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Evaluation of Comparative Efficacy of Brahmi vs. *Haritaki* Extract in the Management of Academic Stress in Adolescent Students- A *Prakriti* based Double-blind Randomized Controlled Trial

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Introduction: Prevalence of mental illnesses among adolescents was found 7.3% (N=1191) by NMHS survey 2015-16 whereas the national crime record bureau in 2014 stated 1.8% of students committed suicide due to failure in their exams. The root cause, that is academic stress is often ignored which occurred due to various stressors like physical, mental, family, school, relationship, and social factors of which School factor (56.7%) and academic tests (45.6%) hold maximum association. Proper management can be provided with Ayurveda by *Prakriti* wise (exploring one physical, physiological and psychological factors) analysis of stress and their coping up strength and effect, when assisted with oral intakes of Ayurveda drugs like *Brahmi* and *Haritaki* along with *Sattvavajaya Chikitsa* having *Achar Rasayana*, *Surya Namaskar*, *Dharna*, and *Dhyana* practices.
Aim and Objectives: The aim is to evaluate the comparative efficacy of *Brahmi* extract with

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Sattvavajaya Chikitsa over the effect of *Haritaki* extract with *Sattvavajaya Chikitsa* in the management of Academic Stress among adolescent students of different *Prakriti*.

Material and Methods: A double-blind reference standard controlled stratified randomized superiority clinical trial is planned. The sample size of 198 participants with 13% dropout consideration will be enrolled after analysis of their *Prakriti* and stress level between 5-25 according to the SAAS scale. Total 6 subgroups (3 each for trial drug group and 3 for standard control) will have *Vata*, *Pitta,* and *Kapha Doshic* (V, P & K) dominant *Prakriti* participants of 10 to 17years of age. Total 33 participants in each subgroup will have the interventions for 90 days.

Observation and Results: Participants will be assessed for changes in salivary cortisol, level of academic stress, IQ, and memory before and after the trial. The standard descriptive and inferential statistical measures will be used to assess the effect of interventions.

Conclusion: *Prakriti* analysis will help stressed adolescents to know their strengths and interventions provided will be expected to help a stressed one to minimize stress level and also assist in developing their stress-coping mechanism.

Keywords: Ayurveda; academic stress; chittodevega; sattvavajaya chikitsa; prakriti; IQ; memory; salivary cortisol.

1. INTRODUCTION

The adolescent stage is the stage of various mental and physical transformations in a developing body and a derangement can lead to developing a variety of related disorders. In an Indian study, adolescents feeling Academic Stress (AS) were 2.4 times more at risk for depression than those without it. [1] Furthermore, according to the National Mental Health Survey (NMHS) in India 2015-16, the prevalence of mental morbidity among adolescents was found as 7.3% (n=1191). [2] Among which anxiety disorder (3.6%), mood disorder (2.3%), and suicidal tendency (1.4%) are the commonest ones. Suicide is the third leading cause among reasons of death in adolescents and the national crime record bureau in 2014 stated that 1.8% of students committed suicide to failure in their exams. [3-4] That's why an early understanding of stressors and their proper coping mechanism should be developed in adolescents [3]. According to a survey of various factors like physical, mental, family, school, relationship, and social factors work as the source of a stressor for an adolescent of which school factors (56.7%), and academic tests (45.6%) are responsible for maximum. [3] Excess of homework, poor Academic Performance (AP), exam preparation, less concentration in some subjects, and teachers' punishments are the possible reasons for AS [3-4].

