A Protocol for Effectiveness of Ayush Rasayana A & B on Quality of Life of elderly population- a cluster randomized study

Pallavi Mundada, Deepa Makhija, Sunita Mata, Kalpana Kachare, Abha Sharma, Bhogavalli Chandra Sekhara Rao, Rakesh Kumar Rana, Arunabh Tripathi, Aparna Manathottathil, Kiran Rana, Vandana Joshi, Ashish Raturi, Narayanam Srikanth, Rabinarayan Acharya

Submitted to: JMIR Research Protocols
on: March 08, 2024

Table of Contents

A Protocol for Effectiveness of Ayush Rasayana A & B on Quality of Life of elderly population- a cluster randomized study

Pallavi Mundada[1*] MD; Deepa Makhija[1*] MD; Sunita Mata[1] MD; Kalpana Kachare[1*] PhD; Abha Sharma[1*] MS; Bhogavalli Chandra Sekhara Rao[1*] MD; Rakesh Kumar Rana[1*] PhD; Arunabh Tripathi[1*] PhD; Aparna Manathottathil[1*] MD; Kiran Rana[1*] BAMS; Vandana Joshi[1*] BAMS; Ashish Raturi[1*] BAMS; Narayanam Srikanth[1*] MD; Rabinarayan Acharya[1*] PhD

[1]Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Government of India Delhi, IN
[*]these authors contributed equally

Corresponding Author:
Deepa Makhija MD
Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Government of India
61-65, opp. D' Block, D Block, Janakpuri Institutional Area, Janakpuri, New Delhi,
Delhi,
IN

Abstract

Background: With advancing age amongst the elderly, the associated debilities increase, indicating a deteriorating health status as there is a gradual loss of muscle mass, strength, and functionality. The study has been planned to prevent debilitating conditions and improve the quality of life in the elderly population.

Objective: To assess the effectiveness of Ayush Rasayana A & B on the quality of life (QOL), quality of sleep and functionality of the elderly population along with the assessment of the tolerability of the intervention among the elderly population.

Methods: It is a multicenter cluster randomized study with a total sample size of 720, of age ?60 to ?75 years. Group I is being administered Ayush Rasayana A, 10 grams orally once daily at bedtime for the duration of 6 days followed by administration of Ayush Rasayana B, 1.5 grams orally twice daily before food for the consecutive 84 days. Group II is being given Ancillary care through Ayurveda for 3 months. The effectiveness and safety of the intervention is being assessed through haematological and biochemical parameters, clinical examination and incidence of adverse events.

Results: The execution of the study has been initiated in April 2023. As of 29th February 2024, the enrolment of the participants for the study has been completed at all the designated study sites and follow up is being done at subsequent visits. 660 participants are continuing till date, while 13 participants have dropped out due to poor compliance.

Conclusions: The present study will assess the effects of Ayurveda interventions among the elderly populations The study findings will provide vital information that can be used to establish a preventive treatment to enhance the quality of life and functionality amongst the aged population. Clinical Trial: The trial is subsequently registered with the Clinical Trial Registry of India (CTRI/2023/06/054204) on 20th June 2023.

(JMIR Preprints 08/03/2024:58186)
DOI: https://doi.org/10.2196/preprints.58186

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**
Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.
No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**
Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http

Original Manuscript

Protocol

A Protocol for Effectiveness of *Ayush Rasayana* A & B on Quality of Life of elderly population- a cluster randomized study

Abstract

Introduction

With advancing age amongst the elderly, the associated debilities increase, indicating a deteriorating health status as there is a gradual loss of muscle mass, strength, and functionality. The study has been planned to prevent debilitating conditions and improve the quality of life in the elderly population.

Objectives

To assess the effectiveness of ***Ayush Rasayana* A & B** on the quality of life (QOL), quality of sleep and functionality of the elderly population along with the assessment of the tolerability of the intervention among the elderly population.

