

Study Protocol

A Protocol RCT on Comparative Evaluation of Efficacy of *Prakriti* (Unique Constitution) Based *Pathya-Apathya* with routine diet in Healthy Children to evaluate its Future observation towards diseases to prevent and treat morbidities

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*, *Ahara*, *Vihara*, disease, morbidity prevention etc.

BACKGROUND& RATIONALE-

Prakriti is a term that refers to an individual's inherent behavioural tendency. *Ayurveda* is an ancient health discipline that explains about the *Prakriti*, as well as dealing with numerous body metabolic pathways and chronic illnesses.¹ The *Tridosha* is a way of comprehending health and sickness that is central to *Ayurveda's* fundamental belief.² According to *Charaka Samhita*, the idea of *Tridosha* is a key premise of *Ayurveda*.³ According to the *dosha*, different combinations of *Vata, Pitta, and Kapha, Prakriti is categorised and will be unique to each individual*. The sort of *Prakriti* that an individual possesses determines susceptibility to certain illnesses.⁴ As a result, evaluating the *Prakriti analysis* not only 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^{5,6}.

Concept of Pathya-Apathya: -

According to *Ayurveda*, *pathya* (proper nutrition and routine) is just as vital as medication. There is no need for medicine if a patient follows a proper diet and regimen. Similarly, there is no need for medication if a patient does not follow a suitable diet and regimen as instructed.⁴ This might be the explanation for *Charaka Samhita's* inclusion of *Pathya* as a synonym for *Chikitsa* (treatment).⁵ In *Ayurveda*, many guidelines recommended such as *Ritucharya-seasonal care, Dinacharya-daily care*, and so on in order to preserve a person's immunity and health. One of the unique ideas that is equally essential in the treatment of illnesses is *Pathya* (healthy diet) and *Apathaya* (unhealthy food)^{4,5}. It is described as drugs or regimens that do not have a detrimental impact on the body and psyche. *Apathya* is opposite to *Pathya*⁵ *Ahara* (diet) is one of the three foundations of the human body; the other two are *Nidra* (sleep) and *Maithuna* (sexual life). When *Vyayama* (exercise), *Vyasana* (addiction), and *Vrutti* are added, *Vihara* (regimen) is formed (occupation).⁶ The metabolic *Agni* transforms *Ahara* (diet) into *Prasada* (essence) and *Kitta* (waste) when it is ingested. These terms have come to refer specifically to meals, refer to both material items and precise routines.⁷

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 *Apathya* 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 illnesses⁷⁻⁸. 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 (*Ahara*) and routine actions (*Vihara*) in prevention of diseases within short duration of three months.

Research gap Analysis:

1. In *Kashyap Samhita* it is given that *Ahara* is the great medicine- '**Mahaushadh**'⁹.
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 *Ahara* is undertaken as an intervention.
5. As children do not like to take medicine so to maintain the *Ahara* 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 life⁷⁻⁹.
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-Apathya* to 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 observation towards diseases to prevent and treat morbidities-A Randomized Clinical Trial.

Objectives:

1. To Study *Prakriti* analysis tool as per systematic protocol (C-DAC¹⁰) 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)¹¹, Gastrointestinal (GI) Health Assessment,¹² Questionnaire on Respiratory Symptoms¹³ 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 for all groups of the study.

Hypothesis

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

Alternative Hypothesis:

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

METHODOLOGY:

Data collection methods- 12-16 years age group 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%.

Ethics and dissemination

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

Registered in CTRI, number is awaited

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) [There is no seasonal diet pattern is mentioned but participants have to follow general pathya/congenial and Apathya/non-congenial diet for the said duration. To develop immunity and transformation of Rasa dhatu to Shukra dhatu requires 90 days period hence, duration of the study is 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 Software¹⁰. 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 & Kapha dwandwaj 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	<i>Pitta-kapha</i> dominant- GI scale	Routine diet	30
3	<i>Kapha-vata</i> 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	<i>Vata-pitta</i> dominant-Musculo-skeletal scale	<i>Prakriti</i> opposite diet	30
2	<i>Pitta-kapha</i> dominant-GI scale	<i>Prakriti</i> opposite diet	30
3	<i>Kapha-vata</i> dominant-Respiratory scale	<i>Prakriti</i> opposite diet	30

Inclusion criteria

1. Healthy adolescent of age & both gender between 12 to 16 years, [As small age group children are moody to follow dietary instructions and adolescent group is mature to follow if counselled properly and they could easily fill up the long questionnaire formats of *Prakriti* as well as different scales of GIT, Respiratory & Musculoskeletal Health Questionnaire (MSK-HQ)]
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.
3. *Ekdoshaja Prakriti* and *Sannipatika Prakriti* [3 dominant Dwandaj *Prakriti* are only available currently, no availability of *ekdoshaj* or *sannipataj Prakriti* in equal proportion]

