सत्यमेव जयते
Ministry of Ayush
Government of India

Ayush Export Promotion Council

सत्यमेव जयते
Ministry of Commerce and Industry
Government of India

Ayush Works

A Compendium of Scientific Evidence

Volume I

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ACKNOWLEDGEMENT

The **Ayush Export Promotion Council** (**AYUSHEXCIL**) takes this opportunity to express its deepest gratitude for the invaluable contribution of the Ayush industry in compiling this comprehensive booklet of scientific research papers. This compendium of 88 research papers stands as a testament to the industry and academia unwavering commitment to fostering evidence-based practices and advancing the frontiers of Ayush knowledge.

We are particularly indebted to our founding members for sharing their data and esteemed researchers and institutions whose meticulous work forms the bedrock of this publication. Their dedication to unraveling the intricacies of Ayush practices and their unwavering pursuit of scientific excellence have enriched our understanding of the immense potential inherent in Ayush practices.

The AYUSHEXCIL extends its heartfelt appreciation to our directors PRAVEEN KUMAR MITTAL and SANJAY SRIVASTAVA for their exceptional leadership and guidance in bringing this project to fruition. Their unwavering commitment to promoting Ayush research and innovation has been instrumental in shaping the success of this endeavour.

The Ayush Export Promotion Council (AYUSHEXCIL) extends its sincere appreciation to Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of Ayush and our Industry. The AYUSHEXCIL is deeply grateful for the dedication and expertise of these organizations in advancing the frontiers of Ayush knowledge and promoting its immense potential for the betterment of human health.

As we delve into the pages of this booklet, we are struck by the sheer diversity of research topics covered, ranging from the exploration of ancient Ayush modalities to the integration of modern scientific techniques. This breadth of knowledge aptly reflects the multifaceted nature of Ayush and its ability to address a wide spectrum of health concerns. It will undoubtedly contribute to the continued growth and development of the Ayush industry, enabling it to reach new heights of excellence and recognition on the global stage.

Once again, AYUSHEXCIL expresses its deepest gratitude to the Ayush industry for its dedication towards growth of this sector. This booklet stands as a shining symbol of the industry's endeavours to advancing the frontiers of Ayush knowledge and promoting its immense potential for the betterment of human health.

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Himalaya Wellness Company

Himalaya™
SINCE 1930

DIRECTOR's MESSAGE

As the world embraces holistic wellness, the Ayush industry stands at the threshold of a golden age. This research booklet, a testament to tireless research, serves as a powerful tool in our shared mission to elevate Ayush to its rightful place as a cornerstone of global healthcare.

Within these pages lies a treasure trove of knowledge, unearthed through meticulous research by various stakeholders of Ayush sector, revealing the effectiveness of these sciences in addressing a multitude of health concerns viz. chronic diseases to pain relief, mental well-being, and preventive care, solidifying the scientific foundation of Ayush practices.

This booklet serves its purpose more than just research; it's a call to action, a beacon of hope, and a shield of trust. By sharing this knowledge, we intent to encourage more evidence-based studies and products to solidify Ayush position as a cutting-edge global brand.

It is the first step towards our commitment of getting Ayush globally recognised as a system of medicine. This indicates a revolutionary system of healthcare by offering a personalized, preventative, and cost-effective approach. It will further empower the practitioners by arming them with evidence, thus, fostering greater trust and understanding for the Ayush system. Lastly, promotes innovation by paving the way for further exploration and development, leading to novel therapeutic solutions.

This research is crucial for building trust in Ayush brand and its products. By showcasing the scientific basis for their effectiveness, we can address scepticism and empower consumers to make informed decisions about their health. This, in turn, will lead to increased demand for Ayush products and services, propelling the industry to new heights.

Praveen Kumar Mittal
Director, AYUSHEXCIL

MESSAGE FROM
Director General, CCRAS

केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद्
आयुष मंत्रालय, भारत सरकार
CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Ministry of Ayush, Govt. of India

प्रो.(वैद्य) रबिनारायण आचार्य
महानिदेशक
Prof.(Vaidya) Rabinarayan Acharya
Director General

16th February, 2024

MESSAGE

I am really happy to thank the Ayush Export Promotion Council on this special day for launching the Ayush Scientific Evidence Compendium. This booklet is full of evidence that shows how Ayurveda, Yoga, Unani, Siddha, and Homeopathy can be beneficial, highlighting the scientific work being done in Ayush.

This compendium encompasses evidence on AYUSH interventions in various health conditions like Lifestyle Disorders, Infectious diseases, Mental Health, Women wellness, Bone & Joint support etc. . and is an important step towards showing the world the great value of Ayush practices. Nowadays, it's important for patients to be involved in making decisions about their healthcare. The Ayush Scientific Evidence Compendium helps with this by providing strong scientific evidence about Ayush. It's a key tool for increasing awareness among the public. I think this booklet will give people the information they need to make good choices about their healthcare options, especially showing the proof behind these practices.

I hope this compendium will guide researchers, practitioners, and anyone interested in Ayush, pushing the sector to achieve more. By making these findings easy to understand and access, it helps those who support Ayush healthcare around the world to make better decisions.

I am excited about the good changes this compendium will bring in raising awareness and helping people make informed choices, especially regarding Ayush evidence-based practices

(Prof. Vaidya Rabinarayana Acharya)

जवाहर लाल नेहरू भारतीय चिकित्सा एवं होम्योपैथी अनुसंधान भवन, 61-65, सांस्थानिक क्षेत्र, सम्मुख 'डी' ब्लाक, जनकपुरी, नई दिल्ली-110058
Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoepathy Anusandhan Bhawan, Institutional Area, Opp. 'D' Block, Janakpuri, New Delhi-110058
Phones: 011-28524457, 011-28520748
Website: www.ccras.nic.in **E-mail:** dg-ccras@nic.in, drmacharya@gmail.com

PREFACE

This booklet embodies a carefully distilled collection of research exploring the fundamentals and promise of Ayush. To ensure the utmost authenticity and uphold the standards of the Ayush research community, the summarized papers within have been exclusively sourced from the esteemed Central Council for Research in Ayurvedic Sciences (CCRAS) and other intramural institutes of Ministry of Ayush and Ayush Industry.

Our approach transcends the confines of pure academia. Guided by the wisdom and needs of the Ayush industry, we meticulously evaluate each included research summary through an industry-focused lens. This innovative method guarantees that the insights extracted hold direct relevance to the practical applications of Ayush, effectively bridging the divide between scientific discovery and the optimization of Ayush practices.

