PROTOCOL

Efficacy and Safety of Ayurveda Interventions for Obesity: Protocol for a Systematic Review

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Abstract

Background: Obesity is similar to *Sthaulya* or *Medoroga* described in Ayurvedic classical texts. Results from case studies/series and small clinical trials concluded that Ayurveda interventions have been effective in the management of obesity. This protocol aimed to do a systematic review of clinical studies related to Ayurvedic interventions in the management of obesity and further meta-analysis of eligible studies to generate the evidence regarding effectiveness and safety of Ayurvedic treatment modalities for obesity.

Materials and methods: Clinical studies related to Ayurvedic interventions in the management of *Sthaulya*/*Medoroga* or overweight/obesity published in English/Hindi will be screened as per the inclusion criteria without restriction on publication date and type. Primary outcomes to be assessed will be improvement in clinical features of *Sthaulya*/*Medoroga* and change in body weight, body mass index (BMI), waist circumference, waist–hip ratio, and skin-fold thickness. Data will be extracted independently by two review authors on study characteristics (authorship, publication-related information, methodology, participants, interventions, comparators, outcomes, and results) in a prestructured format for assessment of study quality and data analysis. Two authors will independently assess the risk of bias in included studies. We will conduct meta-analyses only when the included studies will be sufficiently homogeneous in terms of design, study population characteristics, interventions, and outcome measures. If meta-analyses will not be conducive, we will summarize the results of included studies as systematic qualitative synthesis.

Conclusion: The results generated from this review will be helpful in identifying the status of evidence for Ayurvedic interventions in management of obesity. It will also provide way for future research to generate stronger evidence regarding efficacy of Ayurvedic interventions in the treatment of obesity.

Clinical significance: The study will be able to generate evidence for effective implementation of Ayurvedic interventions in treatment and prevention strategies for obesity.

Study registration: PROSPERO 2019—CRD42019130104.

Keywords: Ayurveda, *Medoroga*, Obesity, Overweight, *Sthaulya*, Systematic review.

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Introduction

Obesity represents a medical state of excess body fat accumulation as a consequence of energy imbalance between calories consumed and calories disbursed.[1] Globally, there has been an increase in the intake of energy-dense foods rich in fat, a lack of physical activity due to sedentary nature of work, and advancing urbanization. Obesity is associated with a host of potential comorbidities such as type II diabetes mellitus, hypertension, coronary heart disease, osteoarthritis, stroke, depression, nonalcoholic fatty liver disease, infertility (women), erectile dysfunction (men), risk of stillbirth, gallbladder disease, obstructive sleep apnea, gastroesophageal reflux disease, and some cancers (endometrial, breast, and colon).[2–6] At least 2.8 million people die each year globally, as a result of being overweight or obese. Forty-four percent of the diabetes burden, 23% of the ischemic heart disease burden, and 7–41% of certain cancer burdens are attributable to overweight and obesity.[7] Overweight and obesity, though considered a disease of high-income countries at one time, are now on the rise in low- and middle-income countries, particularly in urban settings.[7] Worldwide prevalence of obesity has increased nearly three times since 1975. In 2016, more than 1.9 billion adults were overweight; out of which over 650 million were obese.[8] In India, obesity has reached epidemic proportions in the 21st century, with morbid obesity affecting 5% of the country's population. The rise in overweight/obesity prevalence in India has become an emerging concern that needs urgent attention.[9]

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For adults, the World Health Organization define overweight as body mass index (BMI) greater than or equal to 25 kg/m^2 and obesity as BMI greater than or equal to 30 kg/m^2. According to BMI, obesity is classified into three categories: class I obesity—BMI 30.0 to 34.9 kg/m^2, class II obesity—BMI 35.0 to 39.9 kg/m^2, and class III obesity or extreme obesity—BMI > 40 kg/m^2. In general, obesity can be categorized as "apple type" and "pear type," which are also known as upper truncal obesity and lower truncal obesity, respectively. Asian population due to predominance of central fat distribution have lower cutoff limits of BMI for diagnosis of obesity,

i.e., overweight with BMI 23.0–24.9 and obesity with BMI of more than 25.[10]

Conventional medical approaches have shown limited success in the treatment or prevention of obesity.[11] Unfortunately, pharmacotherapy for obesity despite short-term benefits is often associated with numerous shortcomings such as rebound weight gain after the cessation of drug use, considerable adverse effects from the medication, and the potential of drug abuse.[12] Most of the antiobesity drugs have been withdrawn from the market, as a result of their substantial side effects. Also, relative effectiveness of conventional pharmacological therapies and endoscopic treatments in obese patients remains unclear in published systematic reviews and meta-analyses.[13,14] In spite of the promising results obtained by bariatric surgery, the procedure is invasive, costly, and associated with long-term morbidity and complications, so it is only reserved for obese patients with very high BMI.[15]

