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Protocol

Evaluation of Panchkol Churna against lifestyle modification in cardiovascular risk management: a protocol for an open-label, randomized comparative clinical trial

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ABSTRACT

Background: Cardiovascular disease (CVD) remains the leading cause of global mortality, with significant variations in prevalence and mortality rates. Ayurveda advocates the Rasadhatu dushti (RDD) as a component in the development of Hrid rogas. Also, Hridaya has been described as the root (Moola) of Rasavaha srotas, therefore any kind of vitiation in Rasadhatu is liable to affect the heart causing pathologies. The study aims to provide evidence for the role of RDD in CVD and explore integrative approaches to reduce the risk of CVDs.
Methods: This is a study with two phases including a screening and recruitment phase to assess prevalence of RDD with sample size of 390 participants and a clinical trial phase with two groups (A & B) with 30 participants in each group. The participants in group-A will receive Panchkol churna in dose of 3gm for 30 days with Luke warm before meal and group-B will receive life style modification for 30 days. The primary outcome is the assessment of prevalence of RDD in participants at risk of CVDs. The secondary outcome is the changes in Gene expression (Apo-E and IL-6), Framingham risk score (Appendix 2), RAS-RCVD (Appendix 1) score and lipid profile.
Conclusions: This protocol outlines a mixed-method study to investigate the prevalence of RDD in participants at risk of CVD and evaluate the comparative efficacy of Panchkol Churna against lifestyle modification (LSM) as risk reduction measures. The study integrates Ayurvedic concepts with modern clinical markers, such as inflammatory markers (IL-6) and gene expression (Apo-E).
Trail Registration: Clinical Trial Registry of India (CTRI/2023/05/053143)

Keywords: Ayurveda, Cardiovascular disease, Gene expression, Panchkol churna

INTRODUCTION

Cardiovascular disease (CVD) remains the leading cause of global mortality, with significant variations in prevalence and mortality rates across different regions and income levels. The number of prevalent CVD cases nearly doubled from 271 million in 1990 to 523 million in 2019.[1] Global CVD deaths increased from 12.1 million in 1990 to 18.6 million in 2019.[1] CVDs refer to any disorder of the heart and blood vessels. CVDs encompass a range of disorders affecting the heart and blood vessels.[2] Nutritional researches are now targeting on dietary impacts in the primary as well as secondary prevention of CVD. Rasadhatu (RD) mentioned in Ayurvedic literature, is a structural entity which regulates the constant supply of nutrients to the cells and tissues. Ayurveda attributes ailments related to heart and other body channels to vitiated Rasadhatu, one of the seven types of functionally distinct tissue elements in human body.[3] From ayurvedic perspective, it can be observed that CVD as well as the present-day life style disorders are Santarpanotha vyadhis (~ Diseases caused by over nutrition).[4] Excess energy intake (~Atipurana) along with sedentary life style (~Avyayama) leads to deranged

metabolism of the macronutrients; mainly carbohydrate and fat. Such factors are considered in ayurevda as definite causes leading to RDD. Though literary review provides a fair theoretical correlation, empirical evidences on the relation between RDD and CVD are lacking.[5]

Inheritance is a non-modifiable risk factor, and influences the cardiovascular system profoundly.[6,7] Inherited or genetic medical conditions run in a family as they occur due to changes in genes that pass from one generation to another.[8] Ailments such as a blockage in arteries or high blood pressure occur due to several dietary and lifestyle factors which are added up by genetic changes leading to other heart diseases.[7]

Background and rationale

Ayurveda advocates RDD as a component in the development of Hrid rogas.[9] Further, Hridaya Roga is also mentioned as a Santarpannotha Vikaras, the root of which again is present in Rasa Dhatu Dushti as it has been mentioned that Sthaulya (~Obesity) and Karshya (~leanness) are pathological manifestation of rasa dhatu only.[10,11] Also, Hridaya has been described as the root (Moola) of Rasavaha srotas, therefore any kind of vitiation in Rasadhatu is liable to affect the heart causing pathologies.[12]