Ayurveda, with safe and effective anti-stress medicines along with *Sattvavajaya Chikitsa* (*SC*), holds an upper hand in the treatment of mental disorders [5]. Ayurveda believes that mental disorders occur due to the malfunctioning of *Sattva* (*Manas* or *Chitta*) and vitiation of *Raja* and *Tama Mansika Doshas* and advocates *SC* for their management [6]. *ManoNighrah* (~control of mental wishes) is the basic concept of *SC* [6-8]. Proper counseling, *Achar Rasayana* (*AR*~Ayurved code of conduct)*, Surya Namaskar* (*SN*~sun salutation)*, Dharana*(~concentration)*,* and *Dhyana*(~meditation) are ways to control various mental wishes [9-11]. Further, *Prakriti* is a unique concept of Ayurveda that shows the *Doshik* predominance of *Vata, Pitta*, and *Kapha* (*V, P*& *K*) *Dosha* prevailing among seven physical constituents. The concept of *Prakriti* provides a person with his self-identity, understanding of his abilities, his susceptibility to various disorders, and his response to their treatment [12]. These features will help an adolescent to construct a strong mental, physical immunity towards multi-factorial stressors and provide a way to build up their coping up mechanism. This study plans to evaluate the effect of Ayurveda medicines with *SC* among students suffering from AS with various *Prakriti* and their *Prakriti* wise susceptibility toward AS and its management response.

AS is defined as "the body's response to academic-related demands that exceed capabilities of students." [13]. AS presents with psychological symptoms first and later converts them into psychosomatic if not properly managed. In Ayurveda, *Chittodvega* deals with the psychological part of stress, whereas *Ojah Kshaya* is a somatic part and joins this if *Chittodvega* is not treated properly. *Chitta* is also known as *Manas* or *Satva*. [7, 14-16] *Chittodvega* is a condition related to vitiation of *Sharirika Doshas* (~*V, P* &*K*) along with *Mansika*

Dosha (Rajas and *Tama)* due to *Prajnaparadha* (~unwholesome activities) and *Asatmendriya Samyoga* (~primarily abnormal perception of senses). [7] *Ojah Kshaya* occurs due to untreated *Chittodvega* symptoms like *Shoka* (~grief), *Dhyana* (~wory), and *Kopa* (~anger) present somatic symptoms like *Sandhi Vishlesh* (~looseness of joint), *Gatrasadana* (~weakness of body), *Stabhdh Gurugatrata* (~stiffness and feeling of heaviness in the body), *Glani, Tandra, Nidra* (~exhaustion, stupor, and more sleep), *Vibheti* (~fearful) symptoms, and *Abhikshan* (~always worried) are the symptoms which are very close to the presentation of stress [14-15]. Stress symptoms like feeling of uncontrollability, weakness, and loss of weight are near to *Vyathitendr eeya* (~discomfort in the sense organs), *Durbal* (~debility), *Ruksha* (~dryness), and *Durmana* (~mental disturbance) symptoms of *Ojah Kshaya* [14-15]..

The above symptoms reflect the involvement of *Mansika* and *ShariirikaDoshas* in the situation of AS. Ayurveda Drugs *Brahmi* and *Haritaki* have the property of *Balya* (~increasing power), *Medhya* (~promoting intellect), *Buddhiprada* (~increasing intellect) *Rasayana* (~rejuvenating), *Vayasthapana* (~ longevity promoters), *Deepana* (~increasing appetite), and *Tridosha Shamak* (~pacifying action of all elevated *Doshas*) property which helps in managing above symptoms and combating AS [16-17]. Ayurveda believes in the principle of *Purusham Purusham Veekshya* (~every person is different from others in its physical constitution and mental temperament) [18]. *Prakriti's* concept follows this principle. The Sanskrit prefix "*Pra*" means original and "*Kriti*" means "creation" [19]. Thus the meaning of *Prakriti* comes out as the time of "original creation" hence; both the drugs will be quantified for their effect in various *Prakriti*.

1.1 Recent Researches and Evidence on Research Drugs

Control drug *Brahmi* (*Bacopa monnieri* Linn.) has an established adaptogenic and anti-depressant effect. [20] It is effective in improving mood, attention, and memory in children [20]. Similarly, it is studied for changes in cognitive functions in Indian school children and found to have positive results [21-22]. *Brahmi* has alkaloid Brahmine, nicotine, and herpestine as their chemical constituent. [23] It relieves stress by increasing cerebral blood flow and modulating neurotransmitters like acetylcholine (A ch), 5-hydroxytryptamine (5-HT), and dopamine (DA). [24] So, this drug will be studied as a reference standard control for the research drug *Haritaki*.