Materials and methods

It is a multicenter cluster randomized study with a total sample size of 720, of age ≥60 to ≤75 years. Group I is being administered *Ayush Rasayana* A, 10 grams orally once daily at bedtime for the duration of 6 days followed by administration of *Ayush Rasayana* B, 1.5 grams orally twice daily before food for the consecutive 84 days. Group II is being given Ancillary care through Ayurveda for 3 months. The effectiveness and safety of the intervention is being assessed through haematological and biochemical parameters, clinical examination and incidence of adverse events.

Discussion

The present study will assess the effects of Ayurveda interventions among the elderly populations The study findings will provide vital information that can be used to establish a preventive treatment to enhance the quality of life and functionality amongst the aged population.

Key words: *Ayush Rasayana* A, *Ayush Rasayana* B, *Rasayana*, Geriatrics, etc.

Trial registration: The trial is subsequently registered with the Clinical Trial Registry of India (CTRI/2023/06/054204) on 20th June 2023.

Introduction

The ageing population in India is a major concern across social, political, and economic spheres. The elderly population in India is growing three times faster than the general population attributed to the increased life expectancy. [1] However, along with the increase in longevity, the quality of life has not increased as 27.72% of the senior population reported having a medical condition, either short-term or chronic. [2] There is a gradual loss of muscle mass, strength and functionality with advancing age. The prevalence of age-related diseases is on an upward trend and the management is limitedly applicable at this age owing to the less reciprocation and underlying multiple disorders such as metabolic-vascular diseases, degenerative diseases of the brain, musculoskeletal system and sensory organs; cancer; chronic lung disease; and greater risk of infectious disease. [3] In addition to causing symptoms of structural and functional deficiencies, these age-related illnesses cause a reduction in the elderly person's total functional ability and a variety of limitations. Ageing is inevitable and there is an urgent need to find interventions that help in reducing the incidence of debilitating age-related diseases and promote quality of life.

Ayurveda endures as a traditional and extensive discipline of traditional Indian medicine, used to promote health, prevent illness, and treat physical ailments by *Jarachikitsa* or *Rasayana*. The medicines, food products, and lifestyle-related factors that enhance the quality and longevity of life have been illustrated as *Rasayana*.[4] It is a rejuvenation therapy that has been said to impede the ageing process (*Vayasthapanam*), lengthen life expectancy (*Ayushakaram*), improve intelligence (*Medha*), build strength (*Bala*), and prevent disease development.[5] According to various studies, the *Rasayana* drugs possess potent antioxidant activity when combined with dietary supplements and rejuvenators. It reacts negatively with oxidative stressors, which are what lead to the production of various free radicals. [6,7] This study was planned considering the preventive aspect to retaliate with the ongoing situation which may improve the quality of life of the elderly population.

Ayush_Rasayana A and B, are coded Ayurvedic medicines, that are effective in improving the general well-being of the elderly by enhancing their physical endurance, quality of life (QOL) and cognition. Studies have shown the effect of *Ayush Rasayana* A & B on improving the health-related QOL & functional capacity of the elderly population and also found safe in apparently healthy elderly populations when administered in the prescribed dose [8]. *Ayush Rasayana* A & B are developed from extracts of herbs having *Rasayana* properties. Based on the classical claim, the present work was planned to assess the effectiveness of *Ayush Rasayana* A & B on the Quality of Life of the elderly population in selected Scheduled tribe (ST) and Scheduled Caste (SC) dominant areas.

Objectives

The primary objective of the study is to assess the effectiveness of *Ayush Rasayana* A & B on the quality of life of the elderly population. The secondary objectives comprise an assessment of the effectiveness of the intervention on the quality of sleep and functionality of the elderly population and its tolerability among the elderly population for 3 months.

Methodology

Study Design and Setting

The study is an open-labelled, cluster-randomized, multicentre study. It is being conducted at seventeen institutes of the Central Council for Researches in Ayurvedic Sciences. The institutes at Bangalore, Guwahati, Gwalior, Patna, Jammu, Chennai, Agartala and Vijayawada are selected for the recruitment of participants from the pre-identified areas dwelled with ST population. The institutes Cheruthurthy, Banglore, Nagpur, Gangtok, Ahmedabad, Bhubaneshwar, Kolkata, Mumbai and Jammu have been included for the selection of participants from identified areas with predominance of SC population. The study has a 12-month total period, of which two months are scheduled for preparation activities, six months for recruiting, three months for intervention, one month for statistical analysis, and monthly follow-up visits.