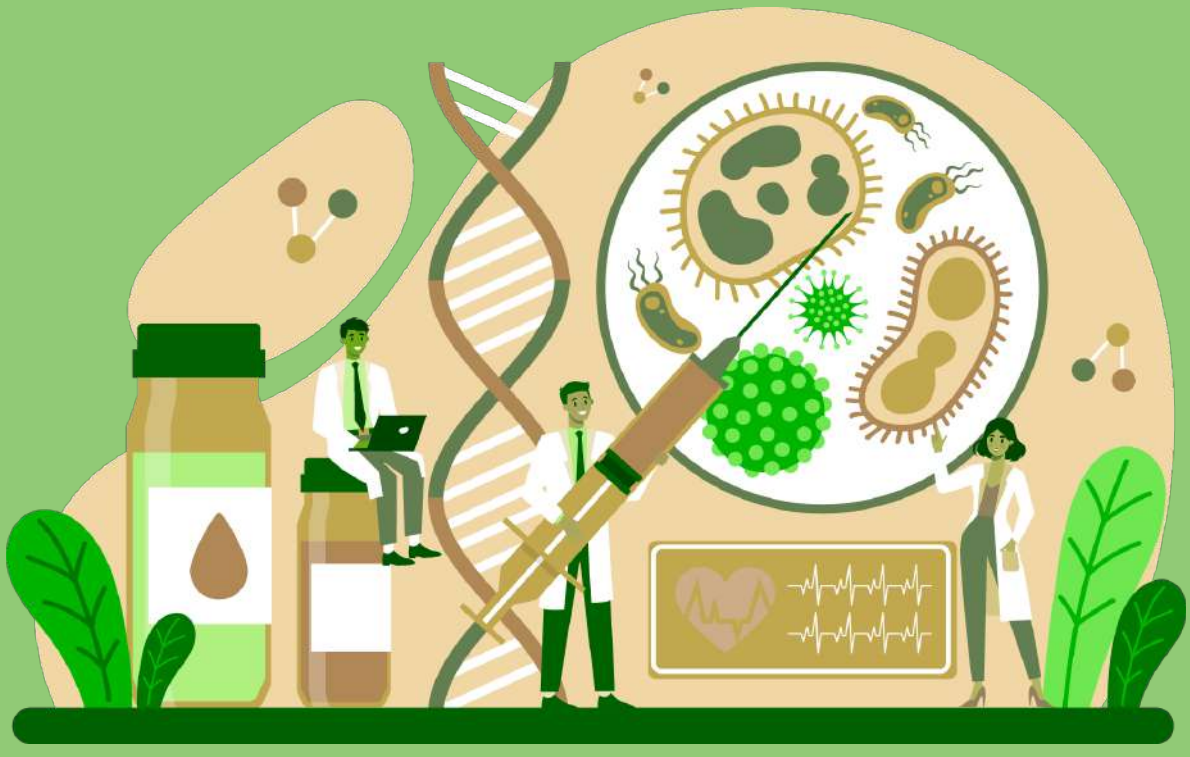
The impetus for this booklet sprang from collaborative discussions with the Ministry of Ayush and a series of in-depth consultations involving prominent figures from the Ayush sector. Guided by this imperative, we strive to align ourselves with the shared national vision of demonstrating the undeniable strength of Ayush – backed by irrefutable evidence-based research – on the global healthcare stage.

Turning these pages, you will encounter meticulously documented accounts of clinical trials undertaken with unwavering adherence to the highest international standards of scientific rigor and ethical considerations. This compilation emerges as a potent instrument designed to illuminate the safety, efficacy, and robust scientific groundwork underpinning Ayush interventions. Our purpose is to empower decision-makers, practitioners, and champions of natural healthcare throughout the global community by presenting these findings in a compelling and readily accessible format.

Chief Editor
Dr. Tripta Dixit

Team
Mr. Ashutosh Srivastava
Mr. Sharad Sharma

6.1 Category-I **Immunity**



Traditional and complementary medicine (T&CM) offers various approaches to strengthen the immune system, promoting overall health and well-being. These practices, rooted in ancient wisdom and refined over centuries, provide a holistic approach to bolster the body's natural defenses.

Dietary modifications, a cornerstone of Ayurveda, emphasize consuming nutrient-rich foods that nourish immune cells. Fruits, vegetables, whole grains, and lean proteins provide essential vitamins, minerals, and antioxidants. Additionally, certain herbs and spices, such as ginger, garlic, and turmeric, possess anti-inflammatory and immune-boosting properties.

Mind-body practices, such as meditation and yoga, play a significant role in stress reduction, crucial for immune system health. Chronic stress can suppress immune function, making the body more susceptible to illness. These practices promote relaxation, mindfulness, and emotional well-being, fostering a conducive environment for optimal immune function.

These T&CM approaches offer a safe and effective means of enhancing the immune system, complementing conventional medical practices and promoting overall health and well-being.

A Phase IV Clinical Study to Evaluate the Efficacy and Safety of Bresol and Septilin Tablets in Combination for Chronic Allergic Rhinitis and Recurrent Bacterial Sinusitis along with Impact on Immune System

Company / Institute(Lab)

HIMALAYA (1-Professor and HOD of ENT, Kempegowda Institute of Medical Sciences, Bangalore, India
2-Consultant Otorhinolaryngologist, Gowri Prasanna Clinic, Bengaluru, India
3-Principal Scientist, The Himalaya Drug Company, Makali, Bengaluru, India)

Type of Study: Clinical Study

Product: Bresol and Septilin Tablets

Abstract

The objective of this research was to evaluate the efficacy and tolerability of Bresol and Septilin tablets as a combined therapy for chronic allergic rhinitis and recurrent bacterial sinusitis.

It aimed to assess the effects of a treatment on chronic allergic rhinitis and recurrent bacterial sinusitis in a group of 200 individuals. The study also examined the impact of the treatment on the immune system. Participants were evaluated based on specific criteria for inclusion and exclusion. Subjects were screened and enrolled in the study according to the protocol. They underwent safety and clinical assessments, as well as haematological and biochemical investigations. Adverse events were recorded during assessment visits at Day 30, 60, and 90.

This study examined the effects of Bresol and Septilin tablets on symptoms such as sneezing, nasal congestion, itching of the eyes and nose, postnasal drip, rhinorrhea, headache, cough, wheezing, nasal obstruction, and watery eyes in adults and paediatric subjects. The results showed a significant reduction in these symptoms when the tablets were used together at recommended doses.

Way forward

In conclusion, it can be inferred that the aforementioned points support the notion that the argument presented Based on the findings of the current clinical investigation, it is possible to infer that the observed positive outcomes may be attributed to the combined and mutually reinforcing actions of the constituents present in Bresol and Septilin pills.