Haritkaki extract will be evaluated for its action in the management of AS. Acharya Charaka has kept *Haritaki* among *Vyasthapana* drugs, which signifies the drug establishes longevity and helps in rejuvenation. [25] Furthermore, study drug *Haritaki* holds a finer position,being helpful in *V*, *P &K* vitiated conditions. [26] In *Ojah Kshaya* various conditions like *Glani* (~guilt) are related to a *Vata nanatmaj Vikara* (~*Vata* vitiated symptom). [27] *Gurugatrata*, *Tandra*, *Nidra* related to *Kapha nanatmaj Vikara* (~*Kapha* vitiated symptom). [27] *Bhaya*(~Fear), *Krodha*(~Anger), and *Moha* (~bewilderment) are the conditions related to vitiated *Pitta dosha* which make a favorable situation for *Haritaki* to act properly as it is a *Tridosh Shamak* drug. [26,28] Aqueous extract of *Haritaki* is found to have a good anxiolytic and antidepressant activity when evaluated against standard drug diazepam and imipramine respectively [29-30]. Tanin rich extract of *Haritaki* resulted in down-regulation of serum cortisol level and maintained the level of 5HT and dopamine in the blood presenting anxiolytic activity [31]. Phytoconstituents found in *Haritaki* have a good therapeutic effect with no toxicity [32]. It constitutes Chebulic acid, chebulinic acid, and Corilagin as the main constituent [33].

1.2 Research Gap Analysis

Observational and cross-sectional studies present various stress factors which are responsible as stressors source for adolescents of which school factors having AP, and self-expectation are major contributors of AS among adolescents [1,3]. This increases the risk 2.4 times to develop depression [1]. Our Indian education system lacks cope up strategies for different stressors among students. The present study will let a stressed student to identify his anatomical, physiological and psychological capacity by *Prakriti* analysis and which help him to recognize his stressors and develop a coping up mechanism with help of *SC* and antistress Ayurveda Drug [34-38]. Participants will be assessed before and after intervention by the SAAS scale covering cognitive, affective, physical, social, and interpersonal factors related to stress [13]. Previous Ayurveda studies on stress present the close association of *Prakriti* in developing stress. Mentioned works are either observational and if interventional, then with less sample size, single-blind, without objective

assessment, or performed on adult and elderly populations [12,39-40]. Present work involves the most vulnerable age group of adolescents, with an objective assessment of salivary cortisol, with optimum sample size, double blind-study, and with new research drug *Haritaki* for as and standard control drug *Brahmi*. One of the previous Ayurveda works shows the beneficial effect of *Panchkarma* on AS [41]. *Panchkarma* is an effective therapy but requires multiple hospital visits to show its effect, which is not possible for a student. Antianxiolytic allopathic medicines like Diazepam and Imipramine have the side effects of addiction, drowsiness, dizziness, and tiredness which are not associated with Ayurveda drugs like *Brahmi* and *Haritaki* [17-18]. *Haritaki* was evaluated for the anxiolytic and antidepressant property, but some researchers mention it as anxiolytic-like and antidepressant-like properties. This gap will be evaluated in the present study [29-30,42]. Most of the antistress research for *Haritaki* was performed in experimental animal models; the present study will evaluate the antistress potential of the drug in humans [27-29,38]. Ayurveda texts say *Haritaki* has *Vayasthapni* and *Smriti Prada* property according to Charka while *Rasayan*, *Brihan*, *Medhya*, and *Buddhi Prada* by *Madanpal Nighantu*. Having best-suited properties to relieve AS, this drug is still not researched in this field and so will be studied as a trial drug [16].