Hence, RDD may be a contributing factor in predisposition to CVDs. This study is planned to evaluate the role of RDD as a risk factor in the participants predisposed to CVDs through study of RDD Lakshana (RDDL) which will be assessed through a validated Performa named as RDD assessment scale in risk for CVD (RAS-RCVD), also simultaneously measuring Framingham risk score (FRS).[13,14]

Thus, this study is planned to evaluate the role of RDD as a risk factor in the patients predisposed to CVDs through study of RDDL and also to study the role of administered study drug on RDD, gene expression (Apo-E) and inflammatory marker (IL-6).

Objectives

The primary objective of the study is to study the prevalence of RDD in participants at risk of CVDs by validated RAS-RCVD score and to compare the risk reduction efficacy of Panchkol churna against life-style modification in participants at risk of CVDs in terms of changes in RAS-RCVD score before and after intervention i.e., between day 0 and day 30 (clinical trial phase). The secondary objectives are to compare the changes in gene expression, Framingham risk score, BMI and lipid profile in participants at risk of CVD before and after intervention of Panchkol churna against life-style modification.[14]

METHODS

Study design

The study consists of two phases:

Screening and recruitment phase

Single cohort of 390 participants to assess the prevalence of RDD.

Clinical trial phase

Open-label, two-arm, parallel group, randomized comparative clinical trial with 1:1 allocation ratio. (Study period 30 days).

Study setting

The study participants are being screened and enrolled in the study from the outpatient department (OPD) of All India Institute of Ayurveda, New Delhi.

Eligibility criteria of participants

For screening and recruitment phase

Participants fulfilling any three of the following criteria will be selected to participate in survey: Overweight/class-1 obese (body mass index [BMI]: 25-35 kg/m^2), Subjects with low BMI but abnormal lipid profile or subjects having both or at least any one of the above diagnostic criteria will be selected for the study, subjects having family history of cardiovascular events like myocardial infarction, stroke, or peripheral vascular occlusive diseases, subjects with history of tobacco smoking, subjects with documented history of hypertension and subjects with documented history of diabetes mellitus.

Inclusion criteria

Subjects of either gender in the age group of 30-60 years (both years inclusive). Subjects fulfilling any one of the following criteria for abnormal lipid profile: Subjects with total cholesterol level (>200 mg/dl), subjects with triglyceride level (>150 mg/dl), subjects with HDL level (<40 mg/dl) and subjects with LDL level (>140 mg/dl).

Exclusion criteria

Patients who are immobilized since >6 weeks; Patients with documented history of endocrine disorders (hypothyroidism, hyperthyroidism, hyperparathyroidism, untreated Cushing‘s syndrome) auto-immune diseases, amavata, jvara and pandu; Patients with history of any organ transplantation; Patients who may require treatment of oral and/or injectable steroids or surgical intervention during the course of study duration; patient with history of drug abuse; subjects having history of psychiatric

disorder that may impair the ability of subjects to provide written informed consent.

Assessment criteria

For included subjects RAS-RCVD score, Framingham risk score, BMI, CBC (Complete blood count) and FBS (Fasting blood sugar) will be recorded along with the vitals and other needed information.

For clinical trial phase

Inclusion criteria

Subjects at risk of CVDs diagnosed from screening phase with RAS-RCVD score ≥10; who are willing to participate and give informed consent.

Exclusion criteria

Subjects having history of cardiovascular events like myocardial infarction, stroke, or peripheral vascular occlusive diseases; subjects with documented history of hypertension; subjects with documented history of diabetes mellitus; patient with history of clinically-active hepatic or peptic ulcer disease; subjects planning to undergo surgery in next 3 months will be excluded from the study; subjects who are pregnant, breast feeding or planning to become pregnant during the study; subjects participated in any other clinical trials within thirty (30) days prior to screening; patient with history of severe allergy or anaphylactic reaction; any other condition which the investigator think may jeopardize the participant condition.