Based on the aforementioned observations, it can be concluded that the administration of Bresol and Septilin treatment yields positive outcomes in effectively ameliorating the clinical symptoms, enhancing specific immunological indicators, and improving the quality of life among both adult and paediatric individuals afflicted with chronic allergic rhinitis and recurrent bacterial sinusitis.

Journal: Annals of Medical and Health Sciences Research
Year: Volume 10 | Issue 3 | May-June 2020

Sub category: Allergy

Standardization in vitro antioxidant activity and brine shrimp lethality of a polyherbal formulation

Company / Institute(Lab)

Sri Sri Tattva (1-Source Natural Foods and Herbal Supplements Limited Plot No 22 & 23, SVCIE, Bachupally, Quthbullapur, RR District. 2-Shri Vishnu College of Pharmacy, Vishnupur, Bhimavaram, West Godavari District, Andhra Pradesh, India.)

Product: Shakti drops

Type of Study: Invivo study

CTRI registration no.: CTRI/2020/07/026655

Abstract

In this research, we evaluate the ability of a compound to scavenge free radicals and protect against oxidative stress using three different assays. We test various concentrations of the compound and compare its performance with standard antioxidants.

The effectiveness of Shakti, an Ayurvedic polyherbal formulation, as a medicine for immuno modulatory activity is examined. A laboratory-prepared formulation was created using authenticated organic plant drugs. The standardisation procedure was performed according to the physicochemical parameters and antimicrobial studies recommended by the Ayurvedic formulary of India. The physical characteristics of the samples were consistent throughout the study. In terms of antimicrobial activity, the total aerobic count was measured to be 18×101 CFU/mL, while the total fungal count was found to be less than 10 CFU/mL.

The study found that no microorganisms were detected, including Staphylococcus aureus, Salmonella typhi, Pseudomonas aeruginosa, and Escherichia coli. The study found that Shiakti drops have strong antioxidant properties and can effectively scavenge free radicals. These findings support the use of Shiakti drops in Rasayana therapy.

Way forward

The results of our formulation exhibited no observable changes in physical characteristics and were found to be free from microbial contamination. The substance exhibits a strong antioxidant activity and demonstrates no symptoms of toxicity in brine prawns cytotoxicity tests, thereby supporting its suitability for human ingestion.

Journal: International Journal of Ayurveda and Pharma Research

Year: January 4, 2016

Sub category: Cytotoxicity analysis

6.2
Category - II
Lifestyle Disorder

Lifestyle disorders, also known as non-communicable diseases (NCDs), are chronic conditions that are preventable and manageable through lifestyle modifications. Traditional and complementary medicine (TCM) offers a range of safe and effective approaches to address these conditions.

TCM practitioners emphasize a holistic approach to health, focusing on the underlying imbalances rather than just treating symptoms. Herbal medicine, dietary therapy, and lifestyle counselling are some of the commonly used TCM modalities that have shown promising results in managing lifestyle disorders.

Dietary therapy, an integral part of TCM, emphasizes the consumption of whole, unprocessed foods and the avoidance of excessive sugar, processed fats, and refined carbohydrates. Lifestyle counselling, provided by TCM practitioners, focuses on identifying and modifying unhealthy lifestyle habits, such as smoking, excessive alcohol consumption, and lack of physical activity.

TCM offers a personalized and comprehensive approach to managing lifestyle disorders, addressing both the physical and mental aspects of these conditions. By combining traditional therapies with lifestyle modifications, TCM can help individuals achieve and maintain optimal health and well-being.

A Prospective, randomized double-blind, placebo controlled study of safety and efficacy of HFSM-02 in reducing stress and anxiety in subjects with chronic medical condition and perceived stress.

Company / Institute(Lab)

BAIDYANATH (Head Clinical Research, Siddhayu Ayurvedic Research Foundation Pvt. Ltd, Nagpur, Maharashtra, India, | Siddhayu Ayurvedic Research Foundation Pvt. Ltd, Nagpur, Maharashtra, India, | Mprex Healthcare, Wakad, Pune, Maharashtra, India, | Consultant, Sai Hospital, Gangai chambers, Akurdi, Pune, Maharashtra, India.)

Product: Winostress Capsule

CTRI registration no.: CTRI/2020/08/027076

Type of Study: Randomized controlled trial

Abstract

This study aims to explore the concept of stress, which is characterised by the experience of emotional or physical tension. The incorporation of this phenomenon into contemporary lifestyles is now prevalent. Stress is a common experience that everyone encounters at some point in life. The study examines the adverse effects of a particular factor on individuals' lives, including the heightened likelihood of developing cardiovascular disease and exacerbating existing medical conditions such as asthma, diabetes, and hypertension. This study addresses the growing issue of stress and anxiety, exploring the need for a solution to this problem. This study examines the effectiveness of HFSM-02 in reducing stress and anxiety in individuals with chronic medical conditions and perceived stress.

In this study, a total of 120 subjects were included. The study involved subjects who were undergoing clinical examination. Vital signs were documented. Blood samples were collected to measure the levels of serum cortisol, a biochemical marker. Subjective questionnaire scores, such as POMS-2 and GHQ-28, were evaluated. This study observed changes in symptom severity, including disrupted sleep and fluctuations in daytime mood.

The study found that cortisol, a stress hormone, was reduced in healthy individuals, as well as in individuals with cardiovascular diseases and diabetes mellitus. The reduction percentages were 33.34%, 41.6%, and 52.64% respectively. The decrease in DASS-21 and POMS-2 scores indicates a decrease in stress levels.

The study demonstrates that HFSM-02 has a notable impact on reducing stress hormone levels in individuals who are both healthy and moderately stressed, and who also have diabetes and cardiovascular complications.

Way forward

To sum up, the results of this study suggest that HFSM-02 is a promising intervention for reducing stress hormones in various populations. Whether they are healthy or have moderate stress and other health issues like diabetes and heart problems, HFSM-02 can help lower their cortisol and adrenaline levels. This may have positive implications for their well-being and quality of life.

Journal: European Journal of Molecular & Clinical Medicine

Year: Volume 08, Issue 04, 2021

Sub category: Stress

Randomized, open-label, controlled, comparative clinical study to evaluate the safety and efficacy of Pilex Forte tablets in combination with Pilex Ointment application for the effective management of common ano-rectal conditions

Company / Institute(Lab)

Himalaya (Department of Surgery, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India; Department of Clinical Pharmacology, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India; Directorate of Indian system of Medicine, Puducherry, India; Himalaya Wellness Company, Makali, Bengaluru, India)

Product: Pilex Forte tablets

Type of Study: Randomized controlled trial

CTRI registration no.: CTRI/2020/03/023725 || CTRI/2020/06/026085

Abstract

The findings of this research examined the prevalence and characteristics of two commonly occurring anorectal conditions: haemorrhoids and anal fissures. This study aimed to assess the safety and effectiveness of combining Pilex Forte tablets with Pilex Ointment, and compare it to the standard treatment. This study involved 162 patients, aged 18-50 years, of both sexes, who were diagnosed with common anorectal conditions. The study design was a randomised, open-label, controlled comparative clinical trial.