1.3 Research Question

- Whether the comparative effect of *Haritaki* with *Stattvavajaya Chikitsa* will be more efficacious than *Brahmi* with *Sattvavajaya Chikitsa* in the management of Academic Stress in adolescents of different *Prakriti*?
- Whether the effect of *Haritaki* with *Sattvavajaya Chikitsa* and *Brahmi* with *Sattvavajaya Chikitsa* varies differently in adolescent students of different *Prakriti***?**

1.4 Aim

To evaluate the comparative efficacy of *Brahmi* extract with *Sattvavajaya Chikitsa* over the effect of *Haritaki* extract with *Sattvavajaya Chikitsa* in the management of Academic Stress in adolescent students of different *Prakriti*.

1.5 Objectives

1. To evaluate the comparative efficacy of *Brahmi* extract with *Sattvavajaya Chikitsa* vs. *Haritaki* extract with *Sattvavajaya Chikitsa* in the management of AS in adolescent students.
2. To evaluate the variability in the effect of *Brahmi* and *Haritaki* with adjuvant *Sattvavajaya Chikitsa* according to different *Prakriti* in adolescent students suffering from AS.
3. To evaluate the change in IQ and memory parameters with change in stress parameters and also find any association in it.

2. MATERIALS AND METHODS

2.1 Study Design

A randomized reference standard control double-blind superiority clinical trial. 2 groups will be made, for control and research drug separately, each group is subdivided into three different groups (total six subgroups, 3 for each standard control and research drug) with different *Doshic Prakriti* dominance *(V, P & K).*

2.2 Participant

Adolescent students of 10-17 years (covering early and middle stages of adolescence, according to WHO) with either *Prakriti* studying in C.B.S.E. Board schools suffering from AS.

2.3 Sources of Data and Place

C.B.S.E. Board schools nearby Mahatma Gandhi Ayurved College, Hospital and research center, Salod, Wardha.

2.4 Duration of Study

The duration of the study will be 24 months, of which 8 months for drug preparation, 10 months for survey and recruitment of sample, and drug administration, and 6 months for manuscript writing.

2.5 Inclusion Criteria

- Students whose parents are willing to participate and sign written informed consent for the research trial.
- Adolescent students of 10 to 17 years age comprise an equal number of girls and boys of the CBSE board.
- Students whose score ranges 5-25 for stress on the SAAS scale.
- Students with *Vata Pitta* and *Kapha* dominant *Dwandaj Prakriti* suffering from AS to be enrolled in stratified sampling.

2.6 Exclusion Criteria

- Students suffering from chronic diseases and taking medicines for the disease.
- Students suffering from diagnosed serious mental diseases and taking medicines.
- Students with physical disabilities and with congenital anomalies.
- Students with an IQ below 70 will be excluded from the study.
- Students who are taking corticosteroids for any illness or any other reason.

2.7 Sample Size

168 participants–84 in each group. The sample size is calculated according to the effect size from the previous study [43]. Total 6 six subgroups will have 28 patients each, a 12% dropout rate increases 33 participants and will be recruited for each subgroup, which makes the total sample size of 198.

2.8 Setting

The study will be conducted on adolescent students of either sex with age group 10 to 17 years studying in C.B.S.E. Board schools nearby Mahatma Gandhi Ayurved College, Hospital and research center, Salod, Wardha [44]. After identification of students suffering from AS, they will be assessed for their *Prakriti* and will be randomly allocated by stratified sampling method to the 2 different groups having their total 6 subgroups.

Each subgroup will have a minimum of 33 participants, 3 groups with V, *P & K Doshic* dominant *Prakriti* will receive standard control *Brahmi* and the other three will receive research drug *Haritaki* for 90 days continuously by oral route. Both the groups will practice *Sattvavajaya Chikitsa* as adjuvant therapy. Initially, a general counseling session will be performed to teach *AR, SN, Dharana,* and *Dhyana*. Later they will be instructed to practice these procedures at home daily for 15 minutes just after a bath with being empty stomach. They will also be instructed to follow general instructions, counseling, and *AR,* as explained in the initial session. Like this total of 198 students will be assessed for drug effects in the management of AS. Detailed explanation in a schematic timeline is explained in the consort diagram in Fig. 1.