Study Participants

The study is comprised of clusters predominantly inhabited by ST or SC population.

Inclusion

The elderly population of any sex, aged between 60 to 75 years, residing in the identified areas; participants who are ambulatory and clinically stable with or without medication; willing to provide written informed consent for their participation in the study for 3 months; and the participants scoring 5 or more in Katz Index of Independence in Activities of Daily Living (ADL) are eligible for participation in the study.

Exclusion

Participants with blood pressure ≥ 160/100 mm of Hg; HBA1C ≥ 8 %; S. TSH>10 mIU/ml with or without medication, elevated liver enzymes (AST and/or ALT > 2 times of the upper normal limit), impairment of renal function (defined as S. creatinine > upper normal limit); a history of serious cardiac dysfunction or Pulmonary Dysfunction (Asthmatic and COPD patients), any severe cognitive or psychiatric illness, neurological disorders, hemorrhagic diseases, coagulation disorders within 90 days prior to the screening; participants having body mass index (BMI) less than 23 or more than 30

kg/m^2; history of cancer or chronic inflammatory conditions including but not limited to chronic infection like tuberculosis, leprosy, HIV, and collagen vascular diseases; participants on hormone replacement therapy, steroid therapy, chemotherapy or immunosuppressive therapy; participants with alcohol use disorder (AUD); participants who are currently on any drugs that affect the cognitive or physical function or on any nutritional supplements or any Ayush or folk medicine for maintaining the quality of life or any other condition that PI may think can jeopardize the study are being excluded from participation.

Study Intervention

Group I is being given *Ayush Rasayana* A, 10 grams in powdered form, orally with lukewarm water, daily after food at bedtime for 6 days from the day of enrolment. Administration of *Ayush Rasayana* B, 1.5 gm per day in two divided doses in Capsule form (2 capsules twice a day, each containing 375 mg extracts) with lukewarm water, Orally, twice daily before food for 84 days (from 7th day onwards to 90^{th} day), along with ancillary care throughout the 90 days.

Group II is being given ancillary care through Ayurveda for the duration of 3 months.

Withdrawal Criteria

A study participant who develops any adverse event requiring hospitalization or emergency management, development of any condition mentioned in the exclusion criteria during the study period and participants not compliant with the protocol or not willing to continue in the study are free to withdraw from the study. Detailed justification for withdrawal of the participant will be prepared indicating the line of further management, if required. The Sponsor and Ethics Committee will be informed within the appropriate time as per AYUSH GCP guidelines.

Concomitant and rescue medication

The drug or medications administered to treat the participant's additional illness will be noted by the study investigators. The participant shall continue any concomitant therapy for diabetes mellitus or hypertension or any other disease during the study, which is not specifically excluded. Any medical emergency may be relieved with the administration of any rescue drug. The same will be properly documented in the Case record form (CRF).

Compliance

The participant's compliance will be documented by means of the compliance assessment form to

evaluate how frequently individuals administer the trial medication in the period of time specified. If the compliance rate of the participant is at least 80%, the patient continues in the study.

Outcome measures

The primary outcome measure is the change in Quality of life (QOL) of the elderly assessed by the independence in Older People's Quality of Life Questionnaire- Brief (OPQOL-BRIEF). The secondary outcome measures change in the Katz Index of Activities of Daily Living; change in Quality of Sleep assessed by using the Pittsburgh Sleep Quality Index (PSQI); change in the time required for Five Times Sit-to-Stand Test in both; change in the grading of shoulder joint mobility assessed through 3 simple physical manoeuvres for active Range of motion (ROM) of the shoulder joints, any change in haematological and biochemical parameters (CBC, LFT and RFT), occurrence of treatment-emergent adverse events during the study period.