In this study, patients were randomly assigned to one of two treatment groups: the standard of care group or a group receiving a combination of Pilex Forte tablets and Pilex Ointment. The treatments were administered according to the recommended dosage for a duration of four weeks. The study found that patients who were treated with the Pilex combination experienced notable improvement in anorectal conditions when compared to those who received standard care. The study observed normal laboratory values and no negative events occurred throughout the research period.

This study concludes that the recommended use of Pilex Forte tablets and Pilex Ointment is safe and effective for managing anorectal conditions such as haemorrhoids and fissure-in-ano.

Way forward

To conclude, the administration of Pilex Forte tablet in conjunction with Pilex Ointment at the appropriate dosage has been determined to be both safe and efficacious in the treatment of anorectal ailments such as haemorrhoids and fissure-in-ano.

Journal: European Journal of Clinical and Experimental Medicine
Year: 2021; 19 (3): 221–232

Sub category: Hemorrhoids

Efficacy and safety of a polyherbal formulation in hemorrhoids

Company / Institute(Lab)

Himalaya (Department of Surgery, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India; Department of Clinical Pharmacology, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India; Directorate of Indian system of Medicine, Puducherry, India; Himalaya Wellness Company, Makali, Bengaluru, India)

Type of Study: Observational study

Product: Arshkeyt

Abstract

This study emphasises the importance of adopting a comprehensive approach in the medical management of haemorrhoids. Polyherbal formulations with various medicinal properties, such as anti-inflammatory, styptic, analgesic, and laxative effects, can be used to achieve an integrated approach. These formulations help to reduce inflammation, pain, and bleeding, while also increasing gastrointestinal motility and softening stools. The study discusses a polyherbal kit called "Arshkeyt™, a 7 day kit," which includes oral tablets, powder, and a topical cream.

The objective of this study is to examine and analyse the research findings in order to provide a simplified abstract that summarises the main points This study aimed to assess the effectiveness and safety of Arshkeyt™, a 7-day kit containing multiple herbal ingredients. The evaluation was conducted by comparing its performance with the conventional therapy commonly used in surgery outpatient departments. This section describes the materials and methods used in the study. In this study, 90 patients with haemorrhoids were randomly assigned to receive either Arshkeyt™ or standard therapy for a duration of 14 days. The standard therapy consisted of a combination of oral Isabgul powder and 2% lidocaine gel. Rectal symptoms and proctoscopic examination were assessed on day 0, 7, and 14. A blinded evaluator derived a "composite score" ranging from 0 to 25 based on these assessments. The study aimed to determine the number of patients who achieved a composite score of 0 at the end of therapy, which was on day 14. A Chi-square test was conducted to analyse inter-group differences.

Results: After 14 days, 15 patients in the Arshkeyt™ group achieved a composite score of 0, compared to 6 patients in the standard therapy group. In the Arshkeyt™ group, there were notable improvements in symptoms such as tenesmus score, anal sphincter spasm, and grade of haemorrhoids compared to the standard treatment group on day 14. The study found that Arshkeyt™ was more effective in treating bleeding haemorrhoids compared to nonbleeding haemorrhoids ($P < 0.05$). The occurrence of negative drug reactions was similar in both groups, and no patients needed any treatment for them. Conclusion: The 7-day kit called "Arshkeyt™" demonstrated effectiveness in treating haemorrhoids and exhibited a favourable safety profile.

This study examines the effects of isabgul and 2% lidocaine gel on anal sphincter spasm, rectal bleeding, and tenesmus.

Way forward

The conclusion enstates the utilisation of Arshkeyt™, a comprehensive treatment regimen spanning a duration of 7 days, exhibited efficacy in addressing the symptoms associated with haemorrhoids while also demonstrating a commendable level of safety

Journal: Journal of Ayurveda & Integrative Medicine

Sub category: Hemorrhoids

Year: Received: 30-Jan-2015 | Revised: 09-Mar-2015 | Accepted: 04-Jun-2015

An Evaluation of the Efficacy, Safety, and Tolerability of Abhraloha Compared With Oral Ferrous Ascorbate on Iron Deficiency Anemia Women: A Randomized Controlled, Parallel-Group, Assessor-Blind Clinical Trial

Company / Institute(Lab)

Dhootapapeshwar (1. Pharmacology and Therapeutics, Seth Gordhandas Sunderdas Medical College - King Edward Memorial Hospital, Mumbai, IND 2. Pharmacology, Seth Gordhandas Sunderdas Medical College - King Edward Memorial Hospital, Mumbai, IND 3. Pharmacology, Rajiv Gandhi Medical College and Chhatrapati Shivaji Maharaj Hospital, Mumbai, IND 4. Department of Swasthavritta and Yoga, DY Patil Deemed To Be University School of Ayurveda, Mumbai, IND 5. Medical Services, Shree Dhootapapeshwar Limited, Mumbai, IND)

Product: Abhraloha

Type of Study: Observational study

CTRI registration no.: CTRI/2019/01/017303

Abstract

This study focuses on Myostaal Forte, a unique blend of nine herbal plant extracts known for their pain-relieving, anti-inflammatory, and joint-protective qualities.

The aim of this study is to investigate and analyse the research topic. This study aimed to assess the effectiveness and safety of Myostaal Forte in patients with knee osteoarthritis. It was a planned study with two groups, randomly assigned and compared. The study was designed to be unbiased, with assessors blinded to the treatment. This section describes the materials and methods used in the study. The study recruited individuals with idiopathic knee osteoarthritis based on the clinical criteria established by the American College of Rheumatology (ACR). In this study, sixty patients were divided into two groups: one group received Myostaal Forte TDS and the other group received Paracetamol 650 mg TDS. The treatment period lasted for six weeks. The effectiveness of naproxen as a rescue analgesic was evaluated. This study utilised the Modified Western Ontario and McMaster Universities Arthritis Index (WOMAC), Visual Analogue Scale (VAS), and global assessment scores to evaluate the progress of patients. These assessments were conducted by an orthopaedic physician at various time points throughout the study. This study evaluated safety by conducting laboratory investigations at the beginning and after six weeks, as well as monitoring adverse events and tolerability. The data were presented as the mean value plus or minus the standard deviation. Statistical analysis was performed using the Chi-square test and unpaired t-test. A significance level of $p<0.05$ was deemed as statistically significant.