Complementary and alternative medicine (CAM) are being used increasingly worldwide nowadays especially in the management of chronic diseases such as obesity due to their efficacy and much less adverse effects. Herbal medicines have been found to have acceptable antiobesity effects with additional antioxidant, hypolipidemic, and insulin-sensitizing effects.[16] Ayurveda, one among the popular CAM in the eastern world, has age-old acceptance in the communities in India and forms the first-line of treatment in case of common ailments and chronic refractory illness such as obesity. Ayurveda has a more extensive and holistic management of chronic refractory illnesses. Personalized approach of Ayurveda such as dosha-specific diet and lifestyle, along with focus on biopurification and healthy digestion, has been the reason for long-term success in the treatment of chronic illnesses such as obesity.

Obesity is similar to *Sthaulya*/*Medoroga* described in Ayurvedic classical texts. *Sthaulya* is described as an excessive and abnormal increase in *meda dhatu* (~adipose tissue) along with *mamsa dhatu* (~muscle tissue) resulting in the pendulous appearance of buttocks, belly, and breasts, though increased bulk does not lead to corresponding increase in physical stamina.[17] Results from case studies/series and small clinical trials concluded that the Ayurveda interventions have been effective in the management of obesity.[18–20] It is the need of hour to generate good quality evidence regarding the effectiveness and safety of Ayurvedic treatment modalities in the management of obesity for their wider acceptability which can be done through systematic reviews of the available studies. This systematic review is planned to identify the status of evidence regarding Ayurvedic interventions in the management of obesity and further meta-analysis of eligible studies.

Objectives

To conduct a systematic review of the available clinical studies in view of efficacy and safety of Ayurvedic interventions in the management of obesity.

Materials and Methods

The review will be systematically done following the Preferred Reporting Items for systematic reviews and meta-analyses (PRISMA) statement.[21–23]

Eligibility Criteria

Studies will be selected according to the criteria mentioned below.

Study Designs

All randomized controlled trials, nonrandomized controlled trials, quasi-randomized controlled trials, controlled clinical trials, before and after comparative trials, and multiarm parallel group comparative trials that assess the efficacy and safety of Ayurvedic interventions in the management of *Sthaulya*/*Medoroga* or overweight/obesity were included in this review. No restrictions on publication date or type. (All studies published by the end of September 2019 will be considered for this systematic review.).

Participants

Studies including participants of both sex and all age-groups based on obesity criteria/symptomatology of *Sthaulya*/*Medoroga* explained in classical Ayurveda texts.[24]

Interventions

Ayurvedic interventions (*Shodhana* or/and *Shamana*) with any drug, dosage form, dose, schedule, and *pathya-apathya* (lifestyle modifications).

Comparators/Control

Ayurvedic interventions with any drug, dosage form, dose, schedule, non-Ayurvedic interventions (*Yoga*, Naturopathy, etc.) or combination of Ayurveda and non-Ayurveda interventions, conventional treatment of obesity, placebo, and/or sham therapy or no treatment.

Outcomes

Primary outcomes will be change in subjective parameters (improvement in clinical features of *Sthaulya*/*Medoroga*) and objective parameters (body weight, BMI, waist circumference, waist–hip ratio, skin-fold thickness). Secondary outcomes involve appearance of serious adverse events (resulting in death, disability, or incapacity; complications; and life-threatening led to hospitalization or prolonged hospitalization) during treatment, withdrawals due to adverse events, or lack of efficacy or inconvenience of therapy/treatment and improvement in the obesity-specific quality-of-life (QoL) scales such as impact of weight on QoL short version (IWQOL-Lite), obesity-specific QoL instrument (OSQOL), etc.[25]

Timings

No restrictions will be made to the length of follow-up outcomes.

Setting

There will be no restrictions by the type of setting.

Language

Studies published either in English or in Hindi.