Withdrawal criteria

Consent withdrawn by the subject or request by the subject; serious adverse events/reactions where continuation of the study poses a serious risk to the subject (according to SAE/R definition); patient condition deteriorates during the course i.e., further continuation of the study is likely to be detrimental to health of subjects; if the patient's compliance to the study drugs is less than 70% or does not take the study drugs for 2 weeks continuously; at the discretion of principal investigator if he thinks that it is in the interest of the patient¸ occurrence of pregnancy in female subjects; development of clinical condition leads to violation of inclusion/ exclusion criteria.

Interventions

Intervention arm (Group A)

Panchkol churna, a polyherbal formulation in 3 gm dosage orally, twice a day with Luke warm water for 30 days duration before meals.[15]

The ingredients of formulations will be indented, authenticated and drug will be prepared in AIIA Pharmacy. Moreover, the analytical study of drug will also be conducted.

Comparator Arm (Group B)

Life-style modification.

Outcome measures

Primary outcome measure

The primary outcome measures for the study include the RAS-RCVD based evaluation of prevalence of RDD in participants at risk of CVDs along with comparative changes in RAS-RCVD score and Gene expression in participants at risk of CVD after intervention of Panchkol churna against life style modification (clinical trial phase).

Secondary outcome measures

Changes in Framingham risk score, BMI and lipid profile after intervention of Panchkol churna against life style modification i.e., at interval of day 0 and day 30.

Participant timeline

Timelines for outcome assessment for clinical trial phase is given in Table 1.

Unscheduled visits

A subject may visit the study site on some other day if required due to adverse effects. The subject will contact the study co-ordinator for the same. This visit will be called as unscheduled visit. All the information will be captured at the unscheduled visit and documented. At any unplanned visit, any procedures, evaluations and/or laboratory assessments may be performed at the discretion of study personnel.

Sample size

For screening and recruitment phase

The sample size for this survey study was calculated based on the prevalence of RDD, which was assessed using the RD score and estimated at 49.4%, approximated to 50% for a conservative estimate. The sample size was determined using the formula $N=Z^2\times P\times Q/d^2$; where $Z=1.96$ for a 95% confidence level, $P=0.5$ (prevalence of RD), $Q=1-P=0.5$, and $d=e\times P=0.1\times 0.5=0.05$ (margin of error). Substituting these values, the sample size calculation resulted in $N=384.16$, which was rounded up to 385 participants. To ensure adequate representation and account for potential non-responses, approximately 390 participants will be recruited for the study.

For clinical trial phase

In view of non-availability of any previous study on gene expression, considering it as exploratory study a sample size of 36 participants in each group (Group A and B) will be recruited considering 20% dropout rate.

Randomization and allocation

In this open-label, parallel group, randomized comparative clinical trial, participants will be randomly assigned to either intervention group/control group in ratio of 1:1. Sequentially numbered, sealed, opaque envelopes (SNOSE) being used for allocation concealment.

Study procedure

Before initiating any trial-related activities, the investigator provides a brief of the trial and trial-related procedures to the participant. The written information in the form of the participant information sheet is provided to the participants in printed form. After ensuring that the potential participants have understood the information, signed consent form are obtained. The patients undergo screening process to assess their eligibility based on predefined criteria, which also include medical history, physical examination, laboratory tests, and other relevant assessments. Those who meet the eligibility criteria are then randomly assigned to either the intervention or control group. Once randomized, participants are formally enrolled in the trial, marking the start of their participation and informed of their group allocation and scheduled for baseline assessments, and study interventions dispensed to the participants as per allocation with instructions for use and recording of compliance. The details of the study procedure are depicted in Figure 1, and the details of trial activities during each visit are presented in Table 1.