Results: The study found that both Myostaal Forte and Paracetamol were effective in reducing the activity of osteoarthritis disease. The study found that Myostaal Forte showed significant improvement in pain, stiffness, and physical function compared to Paracetamol after eight weeks ($p<0.05$). The study observed a notable decrease in WOMAC pain scores after two weeks in the Myostaal Forte group ($p<0.05$), while no such reduction was observed in the Paracetamol group. The study observed a reduction in pain severity in all patients who took Myostaal Forte for two weeks, compared to only half of the patients who took Paracetamol. The study observed the effects of two treatments, Myostaal Forte and Paracetamol, on symptomatic relief after six weeks. The Myostaal Forte group showed sustained relief for two weeks, while the Paracetamol group experienced a relapse of pain and physical disability within two weeks. The statistical analysis did not show a significant difference between the two groups ($p>0.05$). Both groups did not experience any significant negative effects, changes in laboratory measurements, and showed excellent adherence to the treatment. Conclusion: Myostaal Forte is a safe and effective alternative for treating knee osteoarthritis due to its ability to provide pain relief and protect the cartilage, even after treatment is stopped.

Way forward

To Conclude, it can be inferred that Abhraloha exhibits hematinic properties and has been shown to enhance certain blood parameters. The usage of this medicine has been shown to be associated with a notable reduction in side effects when compared to oral iron therapy, indicating its potential for safe utilisation in the treatment of iron deficiency anaemia (IDA).

Journal: Journal of Ayurveda & Integrative Medicine

Year: Received: 30-Jan-2015 | Revised: 09-Mar-2015 | Accepted: 04-Jun-2015

Sub category: Anaemia

A prospective, single centre, open label, single arm pilot study to evaluate the efficacy and safety of Amlapitta Mishran Suspension in participants with endoscopic gastritis

Company / Institute(Lab)

Dhootapapeshwar (Department of Pharmacology and Therapeutics, Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India | b Department of Hepatology & Gastroenterology, Suyash Hospital, India | c Consulting Ayurved Physician Suyash Hospital, India | d Medical Services, Shree Dhootapapeshwar Limited, India)

Type of Study: Observational study

Product: Amlapitta Mishran Suspension
CTRI registration no.:
CTRI/2020/02/023,224

Abstract

Endoscopic gastritis is a condition characterised by symptoms of gastritis and corresponding endoscopic observations. The Amlapitta Mishran is a compound with multiple active components that work through different mechanisms to alleviate gastritis symptoms in patients. The purpose of this study was to evaluate the effectiveness and safety of Amlapitta Mishran in patients diagnosed with endoscopic gastritis.

This study aims to assess the effectiveness of Amlapitta Mishran in patients diagnosed with endoscopic gastritis. This study was conducted to evaluate the effectiveness of a new treatment approach. It was an open-label study, meaning that both the researchers and participants were aware of the treatment being administered. The study was prospective, meaning that data was collected over a specific period of time. It was conducted at a single centre, ensuring consistency in the study environment. In this study, a total of 30 participants were enrolled and administered Amlapitta Mishran Suspension for a duration of 30 days. Blood investigations were conducted at three different time points: baseline (Visit 1), Visit 3, and Visit 4, to ensure safety. Endoscopy was conducted at the beginning of the study and during Visit 4 to assess stomach erosion. The study evaluated the effectiveness of different treatments by measuring the Amlapitta Symptom Rating Scale score, Post-prandial Distress Syndrome (PPDS) score, and Epigastric Pain Syndrome (EPS) score. In this study, 30 participants were initially recruited, but only 28 participants successfully completed the study. It found that the median age of participants was 26.50 years. In this study, a significant decrease in endoscopy score was observed at Visit 4 compared to the initial baseline measurement (Visit 1). This reduction was determined to be statistically significant based on the results of the Wilcoxon Signed Rank test ($P<0.05$). The Amlapitta study found that the Symptom Rating Scale score, PPDS score, and EPS score all showed a significant decrease at Visit 3 and Visit 4 compared to the initial baseline. This was determined through statistical analysis using Friedman's test with post hoc analysis. There was no significant reduction observed in the scores between Visit 3 and Visit 4, except for the EPS score. At the conclusion of Visit 4, 18 participants (64%) had an endoscopy score of 1, indicating the absence of erosions. At the conclusion of Visit 4, a significant improvement of 50% was observed in the Amlapitta Symptom Rating Scale score for 27 out of 28 participants (96%). Additionally, 25 out of 28 participants (89%) experienced a 50% improvement in PPDS score, while 26 out of 28 participants (93%) showed a 50% improvement in EPS score. The safety variables, including laboratory investigation, remained within normal range throughout all visits.

Conclusion: The study found that Amlapitta Mishran Suspension was successful in reducing endoscopic gastritis scores and alleviating gastritis symptoms, as measured by various rating scales. Importantly, no negative effects were observed during the study.

Way forward

In conclusion, the administration of Amlapitta Mishran Suspension demonstrated efficacy in reducing endoscopic scores among individuals with Endoscopic gastritis. Additionally, it effectively alleviated clinical symptoms of gastritis as measured by the Amlapitta Symptom Rating Scale, Postprandial Distress Syndrome (PPDS) scores, and Epigastric Pain Syndrome (EPS) scores. Importantly, this medication was found to be safe with no reported adverse events

Journal: Journal of Ayurveda and Integrative Medicine
Year: Received 31 December 2021| Accepted 10 October 2022

Sub category: Gastritis

A randomized-controlled trial of the effects of a traditional herbal supplement on sleep onset insomnia

Company / Institute(Lab)

MAHARISHI AYURVEDA (Department of Psychiatry,
University of California at San Diego, USA)

Type of Study: A double-blind, randomized, placebo-controlled, cross-over study

Abstract

This study aims to assess the efficacy and safety of a traditional herbal supplement in treating sleep onset insomnia. It followed a specific research design called a double-blind, randomised, placebo-controlled, cross-over design. Participants: 25 healthy individuals (age range: 20-65 years) with sleep onset insomnia were selected from the general population. The primary measure used to assess the main result of the study. This study examines the concept of sleep latency, which refers to the time it takes for an individual to fall asleep after going to bed. The research aims to explore various results like the supplement was found to have a significant effect on reducing the time it takes to fall asleep. On average, participants taking the supplement experienced a decrease in sleep latency of 16.72 minutes, with a standard deviation of 44.8. This effect was statistically significant when compared to the placebo group, with a p-value of 0.003. No self-reported side effects were observed.

