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Protocol on Comparative Clinical Efficacy of *Tryushanadi Guggul* and *Navaka Guggul* in *Sthoulya* (Overweight)

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Authors' contributions

This work was carried out in collaboration among all authors. Author ADP designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors SM and VA managed the analyses of the study. Author VA managed the literature searches. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: *Sthoulya* is *Medovaha Strotodushtijanya vyadhi*, which includes abnormal and excessive accumulation of *Medodhatu* in the body. This is caused by lack of physical and mental activity, daytime sleep, excessive intake of *madhur* (sweet), *snigdha ahar* (oily diet) results in increase *Kaphadosha* and *meda* which results in *Sthoulya* (overweight) having symptoms of mild dysponea, thirst, drowsiness, excess sleep, appetite, offensive smell from the body, incapability to work and incapability to participate in sexual intercourse.
Aim: Comparative clinical efficacy of *Tryushanadi Guggul* and *Navaka Guggul* in *Sthoulya* (overweight).
Materials and methods: Total 60 patients of *Sthoulya* will enrolled and will divided into two groups (each group contains 30). Patients in group A (experimental group) will be given 1 gram *Tryushanadi Guggul* two times a day after meal with honey and in group B (control group)1 gram *Navaka Guggul* will administered two times a day after meal with honey for 30 days. Dietary

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changes and walking (30 minutes) will be advised to patients of both groups. Follow up will be taken on 15th day and 30th day. Assessment of subjective parameters like *kshudrashwasa* (exertional dyspnoea), *swedadhikya* (perspiration), *atikshudha* (increased appetite), *nidradhikya* (increased sleep) and objective parameters like body weight, B.M.I., mid arm circumference, waist-hip ratio and lipid profile will be done before and after treatment.
Results: Subjective and objectives outcomes will be assessed by statistical analysis.
Conclusion: It will be drawn from the result obtained.

Keywords: Lipid profile; navaka guggul; obesity; sthoulya; tryushanadi guggul.

1. INTRODUCTION

Sthoulya is one among the major diseases that falls under the category of *Santarpanotthavyadhi* (disorder of over nutrition) caused due to vitiation of *Medovaha srotasa (*channel*)*. It is an abnormal and excessive accumulation of *Medadhatu* in the body [1] . Acharya Charaka considered *Atisthula* as one among *Astonindita Purusha* (eight undesirable persons) [2]. *Meda* is increased in the body due to lack of physical exercises, sleeping during day time, consuming food which increases *Kapha* and *meda*, ingestion of excess fats/oils and substances that are predominantly sweet in taste. All the channels that continuously supply nutrients to other tissues are blocked by accumulated *meda* (fatty tissue), so further tissues are not properly formed and only *meda* gets accumulated in the body. A person having pendulous appearance of *sphika* (hip), *udara* (abdomen) and *stana* (breast) due to excess deposition of *meda* (fat) along with *mamsadhatu* and also having unequal an abnormal distribution of *meda* with reduced enthusiasm towards life is called *atisthula*.

Acharya Charaka has described eight symptoms of sthaulya like ayuhrasa (reduced lifespan), javoparodha (early onset of senility), alpavyavayita (find difficulty to perform sex), daurbalya (debility or general weakness), daurgandhya (foul smell of body), swedabadha (sweating), atitrisha (increased thirst), atikshudha (increased appetite) [3]. *Sthoulya* can be compared to overweight and obesity. Obesity is defined an increase in number and/or size of adipose cells suggest hypertrophy and/or hyperplasia of adipocytes. It may be caused due to particular age, sex, genetic, endocrine, behavioral, psychological or iatrogenic factors. Obesity can be assessed by measuring Body Mass Index, Waist circumference, Waist / Hip ratio and Skin fold thickness.

The B.M.I. is the actual body weight divided by the height squared in metres (kg/m2). A person having BMI of 25 kg/m^2 to 29.9 kg/m^2 is considered having overweight. Overweight is the fifth leading risk of global deaths. Worldwide, more than 1.9 billion adults of 18 years and older, were overweight. The first adverse effects of overweight to emerge in population in transition are Obesity is a major risk factor for metabolic disorders like hypertension, hyperlipidemia and glucose intolerance, coronary heart disease and diabetes mellitus [4].