Laboratory investigations

The haematological and biochemical tests (hemogram, lipid profile and fasting blood sugar levels) done at screening/baseline and at the end of the treatment (30^{th} day) at All India institute of Ayurveda, New Delhi.

Gene expression analysis of Apo-E and IL-6 is being conducted at Integrated translational molecular biology unit at All India Institute of Ayurveda, New Delhi. The gene expression is carried out by qRT-PCR. The details of gene expression methodology are depicted in Figure 2.

Data collection, management, and analysis

All trial data is being recorded directly on the case record forms (CRF) in English, with a black or blue ink ball-point pen, only by the principal investigator or co-investigator and authorized co-worker, ensuring legibility. Corrections will be made by drawing a single line through the original entry, entering the new value and placing initials and date next to the new entry. Completed CRFs will be dated and signed by the investigator or authorized study personnel and stored in locker with the study investigator. Laboratory results will be transcribed into the CRFs. Original lab data will be kept in a separate file at the investigator's office. Statistical analysis will be done after verification of data accuracy and locking.

Study monitoring, auditing, and inspecting

Study will be monitored as per the predefined monitoring plan by departmental research committee (DRC) at interval of every 6 months, to ensure adherence to the protocol, data integrity, and participant safety. The investigator will allocate sufficient time and resources for monitoring activities and ensure that monitor has access to all relevant study-related documents and facilities (e.g., pharmacy, diagnostic laboratory). Adequate workspace will be provided for monitoring visits.

The investigator will facilitate study-related audits and inspections by ethics committee, sponsor, government regulatory authorities, and quality assurance teams. Access will be provided to all relevant study-related documents, including source documents, regulatory records, data collection instruments, and study data.

Trial drug management and accountability

Study drugs will be securely stored in a restricted-access area at the trial site, accessible only to the investigator and qualified delegated personnel. The drugs containers will be labelled with the study code, expiry date, batch number, storage conditions, and the statement "for clinical trial use only." Moreover, A log will be maintained to record the receipt and dispensation of study drugs, with explanations for any discrepancies. The drugs will be stored at room temperature.

Prior and concomitant medication and rescue medication

The participants would be encouraged to avoid taking any other medications without consulting the investigator unless there is an emergency. They would also be encouraged to report any unusual symptoms to the investigator immediately. However, any concomitant medications that the study participants are using would be allowed to be continued, and their use shall be recorded. The investigator will record the complete information of all the participants' concomitant medicines and rescue medicines with reasons.

Protocol amendments

Any modifications to protocol will be documented as written amendments. Amendments that impact participant safety, study scope/scientific quality will require prior approval from local EC. In urgent cases where immediate

protocol changes are necessary to protect participant safety, investigator may implement changes without prior approval but must notify the ethics committee within 10 working days. All amendments will be submitted for ethics committee review and approval as required.

Confidentiality

Information about study subjects will be kept confidential and managed according to requirements of health insurance portability and accountability act of 1996 (HIPAA).

Declaration of interests

There is no competing interest between the investigators.

The principal investigator has designed this study and will analyse the data and publish the results.

Ancillary and post-trial care

No ancillary studies are planned as part of this trial. Participants will receive routine medical care, if needed, after the study concludes.