2.9 Anticipated Outcomes

2.9.1 Primary outcome

Change in the salivary cortisol level and scoring of the SAAS scale.

2.9.2 Secondary outcome

Change in IQ and memory scoring and variability of all scores in different *Prakriti* pre and post-intervention.

3. METHODOLOGY AND INTERVENTION

3.1 Sampling Procedure

3.1.1 Randomization

Stratified randomization will be done to have an equal number of subjects in each group. Total 6 strata will be made each 3 of standard control and research group will represent V, *P & K Doshic* dominant *Prakriti.* Randomization will be done by using the table of random numbering by computer-based randomization software.

3.1.2 Allotment concealment

Double blinding will be done with a regular change of code by using an opaque envelope. (Sequentially numbered opaque sealed envelopes).

3.1.3 Interventions and distribution into the group

Source of procurement of interventions and authentication

- Crude drug and research material will be procured from approved sources.
- The Physical identity of the raw drugs to be used in the research trial will be verified by the Dravyaguna dept of MGACH & RC.
- Analytical lab under Dattatraya Rasashala will verify the constituents of prepared drugs and raw drugs.
- The standard control group with 3 subgroups of dominant *Prakriti* (Subgroup A, B, C having *Vata, Pitta,* and *Kapha Prakriti* dominant participants, respectively).
- Subgroup A, B, and C will be given *Brahmi* extract (dose of 250 mg), twice a day having aqueous (water) extract solidified

and filled in capsules followed by drinking plain water.

- Trial drug group with 3 subgroups of dominant *Prakriti* (Subgroup D, E, F having *Vata, Pitta,* and *Kapha Prakriti* dominant participants respectively).
- Group D, E, and F will be given *Haritaki extract* (dose of 250 mg), twice a day having aqueous (water) extract solidified and filled in capsules, followed by drinking plain water.
- *SC* will be performed by the practice of *SN, Dharana,* and *Dhyana* 15 minutes per day. *AR,* will be told in general counseling and asked to follow regularly and will be enquired on every follow-up.
- The whole management plan will be administered regularly for 90 days.
- *Achar Rasayana (~AR)*–It is the general code of conduct as explained in Charak Chikitsa Sthana and will be used as a method to redevelop conduct. This will be explained to students during general counseling and asked to follow the same till the end of the trial [45-46].
- *Surya Namaskar (~SN)*–This is also known as sun salutation has 12 Asanas in it. Students will be asked to practice 12 sets of SN daily. This has to be performed in 8 minutes [10].
- *Dharana*–After *SN* the participant will be asked to relax and concentrate on one thing which he wished to do. This has to be performed for 2 minutes after *SN* [11].
- *Dhyana*–In Continuation of *Dharana*, *Dhyana* will be practiced for 5 minutes. Here all the thoughts get away and participants meditate freely [11].

3.2 Monitoring

It will be done by making daily attendance, video calls, and organizing group meetings on online meeting platforms like zoom and google meet.

3.2.1 Dose calculation

Water extracts are considered equivalent to *Ghan Satva*. [47].

- Dose of Haritaki satva in an adult is 1 gm(1 masha) /day (Ayurved Sara Sangrah & Sidhha Yog Sangrah)
- The dose which was found effective as antianxiety action of *Brahmi* was 640mg/day in adults.
- Having adolescents age group in our study who are near to adults and having some limitations for *Haritaki* usage, a 500mg/day dose of the dried aqueous extract (250mg twice a day filled in capsules) is fixed for both the standard control drug and trial drug to perceive maximum benefits. [26,43].

3.3 Data Collection Methods

3.3.1 Survey

A survey of adolescent students of 10-17 years studying in C.B.S.E. Board schools will be performed to identify students suffering from AS.