The study indicates that using traditional herbal supplements could be highly beneficial for individuals with sleep onset insomnia, without the adverse effects commonly associated with prescribed hypnotics.

Result

A repeated measures ANCOVA, controlling for pre-treatment levels of sleep latency and fatigue, showed that, across all subjects, compared to placebo (mean = 74.11 min; S.D. = 69), the supplement (mean = 57.40 min; S.D. = 51) led to a significant mean decrease of 16.72 min (S.D. = 44.8) in sleep latency (P = 0.003). Sleep latency values among the two order-of-treatment groups were as follows:
subjects crossing over from placebo treatment to herb treatment, 86.23 ± 99 to 60.59 ± 58, respectively; subjects crossing over from herb treatment to placebo treatment, 56.58 ± 49 to 62 ± 50, respectively. Subjects with longer sleep latency (median split; >45 min) benefited more from the supplement (a mean sleep latency decrease of 28.11 min (S.D. = 54.9)) than those with shorter sleep latency (a mean sleep latency decrease of 1.91 min (S.D. = 21.06)) (P = 0.01).In contrast to sleep latency, there were no significant treatment effects on self-reported difficulty get - ting off to sleep (placebo mean = 1.65 (S.D. = 0.57) and supplement mean = 1.82 (S.D. = 0.77)).
Self-reported difficulty getting to sleep values among the two order-of-treatment groups were as follows: subjects crossing over from placebo treatment to herb treatment, 1.66 ± 0.60 to 1.82 ± 0.79, respectively; subjects crossing over from herb treatment to placebo treatment, 1.8 ± 0.78 to 1.65 ± 0.56, respectively. There were no significant treatment order effects for either sleep latency or difficulty getting to sleep (F's < 2.20; P's > 0.14).
None of the subjects reported any adverse side effects of treatment. Side effects were assessed on the final visit through an interview inquiring about any notable side effects during any of the nights of the study, particularly morning drowsiness.

Way forward

In conclusion, the results indicate that the use of traditional herbal supplements could potentially provide substantial advantages for individuals experiencing sleep onset insomnia, while also circumventing the adverse effects associated with often used hypnotic medications

Journal: Complementary Therapies in Medicine© 2003 Elsevier Ltd.
Year: 11 February 2004

Sub category: Insomnia

Inhibition of Low-Density Lipoprotein Oxidation by Oral Herbal Mixtures Maharishi Amrit Kalash-4 and Maharishi Amrit Kalash-5 in Hyperlipidemic Patients

Company / Institute(Lab)

MAHARISHI AYURVEDA

Type of Study: Observational study

Abstract

The process of atherosclerosis is primarily driven by the oxidation of low-density lipoprotein (LDL). In previous studies, it has been demonstrated that the herbal combinations known as Maharishi Amrit Kalash-4 (MAK-4) and Maharishi Amrit Kalash-5 (MAK-5) has the ability to hinder the oxidation of LDL (low-density lipoprotein) generated by cupric ions (Cu+2) and endothelial cells in laboratory settings. Additionally, it has been seen that the administration of MAK-4 leads to a reduction in the development of atherosclerosis in Watanabe heritable hyperlipidemic rabbits.

The participants were administered the herbal mixture. This study assesses the antioxidant activity of MAK-4 and its potential implications.In vivo evaluation of MAK-5. A group of ten patients with hyperlipidemia, who were already receiving consistent hypolipidemic medication, were administered MAK-4 and MAK-5 for a duration of 18 weeks. The investigation involved the periodic assessment of plasma lipoprotein, plasma lipid peroxide, and LDL oxidation at six-week intervals. The levels of apolipoprotein A, apolipoprotein B, and lipoprotein (a) were assessed at both the beginning of the study and after a duration of 18 weeks. A time-dependent prolongation of the lag phase and delay in the propagation phase of low-density lipoprotein (LDL) oxidation by copper ions (Cu+2) and endothelial cells was observed following a 12-week treatment with MAK-4 and MAK-5. The lag periods observed at baseline and after 6, 12, and 18 weeks of consumption of MAK-4 and MAK-5 were 6.66 hours ± 0.19 (mean ± standard error of mean), 6.77 hours ± 0.31, 7.22 hours ± 0.24, and 18.00 hours ± 0.73, respectively.

There was no substantial alteration observed in the lipid peroxide levels. There were no notable alterations observed in the plasma lipoproteins and the concentrations of apolipoprotein A, apolipoprotein B, and lipoprotein (a). The findings demonstrate that the compounds MAK-4 and MAK-5 possess inhibitory properties. The process of low-density lipoprotein (LDL) oxidation in individuals diagnosed with hyperlipidemia. Hence, it is possible that both MAK-4 and MAK-5 might be the application of this intervention has proven to be beneficial in both the prevention and management of atherosclerosis.

Way forward

This study aims to explore how MAK-4 and MAK-5 affect the oxidation of low-density lipoprotein (LDL) in people with high blood lipids who take these herbal medicines orally.

The subject of this study is mixtures. Recent studies suggest that the oxidative modification of low-density lipoprotein (LDL) by free radicals plays an important role in the development of atherosclerosis.

Atherosclerosis has several key stages in its origin. Oxidised low-density lipoprotein (LDL) contributes to atherosclerosis through various ways: It is recognised and quickly taken up by specific receptors on macrophages, leading to the formation of foam cells. It also has cytotoxic effects and attracts monocytes. It inhibits the movement of tissue macrophages. It causes the release of monocyte chemoattractant protein 1 and macrophage colony stimulating factor from endothelial cells. These factors stimulate the production of interleukin-1 and other cytokines from macrophages, which activate the endothelial cells.

It stimulates the production of autoantibodies; It interferes with the dilation of arteries in response to agents that act through the endothelium-dependent relaxation factor.

It activates platelets and causes them to aggregate; It increases the adhesion of platelets and monocytes to endothelial cells; It increases the levels of tissue thromboplastin and factor VII, and activates the coagulation cascade, resulting in the formation of fibrin.

Journal: American journal of the medical sciences
Year: November 1997 Volume 314 Number 5

Sub category: Hypercholesterolemia

Effects of a standardized Ayurvedic formulation on diabetes control in newly diagnosed Type-2 diabetics: A randomized active controlled clinical study

Company / Institute(Lab)

King George's Medical University(KGMOU)

Type of Study: Randomized, active control study

Product: Standardized Ayurvedic formulation

CTRI registration no.: CTRI/2014/03/004490

Abstract

This study aimed to assess the effectiveness of a standardised polyherbal formulation, comprising aqueous extracts from six herbs, in individuals diagnosed with Type-2 diabetes mellitus.