Table 1: Laboratory investigations planned in the study

Screening/Baseline	After treatment
Hemoglobin	Hemoglobin
TLC	TLC

DLC **N %** **E %** **B %** **L%** **M%**	DLC N % E % B % L% M%
ESR	ESR
CRP	CRP
Thyroid stimulating hormone	Thyroid stimulating hormone
LFT **I. Total protein** **II. Albumin** **III. Globulin** **IV. A/G ratio** **V. Total Bilirubin** **VI. Conjugated Bilirubin** **VII. Unconjugated Bilirubin** **VIII. SGOT (AST)** **IX. SGPT (ALT)** **X. Alkaline Phosphatase**	**LFT** I. Total protein II. Albumin III. Globulin IV. A/G ratio V. Total Bilirubin VI. Conjugated Bilirubin VII. Unconjugated Bilirubin VIII. SGOT (AST) IX. SGPT (ALT) X. Alkaline Phosphatase
KFT **I. Blood urea** **II. Serum Creatinine** **III. Uric Acid**	**KFT** I. Blood urea II. Serum Creatinine III. Uric Acid
HBA1C	HBA1C

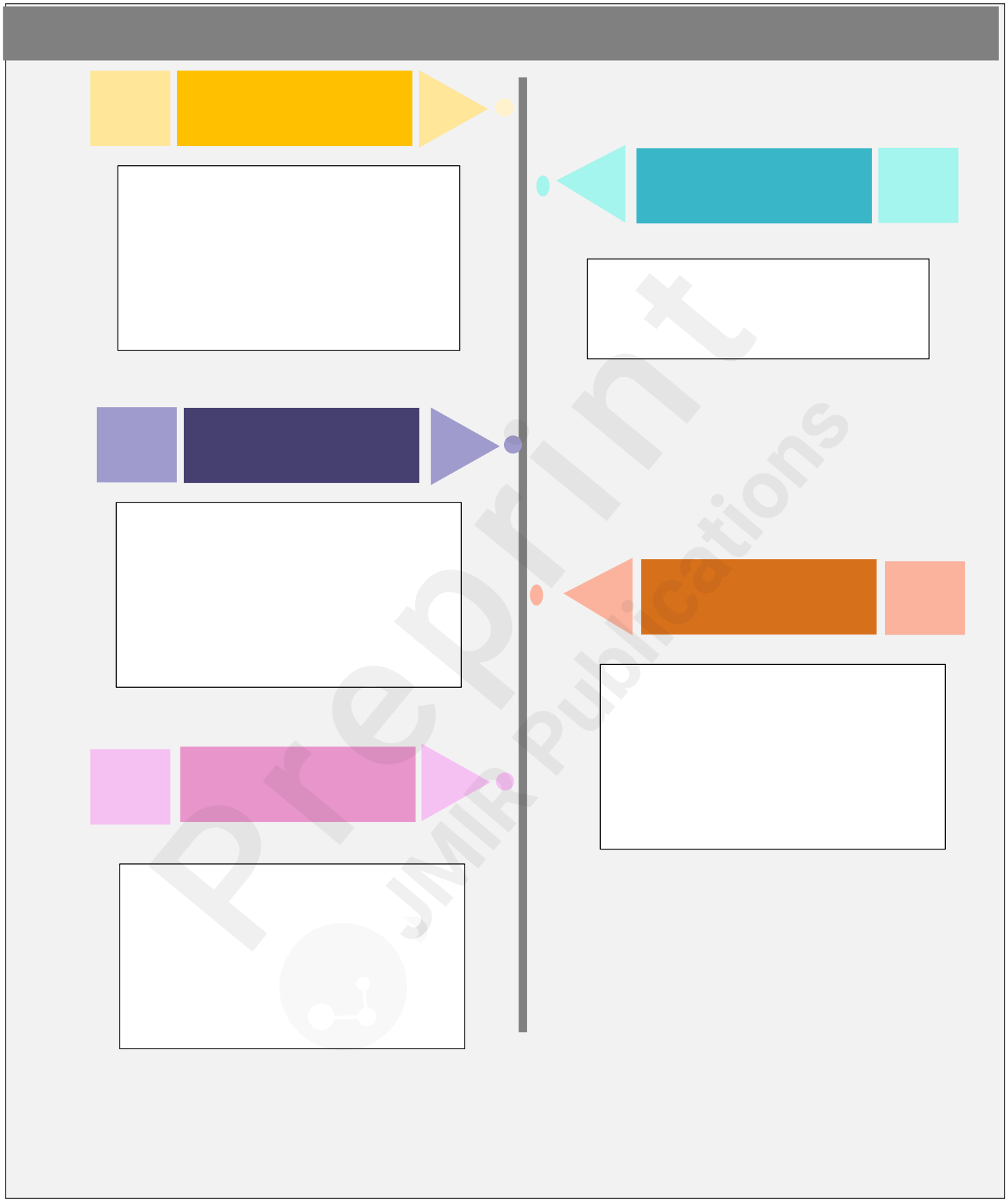

Figure 1: Study Schedule

Screening

- **Informed consent**
- **Assessment of eligibility**

Baseline

Safety outcomes

Recording the frequency of adverse events at each anticipated follow-up visit will provide as a means to evaluate the trial intervention's safety. In accordance with Good Clinical Practice (GCP-ICH) criteria, all adverse events that occur throughout the trial will be documented and closely monitored.

Sample size

A change of 9 points is expected in the intervention group (*Ayush Rasayana* A and B) in OPQOL Brief score as compared to 6 points in the control group. With a standard deviation of 8 points and a 95% confidence interval, a sample of 150 participants per group will be needed to achieve 90% power. The estimates for the intervention group and standard deviation are based on the results of a previously published study. Considering a design effect of 2 being a cluster randomized trial and an attrition rate of 20%, a sample size of 360 participants per group is needed. The sample size of each centre is 20 in both the groups. Therefore, the total sample size for each group is 360 & for the two groups total sample figure is 720 (360*2). Therefore, a total of 720 participants are being enrolled in the study.

Recruitment

The eligible participants are screened from the outreach OPDs/ camps/ door to door visits conducted in the identified areas with predominance of ST or SC population at the selected 17 research institutes of CCRAS, after receiving approval from the Institutional Ethics Committee (IEC) and registering the study with CTRI. Based on the eligibility criteria, the participants are recruited in the study. The participants are explained in their regional language about the study in detail and asked for providing the consent in writing regarding their participation in the study. Through cluster randomization, participants are assigned to one of the two study groups.