3.3.2 Survey questionnaire

- The scale of SAAS to identify sufferers of AS before treatment. It is a 30 item self-reporting tool with a total score of 30 showing maximum stress and 0 lowest or no stress [13,48]. It covers cognitive, affective, physical, social, and interpersonal factors related to stress [13, 48].
- Those who are positive with SAAS inclusion criteria will be analyzed for *Prakriti*. *Prakriti* assessment will be performed by the "*Prakriti* Vichaya" module of AyuSoft software of the center for the development of advanced computing (C-DAC). It covers the anatomical, physiological, and psychological prospects of a person. [34-35]
- IQ, memory will be analyzed after *Prakriti* analysis by Draw a Man test and PGI memory scale, respectively [49-50].

3.4 Assessment

1. Objective-
    i. Salivary Cortisol [51].
2. Subjective–
    i. Scale for Assessing AS (SAAS) [13-48].
    ii. *Prakriti* (*Sharirika Prakriti*) analysis by *PrakritiVichaya* software of Cdac (Only pre-analysis, as it remains the same lifelong). [34].
    iii. I Q analysis by Draw a Man test [49].
    iv. Memory Analysis by PGI memory scale [50].
3. Objective and subjective assessment will be performed before treatment and after

the end of the study that is on the 91st day.

4. Results will be evaluated with findings before treatment and findings after the end of treatment.

3.5 Data Management

Data will be managed in tables of excel sheets properly titled for record and variables.