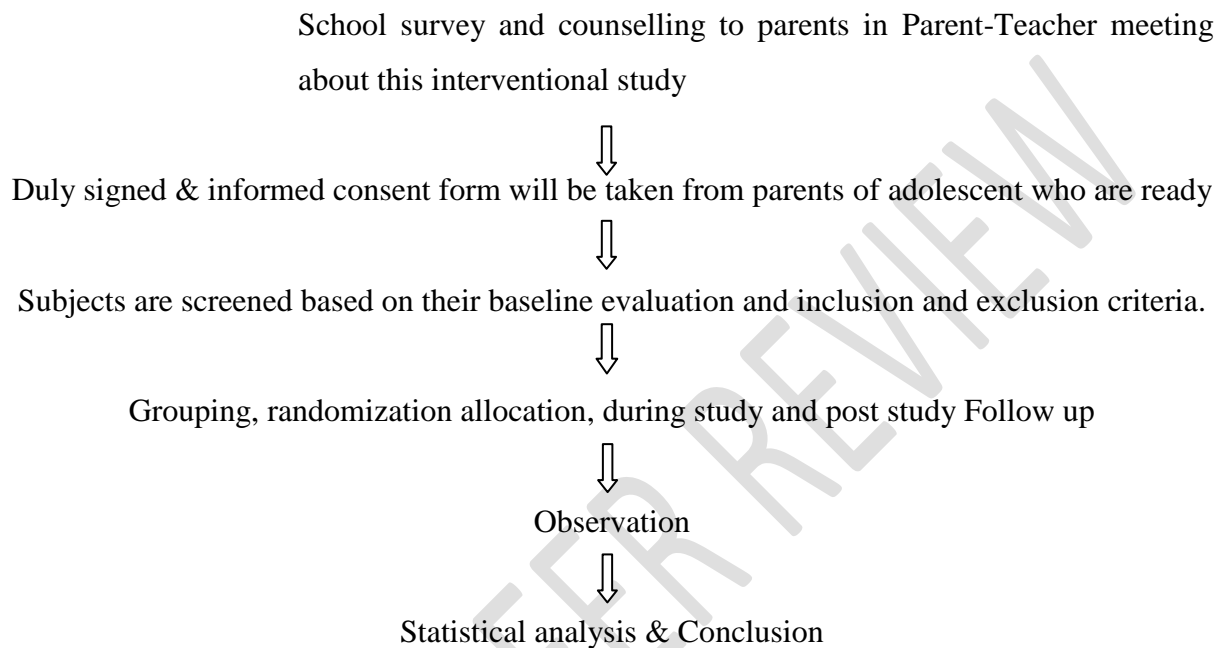
Screening method- History taking and Ayurvedic diagnostic methods with clinical Examination to confirm health status as screening tools for pre-intervention

Subjective criteria

1. *Prakriti* Analysis tool Ayu-soft-CDAC software (Version 1.1.1)
2. Gastrointestinal (GI) Health Assessment
3. Questionnaire on Respiratory Symptoms
4. Morbidity Score will be calculated by using the following formula

Morbidity Score= Incidences (last 3 months) × Severity [Healthy adolescent also come across with minor seasonal ailments so if morbidity occurs, then need to check the efficacy of Prakriti (unique constitution) wise diet in illness as per dominant dosha-Kapha-Respiratory, Pittaj-GIT, Vataj-Musculoskeletal scale]

Trial design Flow chart



Objective Criteria/Investigations –

1. CBC (Complete blood count)
2. RBS (Random Blood Sugar)
3. Serum Calcium

4. Serum Protein (as objective criteria) will be done in 15% samples per group

As healthy children are included in the study plan hence to avoid the cost burden, planned only 15 % participant's investigations pre and post to reflect the whole study population.

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* (*Embllica officinalis Gaertn.*), rain water, *Ghee* (clarified butter), meat from arid-climate animals, and honey are among the foods mentioned¹⁴. 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 consumed¹⁵.