Information Sources

Electronic databases such as PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), AYUSH Research Portal, DHARA, IndMED, Google Scholar, Shodhganga and Ayurvedic Research Database (2001–2009), IPGTRA, Gujarat Ayurved University, Jamnagar, India will be searched for required clinical studies. Indexed Ayurvedic Journals like AYU, J-AIM, Ancient Science of Life, Indian Journal of Traditional Knowledge, International Journal of Ayurveda Research (Govt. of India), Journal of Ayurveda (National Institute of Ayurveda, Jaipur, India), and other relevant journals

Table 1: Search strategy for PubMed

S. no.	*Search terms*
1	Ayurveda OR Ayurvedic therapy OR Ayurvedic treatment OR Ayurveda interventions OR herbal treatment OR traditional medicine OR alternative medicine OR complementary medicine OR herbomineral OR polyherbal OR *Rasaushadhi* OR *Rasakalpa* OR metallic Ayurveda OR *Panchakarma* OR *Shodhana* OR *Shamana* OR *Langhana* OR *Aptarpana* OR *Udavartana* OR *Vamana* OR *Virechana* OR *Basti/Vasti* OR *Lekhan Basti* OR *Vati* OR *Guggulu* OR *Kwatha*
2	Obesity OR overweight OR childhood obesity OR abdominal obesity OR central obesity OR adiposity OR corpulence OR *Sthaulya* OR *Medoroga* OR *Atisthula* OR *Sthula Rogi* OR *Medasvi* OR *Santarpana* OR body weight OR body mass index/BMI
3	Clinical trials OR clinical trial OR RCT OR randomized trial OR non-randomized trial
4	1 AND 2 AND 3) (under title/abstract)

Table 2: Search strategy for AYUSH research portal (http://ayushportal.nic.in/)

S. no.	*Search terms*
1	HOME>AYURVEDA>CLINICAL RESEAERCH>ENDOCRINE/METABOLIC/NUTRITIONAL>OBESITY
2	HOME>AYURVEDA>CLINICAL RESEAERCH>ENDOCRINE/METABOLIC/NUTRITIONAL>OVERWEIGHT
3	SEARCH>AYURVEDA>STHAULYA
4	SEARCH>AYURVEDA>MEDOROGA

will also be searched. The dissertation work available in public domain will also be included. Hand searching will also be done for journals that may not have been indexed in any electronic database. Conference proceedings/reports/compendium/monographs, and official publications (journals) of various Indian societies/associations and website of Clinical Trial Registry of India will also be searched. References of the included studies and relevant systematic reviews will also be screened. Study authors will be contacted if any information is required regarding the study.

Search Strategy

Search strategy for PubMed and AYUSH research portal has been shown in Tables 1 and 2, respectively.

Study Records

Data Management

The records and data collected from the search of all the available sources will be stored in password-protected files in a secure computer and external data storage device in duplicate; it will be accessible only to the authors who are reviewing.

Selection of Studies

The titles and abstracts of all the available studies yielded by the search against the inclusion criteria will be independently screened by two review authors (AKR and HK). Full texts of the selected articles will be obtained, which appear to meet the inclusion criteria or where there is any uncertainty. Two review authors (AKR and HK) will then screen the full text of the publication to decide whether the selected study meet the inclusion criteria. The reason for the exclusion of the studies excluded during the review will be documented at every stage. Any disagreements will be resolved by discussion or involvement of a third review author (SK or AA). Additional information from study authors will be obtained where necessary to resolve questions about eligibility. Preferred reporting items for systematic reviews and Meta-analyses guidelines will be followed for documentation of the complete study selection process.[21]

Data Collection Process

Predesigned format (Table 3) is prepared based on Narahari et al. model to extract data from the included studies on study characteristics (authorship, publication-related information, methodology, participants, interventions, comparators, and outcomes) for assessment of study quality and data analysis.[26] Data will be extracted independently by two review authors (AKR and HK). Any disagreement will be settled through discussion or involving a third author (SK or AA), where necessary. If required, additional information will be obtained from the contact person (authors) of that study through e-mail/post.

Data Items

Participants

Patients having clinical features of *Sthaulya*/*Medoroga* or diagnosed as overweight/obese. We will also collect details such as patient characteristics (average age, gender, average body weight, BMI, etc.), study design, and sample size.

Intervention

Ayurvedic interventions (*Shodhana* or/and *Shamana*) with any drug, dosage form, dose, frequency, duration of intervention, and *pathya-apathya* (lifestyle modifications).

Control

Ayurvedic interventions with any drug, dosage form, dose, schedule, non-Ayurvedic interventions (*Yoga*, Naturopathy, etc.) or combination of Ayurveda and non-Ayurveda interventions, conventional treatment, placebo, no treatment.

Outcomes

Primary outcomes are change in subjective parameters (improvement in clinical features of *Sthaulya*/*Medoroga*) and objective parameters (body weight, BMI, waist circumference, waist–hip ratio, skin-fold thickness). Secondary outcomes are appearance of serious adverse events (resulting in death, disability, or incapacity; complications; and life-threatening led to hospitalization or prolonged hospitalization) during treatment, withdrawals due to adverse events, or lack of efficacy or inconvenience of therapy/treatment and improvement in the patient's QoL.