Allocation

The pre-existing groups of ST/SC population of the selected areas are identified and divided into five pockets each. Through the cluster randomization, the pockets are randomly assigned to either intervention or control group. The participants are recruited from the field through door-to-door survey; therefore, allocation concealment cannot be achieved.

Blinding

The study is an open label in execution; therefore, blinding is not done.

Data Collection

The Investigator complies with the requirements for all assessments and data collection. The demographic data, clinical history, details of concomitant medications, score of OPQOL-BRIEF, Katz Index of Activities of Daily Living, PSQI, Five Times Sit-to-Stand Test, grading of shoulder joint mobility and assessment of haematological and biochemical parameters is being documented. During follow-ups, occurrence of any symptom and need for any rescue medication will be recorded. Data capture for this study is planned to be in both hard copies of CRF and electronic format. All source documentation supporting entries into the CRFs will be maintained and readily available. During this review, participant data are checked for consistency, omissions, and any apparent discrepancies. Confidentiality of the data is being maintained. After the completion of the study, the data will be analyzed and published without disclosing the personal identification of the participants.

Statistical Analysis

After data collection, verification for its accuracy and limits will be done. The filtered data will be utilized for additional analysis and interpretation. The categorical variables in the study data will be summarized as percentages. The continuous data having normal distribution will be represented as Mean +/- SD and for the data not having normal distribution as Median (Q_1, Q_3). For comparison of percentage, Paired t-test/Wilcoxon test will be used to assess the statistical significance between pre- and post-trial. The assessment parameters assigned more than two follow-ups will be analyzed using the r-ANOVA/Friedman test to determine whether there is a statistically significant difference between the different follow-ups. The 5% level of significance will be used throughout the analysis. The SPSS 26.0 software will be used to conduct the analysis.

