugdha, Aja dugha, MahishaDugdha, Go-Ghee, Takra,	Avi(sheep) Dugdha, Aavika, Dadhi

**C)Kapha dominant Prakriti**

	<b>Varga</b>	<b>Pathya</b>	<b>Apathya</b>
<b>Ahara</b>	<b>ShukaDhanya</b>	Raktashali, Yava	,ShastikaGodhuma
	<b>ShamiDhanya</b>	Mudga, Mangalya,	Masha,
	<b>Mansa Varga</b>	Rohit Matshya, Chicken, Eggs	Go mansa, Chilchim fish,
	<b>PhalaVarga</b>	Seasonal fruits like pea nut, fox nut, kashue nut	Nikucha (Atrocarpuslakoocha), banana, Dadima,
	<b>Gorasavarga</b>	All can be taken except and Aja, Avi, Dugdha, Dahi, Mahish	Avi(sheep) Dugdha, Aavika, Dadhi, Ajudugha, MahishaDugdha,

To summarise categorical variables such as gender, religion, education, Ahara, Vihara, and various participant concerns, frequency and percentages will be utilised.

Subjective and objective criteria will be used to calculate the percentage of alleviation and result will be drawn after statistical analysis of all observations of both the groups.

### **Discussion:**

Prakriti is an important tool to not only prevention of disease but also helpful in diagnosis, prognosis and treatment<sup>6,19</sup>. Adolescent is more sensitive to illness because their immune systems is still in developing stage with sudden hormonal change, making them more likely to become sick. Adolescent may suffer from immunodeficiency due to differences in age, race, genders; which might cause the respiratory and gastrointestinal systems to get engaged in recurring infections<sup>20</sup>. Health is maintained by proper nutrition and diseases are also produced by food; happiness and unhappiness depend on the use of suitable and unsuitable foods respectively.

No medicine is equivalent to food. It is possible make person diseases free with just proper diet. Prakriti based immunity boosting diet may prevent future diseases to much extent as per recent studies<sup>21-25</sup>. Covid like infections have promoted deep faith in the society towards dietary instructions, routine actions and Ayurveda too. This research will aware and educate in the discovery of variables that cause disease as well as ones that improve immunity and reduce morbidity in adolescent. As Ayurveda promotes, studies on customised treatment on different areas can be undertaken. Because adolescent's immune system is still at young stage, morbidity can be reduced by the use of *Pathya Ahara*, *Vihara*. After *Prakriti Parikshana*, the *Pathya*, *Apathya* paradigm would be utilised as clinical practise in individual medicine. The study's findings would be used in public health programmes as policy recommendations if found highly significant.

### **Summary:**

The difference in results before and after intervention in this group will be observed, and the results will be presented using statistical data. The entire investigations will be summarized in the results and discussion of dissertation. At the end of the trial, conclusions will be drawn based on statistical analysis, symptom alleviation, and medication effects on numerous parameters.

### **Scope and Implications of the proposed study:**

**Scope:** *Dinacharya* (Diurnal regime) and *Ritucharya* (Seasonal regime) are recommended in Ayurveda, as well as different *Pathya-Apathya Ahara* and *Vihara*, based on *Prakriti*. These regimens can be followed according to *Prakriti*'s needs in order to maintain the body healthy and the *Dosha* in balance. For example, *Kapha Prakriti* people require more exercise and

*LaghuAhara* to stay in shape, and they should avoid *Divaswapna*, whereas *VataPrakriti* people should eat more nourishing and heavier foods, exercise less, and perform *Divaswapna*.

Further, each individual's *Prakriti* and health can be maintained by promoting *PathyaAhara* (favourable foods and drinks) and *Vihara* (behaviour and physical activities) while simultaneously discouraging *ApathyaAhara* (unfavourable foods and drinks) and *Vihara* (unhealthy behaviour and physical activities) (Behavior and physical activities). As a result, it is possible to preserve excellent health in adolescents and minimise morbidity associated with numerous illnesses.

**Conclusion:** If this prakriti wise pathya concept will be significantly efficacious then so many diseases can be prevented which is a need of the hour.

### **Ethics and dissemination**

**Research ethics approval** – Yes Approved, REF- MGACHRC/IEC/JULY-2021/354

Registered in CTRI, number is awaited

### **NOTE:**

*The study highlights the efficacy of " Ayurveda," which is an ancient tradition, used in some parts of India. This ancient concept should be carefully evaluated in the light of modern medical science and can be utilized partially if found suitable.*

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