Results

Reported outcomes, adverse events, follow-up time, and improvement in patient's QoL.

When necessary, means and measures of dispersion will be approximated from figures in the reports. We will use results from an intention-to-treat analysis, if possible.

Risk of Bias (Quality) Assessment

Two authors (AKR and HK) will independently assess the risk of bias in included studies. Randomized controlled trials will be assessed with the help of Cochrane tool of risk of bias, whereas nonrandomized

Table 3: Format for data extraction from included studies

Study particulars
Title of the study, author, and year
Reference: journal/M.D./PhD thesis/conference proceedings, etc.
Study duration
Methodological quality
Study design
Description of participants
Inclusion criteria
Age range and sex
Settings
Sample size
Description of interventions given in each group
Form of administration
Route of administration
Dose and *Anupana* (adjuvant taken alongside medicine)
Timing and frequency of dose with duration of use
Description of outcome
Primary and secondary (if given)
Outcome definitions used in the study and time points
Results
Number of participants identified, excluded, lost to follow-up
Number of participants included
Effect on main outcomes
Adverse events
Adverse events that required discontinuation
A sudden increase in body weight attributed by the patients to the drugs administered
Number of participants developed side effects during follow-up
Serious adverse events
Key conclusions of the study authors
References to other relevant studies
Funding source
Correspondence required
Comments by the review authors

trials will be assessed with risk of bias in non-randomized studies—of interventions tool.[27,28] A judgment regarding the possible risk of bias on each of the domains of the above-mentioned tools will be made from the extracted information and rated as "high risk" or "low risk" or "unclear;" in case of insufficient details in the study. Authors of the concerned study will be contacted for more information. Disagreements between the two review authors will be resolved by discussion or involvement of third review author (SK or AA), if necessary. We will consider each domain in the risk of bias assessment independently and will not assign an overall score.

Data Synthesis

The study data will be quantitatively synthesized (meta-analyses) if sufficient studies are clinically similar with comparable study population characteristics, interventions, and outcome measures; methodologically similar in study design, conduct, quality, and the observed treatment effects are statistically similar.[23]

For dichotomous data, risk ratio will be used, whereas the mean difference will be used for continuous outcomes to measure the treatment effect with 95% confidence intervals. We will try to contact the authors of the study in case of any relevant missing data. Imputation method will be used if missing data are not available.

Heterogeneity among trials will be assessed by applying the Chi-square test (significance level: 0.1) and using the I^2 statistic.[29] The study will not be considered to have heterogeneity if the $I^2 < 50\%$, whereas significant heterogeneity can be observed if $I^2 \geq 50\%$ or $p < 0.1$. If significant heterogeneity is detected and it is still considered clinically meaningful to combine studies, then a random-effects model will be used. In case of no significant statistical heterogeneity, a fixed-effects model will be used. Meta-analyses will be completed using Review Manager 5.3. If significant heterogeneity exists, we will perform subgroup analyses to explore the possible causes. Sensitivity analysis will be used to assess the impact of the inclusion of trials, which have high rates of attrition bias, do not report the intention-to-treat analysis, or with other missing data on the overall treatment effects.[29]

If meta-analyses are not conducive due to substantial heterogeneity, we can summarize and explain the results of the included studies as the systematic qualitative synthesis.

Assessment of Meta-bias

Publication bias and selective reporting of outcomes within the included studies will also be assessed.

Confidence of Cumulative Evidence

The Grading of Recommendations for Traditional Medicine given by World Health Organization will be used to assess the strength of the body of evidence. The assessment will include all the studies included in the review.[30]

Ethics and Dissemination

This review does not require formal ethical assessment and approval, as no confidential participant data will be included. The results of this systematic review will be reported per the PRISMA guidelines and published in an indexed open-access journal as well as presented in national and international conferences to ensure wider dissemination.

Discussion

Ayurveda has shown significant results in the management of obesity in clinical practice as well as in small clinical trials. In spite of this, to generate a good level of evidence on the safety and effectiveness of Ayurvedic management for obesity to have its wider acceptability, there is a need for systematic review of available clinical studies on obesity treatment with Ayurvedic interventions. This review would also aim to compare the effectiveness of different Ayurvedic interventions used in the management of obesity; therefore, trials comparing two different Ayurvedic interventions will also be included for this systematic review. Alongside, we will also assess the quality of reporting of included clinical studies. The results generated from this review will be helpful in identifying status of evidence for Ayurvedic interventions in management of obesity and further its implementation in treatment and prevention strategies for obesity. It will also provide inputs for further research to generate good quality evidence regarding efficacy of Ayurvedic interventions in the management of obesity.