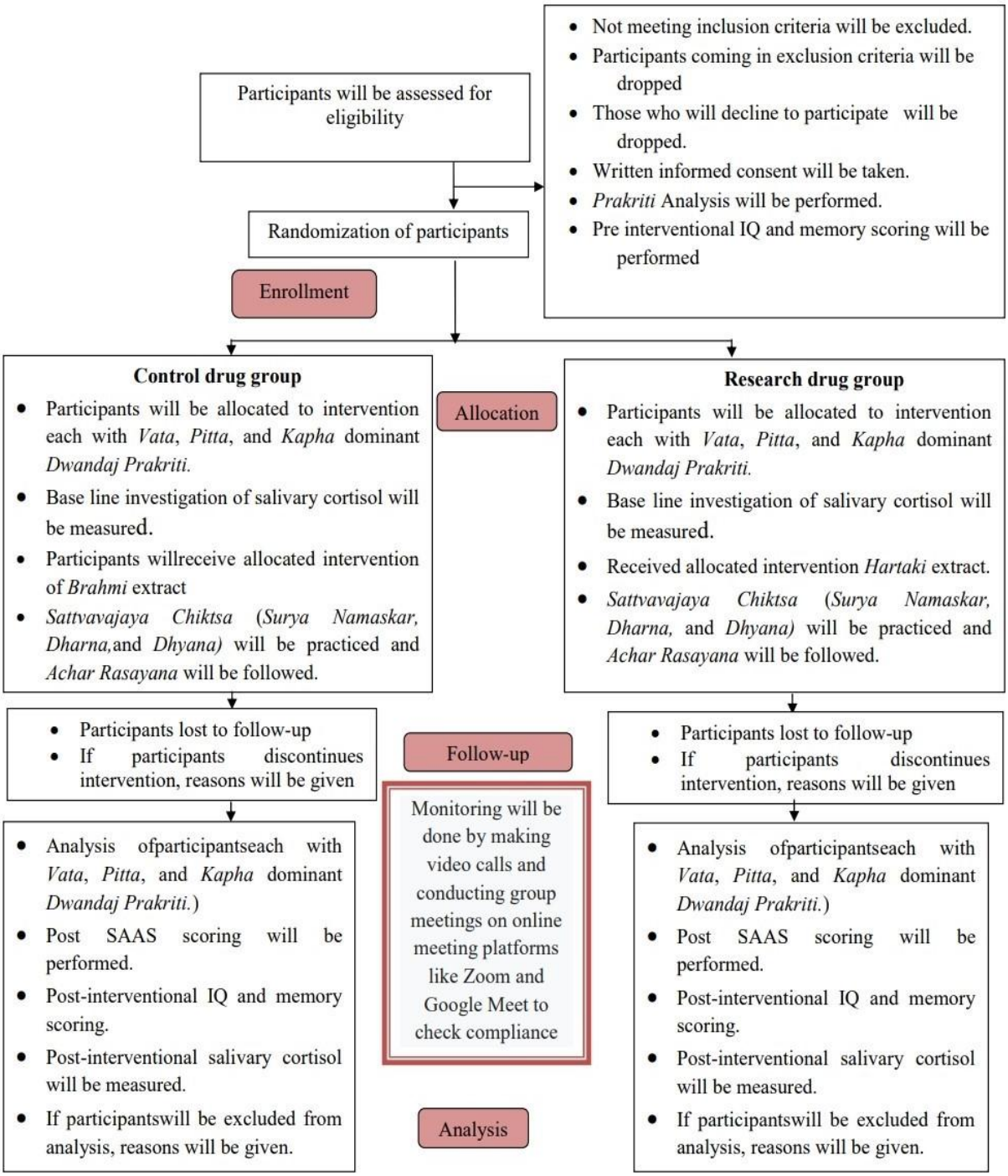

Fig. 1. Showing consort 2010 flow diagram

3.6 Data Analysis Plan

- Descriptive Statistics: percentage, standard deviation, and mean scores.
- Assessment parameters will be subjected to Univariate and multivariate analysis using SPSS 21.0 VER. with appropriate statistical methods.
- The data will be analyzed by using paired t-test & unpaired t-test for objective parameters and Mann-Whitney U test, Wilcoxon rank-sum test, one/two-way ANOVA tests for subjective parameters.
- Chi-square test for qualitative with the frequency of patients & unpaired t-test for quantitative.
- Test of hypothesis superiority analysis will be done through the application of appropriate inferential statistics.

3.7 Safety Recording

3.7.1 Adverse drug events

- All the adverse events will be recorded and their relation to the study drug will be seen.
- All the recorded information and other severity will be immediately notified to the study monitor.
- Periodical reporting of the study will be furnished to the ethical committee.

3.7.2 Discontinuation criteria

- Parents of the student not willing to complete the study
- Development of any acute or chronic illness during treatment.
- Development of any untoward effect by the use of drug administered for the study.

3.7.3 Anticipated translatory component of research

- This *Prakriti*-based study is anticipated to show a pathway of self-recognition to an adolescent.
- This research will produce an extended opinion about the management of vulnerable *Prakriti* towards academic stress and their safe and effective management.
- Self-recognition will help adolescents to develop a self-management plan to cope with various stressors according to their capacity.
- The study will provide a physical and mental management pathway with the help of *Sattvavajaya Chikitsa* and antistress Ayurveda drugs to combat various psychosomatic symptoms of stress.
- This study will help in designing a holistic program having *Sattvavajaya Chikitsa* and other interventions for preventing mental illnesses among adolescents.

3.8 Limitations

The study will evaluate the combined effect of control and study drug along with adjuvant *Sattvavajaya Chikitsa* in various *Prakriti* but not the sole effect of both the drugs, in the future sole effect of the drug should be evaluated and compared with the effect of *Sattvavajaya Chikitsa.*

The study highlights the efficacy of ancient Ayurveda concept in the light of modern medical science and can be publicize if found efficacious.

4. CONCLUSION

AS occurs due to various stressors and *Prakriti* analysis will assess a stressed adolescent with different aspects to know their strength. Interventions provided will be expected to help a stressed one to minimize their stress levels and that will be assessed on standard objective and subjective criteria. Interventions provided will also be expected to assist stressed adolescents to develop their stress coping mechanisms at the end of the trial.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL CONSIDERATION

Approval received by IEC(MGACHRC/IEC/July-2020/322) on 31.7.2021.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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