Overweight is most prevalent in middle-age, but can occur at any stage of life. Normally the women are more prone than men. Overweight may have profound psychological consequences, compounded by stigmatization of the overweight in many societies [5]. Ayurveda described many herbo-mineral formulations for management of *Sthoulya*. Various researches conducted on *Guggul* formulations like *Medohar, Triphala, Amrutadya* and lekhana drugs like *Guduchi* (*Tinospora cordifolia* Willd) and *Musta* (*Cyperus rotundus* Linn) proved their efficacy in *Sthoulya* [6-9]. In Bhavprakash *Tryushanadi Guggul* claimed effective for *Sthoulya*. Contents of *Tryushanadi Guggul* are mostly *Katu* (pungent)*, Tikta* (bitter) which are opposite to *Kapha* and *meda*, thus help in reducing excessive *meda* deposition in the body. Hence this study is planned to evaluate the comparative efficacy of *Tryushanadi Guggul* in *Sthoulya* [10].

Trial plan: Double arm randomized single blind parallel group controlled clinical trial. interventional study having 1:1 ratio on both parallel groups.

2. METHODOLOGY

Case Definition: Subjects having age group 20 to 40 years of either sex irrespective of caste, religion, and *prakruti* having symptoms of *Sthoulya* like *kshudrashwasa* (exertional dyspnoea), *swedadhikya* (perspiration), *atikshudha* (increased appetite), *nidradhikya* (increased sleep) with BMI between 25 kg/m^2 to 30 kg/m^2.

Table 1. Diet plan timing

Timing	Diet plan(dietary regimen) Note- Use luke warm water for drinking (atleast 3.7 L/day for men and 2.7 L/day for women)
9 am -11 am	Horse gram / green gram (100 g) gruel or butter milk (200 ml) or fruits like papaya, orange, coconut water or sprouted bengal gram or green gram (100g)
1 pm	Yava /jowara /wheat chapati (2)-50 gm Leafy vegetables-spinach /fenugreek/amaranthus (100 gm) Other vegetables-soyabean/cabbage/tomato (100 gm) Mixed salad of cucumber, carrot, radish
8 pm	Yava /jowara /wheat chapati (2)-50 gm Leafy vegetable-spinach /fenugreek/amaranthus (100 gm) Other vegetable-soyabean/cabbage/tomato (100 gm) Mixed salad of cucumber, carrot, radish

Trial Design: Randomized single blind parallel group controlled clinical trial.

Allocation Ratio: 60 patients, 30 in each group.

***Vihar*-(activity)**

- Waking up early in the morning,
- 30 minute brisk walking per day,

2.1 Study Setting

Patients will be selected from OPD and IPD of Department of Kayachikitsa, MGACH & RC Salod (H), Wardha.

Trial Registration Number: This trial is registered under **CTRI /2020/08/035982.**

Eligibility Criteria: Subjects between age group of 20-40 years of either sex presenting with classical features of *sthoulya* as per Ayurvedic texts like *kshudrashwasa* (exertional dyspnoea), *swedadhikya* (perspiration), *atikshudha* (increased appetite), *nidradhikya* (increased sleep) and body mass index (B.M.I.) between 25-30 kg/m^2 will be included in the study.

Subjects with known cases of dyslipidemia, hypothyroidism, diabetes mellitus, cardiovascular, renal disorder, drug induced obesity, pregnant and lactating women will be excluded from the study.

2.2 Interventions

Group A- *Tryushanadi Guggul* 1gm two times a day with honey after meal for 30 days.
Group B -*Navaka Guggul* 1 gm two times a day with honey after meal for 30 days.

Patient will be advised to follow *pathya ahar* and *vihar* for *Sthoulya*.

2.3 *Ahar* (Diet) and *Vihar* (Activity)

For both groups *ahar* and *vihar* will be the same as mentioned in Table 1.

Screening Investigations (Base Line): Random Blood Sugar will be done to rule out diabetes mellitus.