General guidelines regarding *Aharaa*^{16,17}:

1. Quantity of food should be appropriate and as per one's hunger.
2. Participants will be advised about wholesome diet, with proper chewing, not to be very slow or fast or other task like watching TV, chatting etc, *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 *Ahara* (Diet) and *Vihar*¹⁵

Particulars	Vata prakriti	Pitta prakriti	Kapha prakriti
Breakfast (Time 8.00 am)	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, Cherry plum, Mulberry, Watermelon, Musk melon, Wood apple, Current, cashew nut, Almond, Wallnut, Pea nut, Pistachio	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	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, cashew nut, Pea nut, Honey

	soft	Custard Apple, Musk melon, Wood apple, Rasin , Current , Alomnd ,Fox nut, Pistachio soft, Honey	
Lunch (11.00 am)	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, Monkey fruit, old ghee, Jaggery, Old jaggery, Sugar, Sesame oil, Mustard oil, Linseed oil, Peanut Coconut oil, Rock salt, Black salt, Common salt	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, Drumstick, Monkey fruit, Lemon Old ghee, Old jaggery, Sugar, Coconut oil, Rock salt	jwar roti, Bajra roti, Rice, masur dal, Eggs, Mutton, Palak, Gobhi, Choulai, Reddish, karela, Pumpkin, Gaurad, Whiregurad, cucumber, Drumstick, Lemon, Old ghee, Sesame oil, Mustard oil, Rock salt
Dinner (7.00 pm)	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 Ahara (Diet) and Vihara

Particulars	Vataprakriti	Pittaprakriti	Kaphaprakriti
Breakfast (Time 8.00 am)	Poha, fast food, Burger, pizza, noodles, Packed junk food, besan, maida oily food	Salty food, sour, pickle, chutney, coloured beverages, packed fast food	Ice cream, cold drinks, halwa, sweets, diary food, stuff.

		pizza, chinese, Spicy oily, fried food	
Lunch (11.00 am)	Bread, pav, bhaji, biscuits	Bread pav, Noodles, chicken spicy, fried	Cheese, cold items, sweet, santarpak Guru Ahara,
Vihar	Diwa-swap, Hurry, exertion	Stress, strain, hurry, worry	Laziness, diwaswap, sedentary lifestyle

Table 5: Pathya-Apathya¹⁸

A) Vata dominant Prakriti

	Varga/group	Pathya	Apathya
Ahaar	Shuka Dhanya/cereals	Raktashali, Shastika Godhuma, Jwar	Yavaka
	Shami Dhanya/Pulses	Mudga, Masura, Mangalya, Aadhaki , Soyabeen	Masha
	Mans Varga/meat	Rohit Matsya, Mutton	Chicken
	Phala Varga/fruits	Seasonal fruits like Anjir, Angur, Khajur, Guava, Apple, Narikel	Nikucha (Atrocarpuslakoocha)
	Gorasavarga/milk products	Milk, Ghee, buttermilk, Navneet/butter, Paneer, Cheese	Avi (sheep milk) Dugdha, Aavika

B) Pitta dominant Prakriti Ahara:

	Varga	Pathya	Apathya
Ahara	Shuka Dhanya	Raktashali, Shastika Godhuma,	Yavaka
	Shami Dhanya	Mudga, Masura, Mangalya, Aadhaki,	Masha, Tuwar dal
	Mansa Varga	Rohit Matshya,	Go mansa, Chilehim fish, Chicken, Eggs
	Phala Varga	Seasonal fruits like Dry plum(ber), Khajur, Musk melon, Apple, Jujube , rasin, Fig, pomegranate	Nikueha (Atrocarpuslakoocha), banana, coconut citrus, fruits.
	Go rasa varga	Dairy products	Avi (sheep) Dugdha, Aavika, Dadhi milk, curd

C)Kapha dominant Prakriti

Varga/group		Pathya	Apathya
Ahara	<i>Shuka (cereals)</i>	<i>Dhanya Raktashali, Yava</i>	<i>Shastika shali-rice, Godhuma-wheat</i>
	<i>Shami (pulses)</i>	<i>Dhanya Mudga, Mangalya,</i>	<i>Masha/black gram</i>
	<i>Mansa (meat)</i>	<i>fish, Chicken, Eggs</i>	<i>Go meat, Chilehim fish,</i>
	<i>PhalaVarga-fruits</i>	<i>Seasonal fruits like pea nut, fox nut, cashew nut</i>	<i>Nikucha (Atrocarpuslakoocha), banana, Dadima,</i>
	<i>Gorasavarga-Dairy products</i>	<i>All can be taken except buffalo milk, curd</i>	<i>Avi(sheep) Dugdha, Aavika, Dadhi, Ajadugha, Mahisha Dugdha, curd, milk</i>

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^{6,19}. Adolescent is more sensitive to illness because their immune systems are 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 infections²⁰. 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 possibly making person diseases free with just proper diet *Prakriti* based immunity boosting diet may prevent future diseases to much extent

as per recent studies²¹⁻²⁵ 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 *Laghu Ahara* to stay in shape, and they should avoid *Divaswapna*, whereas *Vata Prakriti* 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 *Pathya Ahara* (favourable foods and drinks) and *Vihara* (behaviour and physical activities) while simultaneously discouraging *Apathya Ahara* (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.

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