This study follows a randomised design with an active control group. This study involved 93 patients who were recently diagnosed with Type-2 diabetes mellitus. The patients were randomly divided into two groups: group 1 received polyherbal capsules at a daily dose of 500 mg, which was gradually increased to a maximum of 3 g per day, while group 2 received Metformin at a daily dose of 500 mg, which was gradually increased to a maximum of 2 g per day.

Main outcome measures: The main focus of this study was to assess the impact of the intervention on the alteration of blood glucose levels, specifically fasting blood glucose and postprandial blood glucose, as well as glycosylated haemoglobin (HbA1c) levels compared to the baseline. This study examines the impact of the intervention on lipid levels, liver enzymes, and renal function test as secondary outcomes.

In this study, the effects of a polyherbal formulation (PHF) and Metformin on fasting and post prandial blood glucose levels were examined over a period of 24 weeks. The results showed that the PHF treated group experienced a decrease of 25.52% in fasting blood glucose and 24.22% in post prandial blood glucose. In comparison, the Metformin treated group showed a decrease of 31.46% in fasting blood glucose and 24% in post prandial blood glucose. The estimated treatment difference between the two groups was -10.8 for fasting blood glucose and -0.36 for post prandial blood glucose, with corresponding confidence intervals of -22.63 to 1.03 and -12.1 to 11.38, respectively. The reduction in HbA1c levels was found to be comparable between the PHF and Metformin groups, with an estimated treatment difference of 0.01 (95% CI −0.51 to 0.53). The study found that the group treated with PHF experienced a greater decrease in mean total cholesterol levels compared to the group treated with Metformin. The estimated mean difference for the PHF group was 61.3 (95% CI 55.32 to 67.28), while for the Metformin group it was 41.12 (95% CI 34.92 to 47.32). The study found a statistically significant difference in total cholesterol levels between the treatment groups after six months of treatment. The estimated treatment difference was 20.18, with a 95% confidence interval ranging from 12.34 to 28.02.

Conclusion: The study found that consuming this PHF on a daily basis resulted in lower blood sugar levels and improved regulation of lipids. Additionally, all other serum biochemical levels remained within the normal range. These findings suggest that this PHF could be beneficial for individuals with Type-2 diabetes. The trial has been registered in the Clinical Trials database.

Way forward

This study provides empirical evidence supporting the positive impact of the Ayurvedic formulation (PHF) that consists of a combination of herbal ingredients, including C.

The present study examines the impact of rotundus, B. aristata, C. deodara, E. officinalis, T. chebula, and T. bellirica on blood glucose level and HbA1c, providing evidence for their efficacy.

The efficacy of this herbal combination in the management of Type-2 diabetes. Additionally, the administration of this herbal combination resulted in a notable enhancement of the lipid profile among those diagnosed with Type-2 diabetes, while exhibiting no detrimental side effects.

Journal: Complementary Therapies in Medicine
Year: Volume 23, Issue 4, August 2015

Sub category: Diabetes

Effect of Ayurveda intervention, lifestyle modification and Yoga in prediabetic and type 2 diabetes under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)–Ayush integration project

Company / Institute(Lab)

Central Council of Research in Ayurvedic Sciences (CCRAS)

Type of Study: A multi-centric, open-labeled, prospective, comparative clinical study

Abstract

The prevalence of type 2 diabetes in India is significant, impacting approximately 422 million people. This condition is closely associated with lifestyle factors. This study discusses the integration of Ayurveda (Ayush) with the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) in Gaya, Bihar. The aim is to provide integrative treatment for non-communicable disease patients and address the burden of non-communicable diseases in India.

The objectives of this study were to investigate and analyse the impact of various factors on a specific phenomenon. This study aimed to examine the impact of Ayurveda intervention, lifestyle modification, and Yoga on the treatment of type 2 diabetes within the framework of the NPCDCS-Ayush integration project.

This section describes the materials and methods used in the study. This study was conducted at multiple healthcare centres and a district hospital to compare different treatments. This study involved screening individuals over the age of 30 to identify those who were either prediabetic or had type 2 diabetes. These individuals were then divided into two groups: Cohort A, consisting of those who were prediabetic, and Cohort B, consisting of those who had type 2 diabetes. The study involved dividing a cohort into two groups: Group A1 received advice on lifestyle modification and Yoga, while Group A2 received Ayurveda medication along with advice on lifestyle modification and Yoga. In this study, two groups, B1 and B2, were assigned different treatment approaches. Group B1 received lifestyle modification and Yoga, along with allopathic medication. Group B2, on the other hand, received Ayurveda medication, specifically Mamajjaka, Amalaki, and Guduchi powder, in addition to lifestyle modification, Yoga, and allopathic medication. A 6-month treatment period was administered. The data was analysed using a paired t-test.

The results of the study are as follows: This study found a significant decrease in fasting blood sugar levels and postprandial blood sugar levels in groups A2 and B2. The reduction was statistically significant with a p-value of 0.001. This study examined the effects of a treatment on various symptoms associated with a medical condition. The results showed that all groups experienced improvements in symptoms such as increased urination, excessive thirst, excessive hunger, blurred vision, and weakness. However, no improvement was observed in the healing of ulcers.

In this study, the effectiveness of Ayurveda intervention, specifically the use of Mamajjaka Churna, Amalaki Churna, and Guduchi Churna, was examined in pre-diabetic and type 2 diabetic patients. The intervention, administered twice a day, was found to effectively control blood sugar levels and improve disease management when combined with lifestyle modifications, Yogasana, and allopathic treatment.

Way forward

The findings of the study indicate that the implementation of Ayurveda intervention, specifically the administration of Mamajjaka Churna (1 g), Amalaki Churna (3 g), and Guduchi Churna (3 g) twice daily, demonstrates significant efficacy in regulating blood sugar levels among individuals with pre-diabetes and type 2 diabetes. Furthermore, this intervention contributes to the enhancement of disease management through the adoption of lifestyle modifications, Yogasana practises, and allopathic treatment.

The current analysis demonstrates a heightened influx of individuals in cohorts receiving medical care. This suggests that there is a psychological component involved in the use of medicine, lifestyle modification, and Yoga as a combined approach for managing type 2 diabetes. Therefore, in order to achieve a balanced distribution of participants across all groups, future trials could be designed to include a placebo intervention in those groups that were solely assigned lifestyle change and Yoga.

