

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

Comment [A1]: Suitable term can mentioned in brackets *Prakriti* (unique constitution)

Comment [A2]: What it meant here about *pathya*.. healthy in what contest?

Comment [A3]: Mention the sample size.

Comment [A4]: uniformity should follow in entire article

Comment [A5]: All ayurvedic terms should be in Italic

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 beliefs.² According to *Charaka Samhita*, the idea of *Tridosha* is a key premise of *Ayurveda*.³ 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. 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.⁴ 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.^{5,6}

Concept of Pathya-Apathya: -

The ancient seers 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).^{4,5} 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 *Apathya* are described as drugs or regimens that do not have a detrimental impact on the body and psyche (healthy) *Apathya* is the term for people who have a negative impact on them.⁵ As can be seen from the definition mentioned above, *Pathya* and *Apathya* refer to both material items and precise routines, but in *Ayurvedic* literature, these terms have come to refer specifically to meals.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

Comment [A6]: Uniform word can use as diet or food any one.

Comment [A7]: Only first time you write suitable term is enough.

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.

Comment [A8]: Use English term inside the bracket and Ayurveda term outside.

Comment [A9]: UNIFORMLY YOU WRITE AYURVEDA TERM FULLY AS AHARA, VIHARA, AYURVEDA, KASYAPA IN ENTIRE ARTICLE

Research gap Analysis:

1. In Kashyap Samhita it is given that Ahar 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 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 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 perception 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.

Comment [A10]: Is it necessary to do these investigations for your study if yes..explain it.

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-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%.

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

Comment [A11]: Why you selected these particular age group? If you have an particular idea on it.. can do GENDER based comparative study.

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 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 200adolescents 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 dietwhich 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)

Comment [A12]: What is the criteria you using for identifying the prakruthi? When you are assessing it? It have to be mentined.

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 formula¹²

$$\text{Morbidity Score} = \text{Incidences (last 3 months)} \times \text{Severity}$$
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



Comment [A13]: You taken only dwandaja prakruthi that indicates as you excluded ekadosaja and sannipataja for study. That can be mentioned here.

Comment [A14]: Why the morbidity scale in objective criteria? You excluded morbid subjects for study. If you asses morbidity during the study.. then that subject can be excluded for study.

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



Grouping, randomization allocation, 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* (*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 Ahara^{16, 17}:

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

Comment [A15]: Why only for 15% of the samples? Prakruthi is varying for person to person.. Investigation doing only for 15% is not a good criteria to sustain..

Comment [A16]: Use ayurveda terms for this

Comment [A17]: Ayurveda terms

Comment [A18]: Hitabhashi means who are talking good pleasant words..

Comment [A19]: Mitabasi means who taking less.

Comment [A20]: These terms are not suitable with your English meaning..

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 Vihar¹⁵

Particulars	Vataprakriti	Pittaprakriti	Kaphaprakriti
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, 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, Nettle 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
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,	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,

Comment [A21]: Use uniform ayurveda sanskrit terms.. Instead of awla, manuka, angur etc.. if there is no Sanskrit term for few diet items.. that can write after completed all ayurvedic diet.

Comment [A22]: Present days what are using in diet only can include in your study..

Comment [A23]: In apatya you mentioned food items prepared with maida and oil..

	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
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 Ahar(Diet) and Vihar

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, colored beverages, packed fast food pizza, chinese, Spicy oily, fried food	Ice cream, cold drinks, halwa, sweets, diary food, stuff.
Lunch (11.00 am)	Bread, pav, bhaji, biscuits	Bread pav, Noodles, chicken spicy, fried	Cheese, cold items, sweet, santarpakGuruahar,
Vihar	Diwaswap, Hurry, exertion	Stress, strain, hurry, worry	Laziness, diwaswap, sedentary lifestyle

Table 5: Pathya-Apathya¹⁸

A) Vata dominant Prakriti

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

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

Comment [A24]: What it meant by? Already you told avi..

B) Pitta dominant Prakriti ahara:

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

Comment [A25]: Mixed terms can be avoided

C)Kapha dominant Prakriti

Varga	Pathya	Apathya
ShukaDhanya	Raktashali, Yava	,ShastikaGodhuma
ShamiDhanya	Mudga, Mangalya,	Masha,
Mansa Varga	Rohit Matshya, Chicken, Eggs	Go mansa, Chilchim fish,
PhalaVarga	Seasonal fruits like pea nut, fox nut, kashue nut	Nikucha (Atrocarpuslakoocha), banana, Dadima,
Gorasavarga	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^{6,19}. Adolescents are more sensitive to illness because their immune systems are still in developing stage with sudden hormonal change, making them more likely to become sick. Adolescents 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 possible to make persons disease-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 adolescents. 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

Comment [A26]: You have to elaborate this area and explained individual role of prakruthi based diet in the context of prevention, cure of the disease. Have to elaborate role of your study in present days. Qualities of individual food items how they can influence the prakruthi etc..

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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Comment [A27]: Write the reference as per the guidelines.
Reference have to write fully.. like 4th, 23rd references etc

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