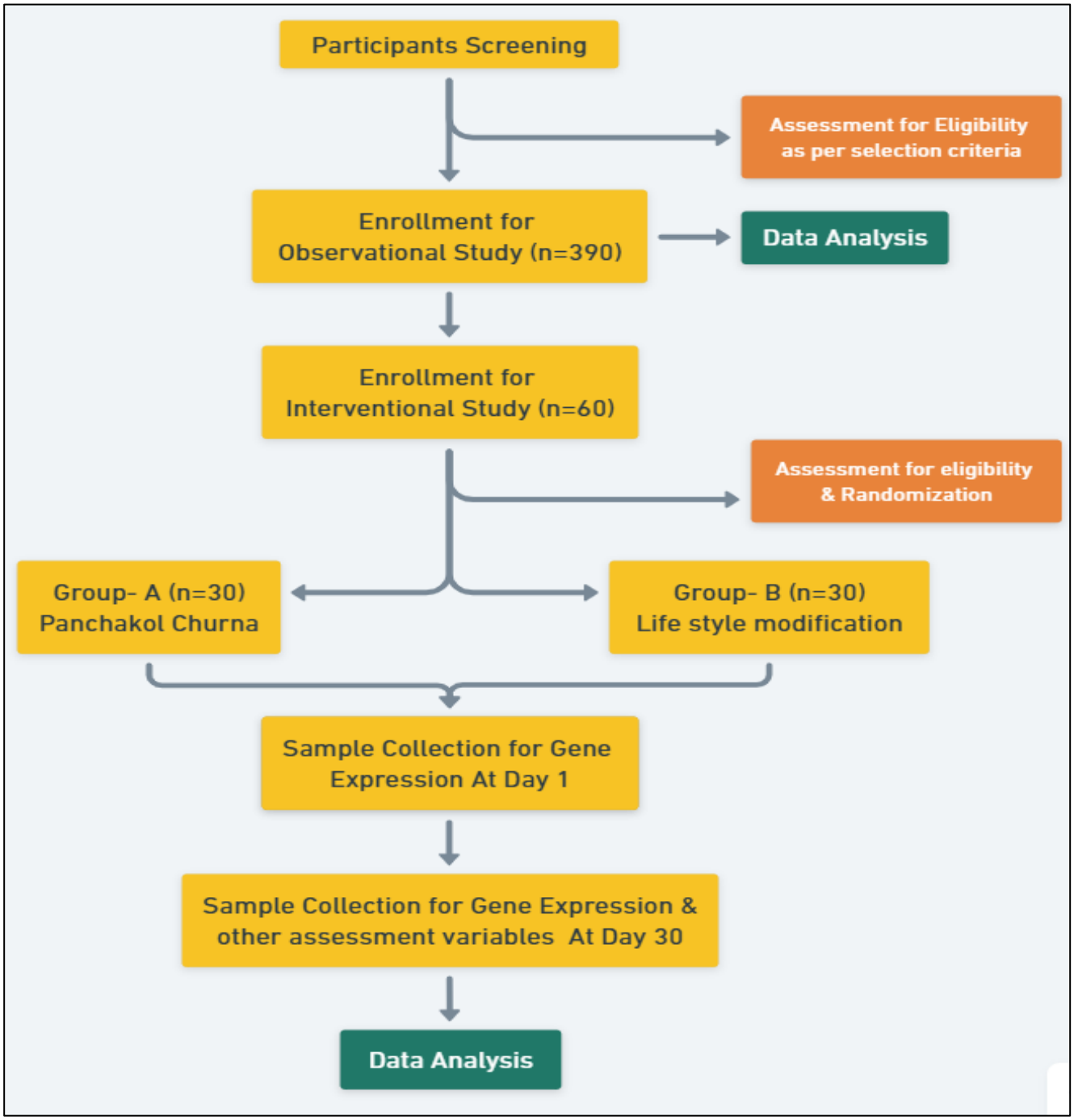

Figure 1: Flowchart of study procedure.