Investigations Before and After Treatment: Lipid Profile (Total cholesterol, High Density Lipoproteins, Low Density Lipoproteins, Very Low Density Lipoproteins, Triglyceride).

Criteria for Discontinuing or Modifying Allocated Interventions: Subject can withdraw himself/herself from the study if any untoward incidence, features of drug sensitivity or any other disease or problem arises and free treatment will be offered to the subject till the problem subsides.

Strategies to Improve Adherence to Drug Protocol: We will measure quantity of *Vati* (pill) for the consumption of appropriate dose for assessment and to check drug adherence, the patient will be followed up15 days during treatment and on 30th day of treatment. Patient will be advised to avoid sweet food.

After Treatment Follow Up: Subjects will be followed up on 30th day after completion of treatment.

Primary Outcomes: Reduction in gradation of subjective parameters like *kshudrashwasa*

(exertional dyspnoea), *swedadhikya* (perspiration), *atikshudha* (increased appetite), *nidradhikya* (increased sleep) and reduction in objective parameters like body weight, B.M.I., mid arm circumference, waist-hip ratio and lipid profile.

Secondary Outcomes: We will see recurrence and any side effects of interventional drug.

Statistical Analysis: Statistical analysis of qualitative data will be done by descriptive statistics, quantitative data tested for normality. Data having normal distribution will be done by paired and unpaired t test, data having non normal distribution will be done by wilcoxon signed rank test & Mann Whitney u test.

Follow Up Time: 15th day during treatment and on 30th day of treatment.

Enrolment and Interventions Time Schedule: Drug will be given from 0 to 30 days and follow up on 15thand on 30th day of treatment.

Recruitment: By computerised random sampling method, 60 patients will be recruited (30 in each group) for study.

Implementation: Principal investigator will enroll and allocate the patients for study.

Methods: Data collection, analysis and management.

2.4 Data Collection Methods

Subjective Parameters: *Kshudrashwasa* (exertional dyspnoea), *swedadhikya* (perspiration), *atikshudha* (increased appetite), *nidradhikya* (increased sleep) will be assessed by gradation of symptoms on day 0, 15 and 30.

Objectives parameters-Body weight of the patient, B.M.I., mid arm circumference, waist-hip ratio will be assessed on day 0, 15 and 30 and lipid profile will be assessed on day 0 and 30.

Gradation with Validation: Assessment will done before, during and after treatment using gradation of symptoms as shown in Table 2 for clinical research methodology [11].

Table 2. Gradation of Subjective parameters

Subjective parameter	Grade 1	Grade 2	Grade 2	Grade 3
***Kshudrashwasa* (exertional dyspnoea):**	No dyspnoea even after heavy work	Dyspnoea after moderate work relieved later tolerable; dyspnoea by climbing up stairs of 10 steps and time taken will be more than 15 sec	Dyspnoea after little work but relieved later and not tolerable; dyspnoea by climbing upstairs of 10 steps and time taken will be more than 30 sec.	Dyspnoea at rest
***Swedadhikya* (perspiration):**	Sweating after heavy work, fast movement or in hot weather	Profuse sweating after moderate work and movement	Profuse sweating after little work and movement	Sweating even at rest or in cold weather
***Atikshudha* (Increased appetite):(1 meal=about 350gm diet)**	As usual / routine	Slightly increased (1 meal extra with routine diet)	Moderately increased (2 meals extra with routine diet)	Markedly increased (3 meals extra with routine diet)
***Nidradhikya* (increased sleep):**	Normal & sound sleep for 6-8 hrs./24 hrs.with feeling of lightness and relaxation in the body & mind	Sleep >8-9 hrs./24 hrs. with slight heaviness in the body	Sleep >9-10hrs./24hrs. with heaviness in the body associated with *Jrimbha*(yawning)	Sleep >10hrs./24hrs. with heaviness in the body associated with *Jrimbha*&*Tandra* (sleep)

2.5 Plan to Promote Participants Retention and Complete Follow Up

We will stay in touch with patient by taking contact number and timely advice them for medication and follow up and data of follow up will be stored in documentation with reason.