Monitoring

To ensure strict adherence to the study protocol and correct documentation of the data CCRAS Headquarters is monitoring the progress of the study. The CCRAS representative(s) and regulatory authority monitors visit the investigator for the purpose of inspecting the facilities and, upon request, inspecting the various records of the clinical study (e.g., CRFs and other pertinent data) provided that subject confidentiality is respected. The Clinical Monitoring Committee is responsible for verifying the CRFs at regular intervals throughout the study to verify adherence to the protocol; completeness, accuracy, and consistency of the data; and adherence to local regulations on the conduct of clinical research. Any problems detected in the course of these monitoring visits, including delays in completing CRFs, will be resolved by the committee.

Confidentiality

The names and identities of participants will remain confidential, and all of the data and documents of the participants will be kept in discreet.

Protocol amendments

Any modification from the study protocol will be executed after prior approval from the IEC.

Discussion

The proposed protocol will provide guidance regarding the utility of *Rasayana* in the targeted population. The intervention is expected to work well through its mode of action as per the earlier research on *Ayush Rasayana* A & B, which comprised healthy volunteers between the ages of 60 and 75 years, had no health issues other than controlled hypertension. *Ayush Rasayana* 'A' was administered for the first six days followed by *Ayush Rasayana* 'B' which was given twice a day for the following six months. The WHOQOL-BREF quality of life questionnaire and the six-minute walk distance were employed as efficacy measures. All previously prescribed medications and regular healthcare were permitted. The six-minute walk distance and quality of life improved, according to the results. This medication appears to have a beneficial effect on the aging process and the present study is being conducted to substantiate the effectiveness and relish full potential of the intervention. The results are comparable in the present study as a control group will be given ancillary care through Ayurveda.

Physical or cognitive assessment is being done by the assessment parameters mentioned before. OPQOL-BRIEF is an internationally recognized highly reliable and valid measurement tool, comprises of 13 items summed for a total OPQOL-BRIEF score, then positive items are reverse coded, so that higher scores represent higher QoL. The total sum-score ranges from 13 to 65. Examples of items include enjoying one's life, looking forward to things, staying involved with things, and feeling safe where one lives, etc [9]. Katz Index of Activities of Daily Living is the most suitable tool to evaluate functional status as a measurement of an individual's capacity to carry out ADL independently by ranking adequacy of performance in six functions: bathing, dressing, toileting, transferring, continence, and feeding [10]. PSQI is designed to evaluate overall sleep quality as psychiatric disorders are often associated with sleep disturbances, which consists of 19 self-reported items belongs to one of seven subcategories: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction [11].

As a result of aging, decreases in muscle strength and endurance, and/or a loss in balance may

occur. Therefore, functional mobility in old age is assessed by Five Times Sit-to-Stand Test [12]. Upper limb mobility is assessed through three simple physical manoeuvres for active ROM of the shoulder joints, haematological and biochemical parameters (CBC, LFT and RFT) will provide valuable information about health of an individual.

The results of both the groups will be analysed and published in reputed journal after completion of the study.

Result

The execution of the study has been initiated in April 2023. As of 29th February 2024, the enrolment of the participants for the study has been completed at all the designated study sites and follow up is being done at subsequent visits. 660 participants are continuing till date, while 13 participants have dropped out due to poor compliance.

Financial support and sponsorship

The Central Council for Research in Ayurvedic Sciences, Ministry of Ayush, Government of India, is the funding source for this study. Additionally, the funding agency provided technical assistance for the design of the study and the drafting of the study protocol.

Conflict of interest

There are no conflicts of interest.

Access to data

Central Council for Research in Ayurvedic Sciences will have access to the final study data.

Acknowledgment

The authors are thankful to Prof. Rabinarayan Acharya, Director-General, Central Council for Research in Ayurvedic Sciences, Ministry of Ayush, Government of India, for his valuable guidance and administrative support.

Abbreviations

ADL: Activity of Daily life
CBC: Complete blood count
LFT: Liver function test
RFT: Renal function test
CRF: Case record form
CTRI: Clinical Trials Registry- India
CCRAS: Central Council for Research in Ayurvedic Sciences
GCP: Good Clinical Practice
IEC: Institutional Ethics Committee
OPQOL-BRIEF: Older People's Quality of Life Questionnaire- Brief
PSQI: Pittsburgh Sleep Quality Index
QOL: Quality of life
ROM: Range of motion
SC: Scheduled Caste
ST: Scheduled Tribe

References

[1] Giridhar G, Sathyanarayana KM, James KS. Introduction. In: Population Ageing in India [Internet]. Delhi: Cambridge University Press, 2014. xvii–xxvi. Available from: https://doi.org/10.1017/CBO9781139683456.