Study Registration

The protocol for this systematic review has been registered with PROSPERO, the International Prospective Register of Systematic Reviews (PROSPERO 2019: CRD42019130104).

Authors' Contribution

Amit K Rai: conception and study design, development of the selection criteria, search strategy, risk of bias assessment strategy, data extraction criteria, and drafting the manuscript; Harit Kumari: helped design the study and drafting the manuscript; Azeem Ahmad: study design, methodological advice and final approval of the manuscript; Sanjiv Kumar, BCS Rao and Narayanam Srikanth: critical revision of the manuscript and final approval of the manuscript; all authors read, provided feedback, and approved the final manuscript.

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हिंदी सारांश

स्थौल्य मे आयुर्वेदीक चिकित्सोपचार के प्रभावशीलता एवं सुरक्षितता: प्रणालीगत समीक्षा का प्रोटोकॉल

अमित राय, हरित कुमारी, अज़ीम अहमद, सजीव कुमार, भोगवल्ली चंद्रशेखर राव, नारायणम श्रीकान्त

पृष्ठभूमि: मोटापा आयुर्वेदिक शास्त्रीय ग्रंथों में वर्णित स्थौल्य/मेदोरोग व्याधि के समान है। विभिन्न चिकित्सा अध्ययनों में यह पाया गया है कि आयुर्वेदिक चिकित्सा स्थौल्य के उपचार में प्रभावी है। इस प्रोटोकॉल का उद्देश्य स्थौल्य के उपचार में आयुर्वेदिक चिकित्सा से संबंधित चिकित्सा अध्ययनों की एक व्यवस्थित समीक्षा करना और स्थौल्य में आयुर्वेदिक उपचार की प्रभावशीलता और सुरक्षा के बारे में साक्ष्य उत्पन्न करना है।

विधियां और विश्लेषण: इस अध्ययन के अंतर्गत अंग्रेजी / हिंदी में प्रकाशित स्थौल्य/मेदोरोग के उपचार में आयुर्वेदिक चिकित्सा से संबंधित चिकित्सा अध्ययनों का विभिन्न मानदंडों के अनुसार विश्लेषण किया जाएगा। समीक्षा में सम्मिलित चिकित्सा अध्ययनों में वर्णित स्थौल्य/मेदोरोग के लक्षणों, शरीर भार, बॉडी मास इंडेक्स, कमर परिधि, कमर-कूल्हे का अनुपात आदि में सुधार का आकलन किया जाएगा। अध्ययन की गुणवत्ता और डेटा विश्लेषण के आकलन के लिए पूर्व-संरचित प्रारूप में अध्ययन विशेषताओं (लेखक, प्रकाशन-संबंधित जानकारी, कार्यप्रणाली, प्रतिभागियों, चिकित्साविधि, आदि) पर दो समीक्षा लेखकों द्वारा स्वतंत्र रूप से डेटा निकाला जाएगा। दो लेखक स्वतंत्र रूप से शामिल अध्ययनों में पूर्वाग्रह के जोखिम का आकलन करेंगे। सम्मिलित अध्ययनों के डिजाइन, उनमें सम्मिलित रोगियों की विशेषताएं, दी गयी चिकित्सा और उसके परिणाम सजातीय होने की स्थिति में ही मेटा-विश्लेषण किया जाएगा। यदि मेटा-विश्लेषण अनुकूल नहीं होगा, तो हम शामिल अध्ययनों के परिणामों को व्यवस्थित गुणात्मक संश्लेषण के रूप में प्रस्तुत करेंगे।

निष्कर्ष: इस समीक्षा से उत्पन्न परिणाम स्थौल्य के उपचार में आयुर्वेदिक चिकित्सा के लिए साक्ष्य प्रस्तुत करने में सहायक होंगे। साथ-साथ स्थौल्य के उपचार में आयुर्वेदिक चिकित्सा की प्रभावकारिता के संदर्भ में उच्चकोटि के साक्ष्य उत्पन्न करने के लिए भविष्य में होने वाले चिकित्स्य शोध हेतु भी मार्ग प्रशस्त करने में सहायता मिलेगी।

नैदानिक महत्व: यह अध्ययन स्थौल्य के उपचार एवं रोकथाम की रणनीतियों में आयुर्वेदिक चिकित्सा के प्रभावी कार्यान्वयन के लिए साक्ष्य उत्पन्न करने में सक्षम होगा।