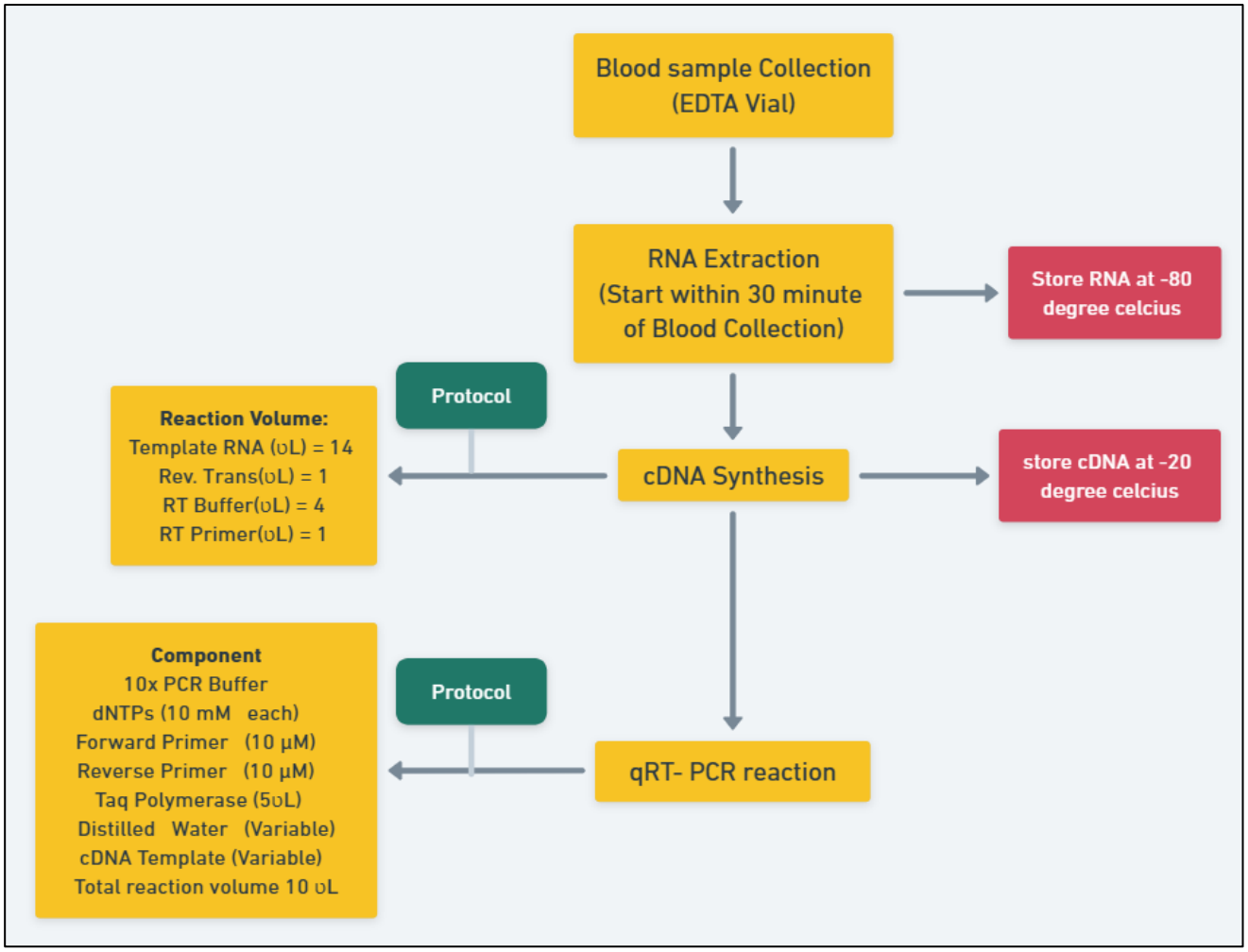

Figure 2: Methodology for gene expression study.

Table 1: Timelines for outcome assessment for interventional study.