[2] Banerjee S. Determinants of rural-urban differential in healthcare utilization among the elderly population in India. BMC Public Health. 2021, 21(1):939. Available from: https://doi.org/10.1186/s12889-021-10773-1

[3] Mundada P, Sharma S, Gupta B, Padhi MM, Dey A, Dhiman KS. Review of health-care services for older population in India and possibility of incorporating AYUSH in public health system for geriatric care. Ayu. 2020, 41(1):3. DOI: 10.4103/ayu.AYU_172_16 Available from: http://dx.doi.org/10.4103/ayu.ayu_172_16

[4] Acharya YT. Charaka Samhita of Agnivesha. Chikitsa Sthana. Ch. 1, Ver. 44. 3rd ed. Varanasi: Chaukhamba Surbharati; 2005. p. 387.

[5] Acharya YT. Sushrut Samhita of Acharya Sushruta. Sutra Sthana. Ch. 1, Ver. 8. 9th ed. Varanasi: Chaukhamba Orientalia; 2007. p. 3.

[6] Balasubramani SP, Venkatasubramanian P, Kukkupuni SK, Patwardhan B. Plant-based Rasayana drugs from Ayurveda. Chin J Integr Med. 2011 Feb, 17(2):88-94. doi: 10.1007/s11655-011-0659-5. Epub 2011 Mar 9. PMID: 21390573. Available from: https://pubmed.ncbi.nlm.nih.gov/21390573/

[7] Govindarajan R, Vijayakumar M, Pushpangadan P. Antioxidant approach to disease management and the role of 'Rasayana' herbs of Ayurveda. J Ethnopharmacol. 2005 Jun 3, 99(2):165-78. doi: 10.1016/j.jep.2005.02.035. Epub 2005 Apr 26. PMID: 15894123. https://pubmed.ncbi.nlm.nih.gov/15894123/

[8] Sharma S, Dey A, Gambhir I, Hazra J, Mundada P, Mata S, et al. Safety and efficacy of ayush rasayana A and B in improving functionality of the elderly – A single-arm multicenter study. J Indian Acad Geriatr [Internet]. 2022, 18(2):49. DOI: 10.4103/jiag.jiag_5_22 Available from: http://dx.doi.org/10.4103/jiag.jiag_5_22

[9] Haugan G, Drageset J, André B, Kukulu K, Mugisha J, Utvær BKS. Assessing quality of life in older adults: psychometric properties of the OPQoL-brief questionnaire in a nursing home population. Health Qual Life Outcomes. 2020, 18(1). Available from: https://doi.org/10.1186/s12955-019-1245-3

[10] Sharifi, F., Alizadeh-Khoei, M., Saghebi, H. et al. Validation Study of ADL-Katz Scale in the Iranian Elderly Nursing Homes. Ageing Int. 2018, 43:508–523. Available from: https://doi.org/10.1007/s12126-017-9314-6

[11] Shahid A, Wilkinson K, Marcu S, Shapiro CM. Pittsburgh sleep quality index (PSQI). In: STOP, THAT and One Hundred Other Sleep Scales. New York, NY: Springer New York. 2011, p. 279–283. DOI 10.1007/978-1-

4419-9893-4_67. Available from: https://www.med.upenn.edu/cbti/assets/user-content/documents/Sleep-Instruments-book.pdf

[12] Muñoz-Bermejo L, Adsuar JC, Mendoza-Muñoz M, Barrios-Fernández S, Garcia-Gordillo MA, Pérez-Gómez J, et al. Test-retest reliability of Five Times Sit to Stand Test (FTSST) in adults: A systematic review and meta-analysis. Biology (Basel). 2021, 10(6):510. Available from: https://doi.org/10.3390/biology10060510