Data management: The data will be collected from patients by assessor by doing clinical assessment after taking written consent form the patient. Data will be collected using structured questionnaire filled during interview of the patient. Data will be entered in master sheet and analysed by using appropriate statistical technique and data coding will be done by principal investigator.

Outcome will be compared using paired and unpaired student 't' test.

Dissemination Policy: The data will be disseminated by paper publication.

Any intended use and authorship eligibility guidelines of professional writers.

Informed Consent Materials: Model consent form and other related documentation with all information will be given to participant.

3. RESULTS

Expected outcome result in control group with intervention *Tryushanadi Guggul* is potentially added effectual in subsiding the symptoms of *Sthoulya* like *kshudrashwasa* (exertional dyspnoea), *swedadhikya* (perspiration), *atikshudha* (increased appetite), *nidradhikya* (increased sleep) and also in with regards to bodyweight, BMI, mid arm circumference, waist hip ratio, and lipid profile. By following *Pathya* (wholesome diet) and *Apathya* (unwholesome diet), during treatment patient who will take all follow up will have a reduced amount of chance of reccurrence of symptoms.

4. DISCUSSION

This study will be conducted with the aim to compare clinical efficacy of *Tryushanadi Guggul* and *Navaka Guggul* in *Sthoulya* (overweight). In Charak Samhita, *Guru* (heavy) and *Apatarpana Chikitsa* (under nutrition treatment) is recommended in the management of *Sthoulya.* The drugs having *Katu* (pungent), *Tikta Rasa* (bitter taste), *Ruksha* (dry), *Ushna Guna* (hot properties), *Kapha-medohar* and *Lekhana* (scrapping) properties are indicated in the management of *Sthoulya* [12]. *Navaka Guggul* is a known drug used for *Stoulya* and its efficacy is proved by various research studies. So it is taken as a standard treatment group to compare the efficacy of *Tryushanadi Guggul* in *Sthoulya* (overweight). The efficacy will be assessed by comparing the improvement in subjective and objective parameters as compared to standard drug after completion of treatment. *Tryushanadi Guggul* contains *Sunthi* (*Zinziber officinalis. Roxb.*), *Marich* (*Piper nigrum*), *Pippali* (*Piper longum*), *Chitrak* (*Plumbago zeylanica.Linn*), *Musta* (*Cyperus rotundusLinn.*), *Vidanga* (*Embeliaribes*), *Vaca* (*Acorus calamus Linn*), *Shudha Guggul* (purified *Commiphoramukul*). *Navaka Guggul* contains *Triphala* (*Amalaki, Haritaki, Vibhitaki*) , *Trikatu* (*Sunthi*, *Marich*, *Pippali*), *Musta, Vidanga, Chitrak* and *Shuddha Guggul.* All ingredients of both drugs having *Katu, Tikta Rasa* and having *Laghu* (light), *Ruksha* (dry), *Tikshna* (penetrating properties) property opposite to *Kapha* and *meda.* Most of the ingredients have *deepan* (appetizer)*, pachana* (digestive) property which reduces *ama* and *strotorodha* (obstruction in channels). This is helpful in breaking the *Samprapti* (pathogenesis), so will help to reduce all symptoms of *Sthoulya. Tryushanadi Guggul* and *Navaka Guggul* are effective in management of *Sthoulya*, but in this study we assess the comparison between both drugs efficacy on subjective and objectives criteria. Total effects will show which drug is highly effective in *Sthoulya*. We reviewed the case studies, research articles and protocols to collect information on study drugs [13-15]. Various research studies on obesity were reported increasing prevalence and associated risk with obesity [16-18]. Studies on assessments of obesity and lipid profiles in different conditions were reviewed [19-21].

5. CONCLUSION

From the above assumed result it is concluded that the interventional drug *Tryushanadi Guggul* is 10% further more effective in *Sthoulya* patient as compared to *Navaka Guggul* with minimum side effects.

CONSENT

The written consent will be taken from the patient before starting the study. During the study, confidentiality of each patient will be maintained.

ETHICAL APPROVAL

Approval from research ethics committee has taken-Ref.No.MGACHRC/IEC/July-2020/61.After ethical approval from IEC study will be started.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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