Activity	Visit 1(Day 0)	Visit 2 (Days 15)	Visits3 (Day30±6)
Assessment of IC/EC	√	-	-
Informed consent process	√	-	-
Demographics	√	-	-
Medical history	√	√	√
Vital signs	√	√	√
Physical examination	√	√	√
Framingham risk score assessment	√	-	√
BMI	√	-	√
RAS-RCVD score	√	-	√
Laboratory investigations (FBS, lipid profile)	√	-	√
UPT (for female participants of childbearing age)	√	-	-
Gene expression (Apo-E & IL-6	√	-	√

DISCUSSION

Researches for the genetic predisposition of CVD started around 20 years ago, and it is anticipated that genetic polymorphism may be analogous to the already known CVD risk factors.[16] Genomic conditions are triggered by changes in one or more genes passing on to the next generation.[17] When a normal copy of gene gets combined with its copy inherited from family, chances of passing on a heart disease increase. Moreover, CVD is a condition that results from inflammation or cholesterol deposition in the inner walls of major arteries supplying blood,

oxygen, and nutrients to the heart. Also, cholesterol wouldn't be nearly as dangerous without inflammation, which is thought to play an essential role in atherosclerosis, the hardening that occurs when LDL cholesterol builds up in the arteries.[18] According to ayurveda, Ahara (~food) is digested with the assistance of Jatharagni and transformed into Rasa. This Rasa enters the microcirculatory channels and, with the aid of Vyana Vayu, reaches the heart, from where it is circulated throughout the body.[19] If Agnimandya occurs at the level of Jatharagni, the resulting Ahara Rasa will be of suboptimal quality. This leads to the formation of various metabolic byproducts at different levels, resulting in the accumulation of Ama (undigested or partially digested molecules). which is believed to clog bodily channels, leading to inflammation and various chronic conditions.[20] Free radicals and Ama share a similar role in disease initiation and this inflammation causing free radicals are generated during the metabolism of fats, carbohydrates, and proteins.[20,21] The inflammatory response accelerates the accumulation of cholesterol within the arterial walls, creating a cycle of increasing inflammation. Over time, the deposited cholesterol hardens into plaques, which may rupture, leading to the formation of blood clots that cause heart attacks and strokes.[22] IL-6 is associated with increased risk of coronary heart disease (CHD) and ischemic stroke (IS), and its levels can attenuate the significance of other inflammatory markers when adjusted for IL-6.[23] Apo-E is a glycoprotein with antiatherogenic properties, meaning it can help prevent the formation of atherosclerotic plaques, which are a major cause of CVD. Correcting dysfunctional Apo-E alleles, can enhance these protective effects.[24] The impact of Apo-E genotypes on CVD can be modified by factors such as diet and physical activity, which may mitigate some of the genetic risks associated with Apo-E.[25] Therefore, targeting inflammation and cholesterol-regulating genes represents a strategic approach in dyslipidaemia. Apo-E variants influence lipid profiles, which are critical in CVD risk and it can affect cholesterol and triglyceride levels, impacting cardiovascular health.[26]

The FRS is instrumental in identifying individuals at high risk for CVD, thereby informing decisions on interventions such as cholesterol-lowering medications.[27] It also helps in stratifying patients based on their risk levels, which is crucial for targeted preventive strategies.[28]

Based on the all these principals of correcting the RDD, the exploratory clinical study is planned. Prevention has always been considered superior to management, however, since not much work is being done on the preventive aspects, this study was planned to find out the risk reduction effect of Deepana-pachan polyherbal formulation in Ayurveda-Panchkola Churna in comparison to LSMs which are considered as a mainstay in the predisposition and management of lifestyle disorders in CVDs.

CONCLUSION

This study aims to determine the prevalence of RDD in participants at risk of CVD using the validated RDD assessment scale in risk for CVD (RAS-RCVD Score). Additionally, it evaluates the risk reduction effect of Panchkola Churna compared to LSM in these participants. Also, the present study is a first report to the best of authors' knowledge in Ayurveda, which is meticulously designed to evaluate the gene expression and elucidate the molecular mechanisms underlying the therapeutic effects of a polyherbal Ayurvedic formulation. By integrating traditional knowledge with advanced molecular biology techniques, this research aims to provide novel insights into the mechanistic basis of Panchkola Churna in CVD risk management.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee(Ref No. IEC-304/19.12.2022/PhD-14/2022; dated April 27, 2023), Trail no. CTRI/2023/05/053143.

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