Journal: AYU (An International Quarterly Journal of Research in Ayurveda) **Sub category:** Diabetes

Year: Volume 40 ¦ Issue 1 ¦ January-March 2019

Outcomes from a Whole-Systems Ayurvedic Medicine and Yoga Therapy Treatment for Obesity Pilot Study

Company / Institute(Lab)

National Institutes of Health, Centre for Integrative Medicine

Type of Study: Longitudinal Pre-post interventional study

Abstract

The aim of this study is to assess the viability and acceptability of an intervention combining Ayurveda and Yoga for the purpose of weight loss. This will be achieved by employing inclusion criteria that consider individuals with dual-diagnosis, evaluating outcomes using a dual-paradigm approach, and implementing a semi-standardized protocol that can be customised based on the Ayurvedic constitution or imbalance profile of each participant.
Methodology: A total of seventeen individuals voluntarily participated in a weekly intervention programme over a period of three months. Outcome measurements were conducted at the initial assessment, immediately after the intervention, and at the 3-month and 6-month follow-up periods. The intervention was implemented by the University of Arizona, namely the Department of Family and Community Medicine, throughout the period of April to December 2012.
Participants: The sample consisted of 2 male and 15 female individuals who were recruited from the Tucson, AZ community through the distribution of flyers and posting on hospital message boards. A total of seventeen individuals were initially registered for the study, out of which twelve participants successfully provided complete follow-up data.
Intervention: The participants engaged in bi-monthly meetings with an Ayurvedic practitioner, totaling six sessions. They also adhered to semi-standardized dietary guidelines, which were tailored to address specific psychophysiological imbalances that hindered weight loss. Additionally, the participants followed a standardised protocol of therapeutic yoga classes, attending three sessions per week, and were encouraged to practise yoga at home for an additional two to four sessions.
The primary outcome assessed in this study was weight loss. Additional biological outcomes encompassed in the study were body mass index (BMI), body fat percentage, waist circumference, hip circumference, waist-to-hip ratio, and blood pressure measurements. Novel measures were developed for the purpose of gathering data pertaining to the results linked to the Ayurvedic medical framework. These instruments encompassed several aspects such as dietary modifications based on food characteristics, mood and affect, interpersonal connections, and alterations in Ayurvedic imbalance profiles.
The findings indicate that the participants experienced a mean weight reduction of 3.5 kg during the course of the three-month intervention. The average weight reduction at 3 and 6 months after the intervention showed an increase to 5.6 kg and 5.9 kg, respectively. The individuals who saw a reduction of 3% in their body weight throughout the course of the 12-week intervention, exhibited an average further decrease of 3% during the subsequent follow-up period. There was also an improvement in psychosocial outcomes. No supplementary services were offered to the participants during the duration of the follow-up period.

Way forward

A holistic approach to weight management based on Ayurveda and yoga can be effective and feasible. The data collection process, which required self-tracking and measuring both conventional and Ayurvedic outcomes, was not too burdensome for the participants. The dropout rate observed in this study was similar to that of other weight loss research. The results show a significant weight loss of 3.5 kg right after the intervention, and an additional loss of 5.9 kg at the 6-month follow-up. These findings suggest that long-term weight loss can be achieved through comprehensive lifestyle changes. Moreover, the participants reported improvements in energy, mental health, quality of life, self-awareness, and relationships, indicating the positive impact of these changes. The combination of Weight Stabilisation and Active Lifestyle (WSAY) interventions for obesity shows potential for lasting health benefits and the possibility of preventing or reducing the risk of other chronic diseases related to obesity or its complications.

Journal: The Journal of alternative and complementary medicine
Year: Volume 25, Supplement 1, 2019, pp. S124–S137

Sub category: Obesity

Clinical study to assess efficacy and safety of Purifying Neem Face Wash in prevention and reduction of acne in healthy Adults

Company / Institute(Lab)

The Himalaya Drug Company

Type of Study: Clinical Study

Product: Purifying Neem Face Wash

Abstract

This research investigation analyses the conventional treatment methods for acne vulgaris, a long-lasting and inflammatory skin condition that affects the hair follicles and oil glands. These treatments typically involve the use of antibiotics, retinoids, and synthetic compounds, which can have negative side effects. Herbal skincare products are increasingly popular as a natural alternative in response to this trend.

The objective of this study was to assess the effectiveness and safety of Purifying Neem Face Wash (PNFW), a herbal skincare product, in the prevention and reduction of mild-to-moderate acne. This study was conducted for a duration of four weeks in a single centre, using a single-arm design. The participants included individuals with mild-to-moderate acne or oily skin.

This study evaluated the performance of a specific treatment (PNFW) by analysing the number of acne lesions and measuring sebum levels and skin hydration at four different visits. This study utilised self-assessment questionnaires to collect feedback from participants. The study found that a notable proportion of the 120 participants observed a decrease in acne lesions or the prevention of new ones. This study found significant changes in sebum levels and skin hydration. This study observed high levels of satisfaction among subjects in relation to the effectiveness, ease of use, and fragrance of the product. This study examines the efficacy of Himalaya's PNFW, a product containing neem and turmeric, in the prevention and reduction of mild-to-moderate acne.

The findings indicate that PNFW is effective in treating acne without any reported adverse effects.

Way forward

In conclusion, the findings of this study demonstrate the positive impact of the herbal components, namely neem and turmeric, found in Himalaya's PNFW, in the prevention and reduction of mild-to-moderate acne, without any observed adverse effects.

Journal: Journal of Cosmetic Dermatology: (A Wiley publication)

Year: 9/1/2021

Sub category: Obesity

Safety and efficacy of Oro-T oral rinse in oral mucositis during cancer radiotherapy and/or chemotherapy: Cumulative analysis of two studies

Company / Institute(Lab)

Himalaya (Affiliations- 1. Department of Radiotherapy, M S Ramaiah Medical College and Hospital, Bengaluru, Karnataka, India. 2. Head Medical Services and Clinical Development, The Himalaya Drug Company, Bengaluru, Karnataka, India. 3. Chief Scientific officer, The Himalaya Drug Company, Bengaluru, Karnataka, India. 4Principal Scientist-Medical Services and Clinical Development, The Himalaya Drug Company, Bengaluru, Karnataka, India.)

Type of Study: Cumulative Study

Product: Oro-T mouthwash

Abstract

The present research focuses on the topic of oral mucositis, a prevalent ailment that arises as a consequence of cancer therapy. It is characterised by the presence of inflammation and the probable development of ulcers in the mucosa of the oral cavity. This study integrates two separate inquiries, one involving a comparative analysis and the other employing an open-label approach, in order to evaluate the safety and efficacy of Oro-T mouthwash in persons undergoing cancer radiotherapy and chemotherapy, with a comparison to normal saline.

The study revealed that the utilisation of Oro-T resulted in considerably improved results, both in terms of subjective and objective measures, characterised by delayed onset of symptoms and reduced severity of mucositis. There were no documented side effects that required withdrawal of medication, and the general adherence to the treatment was deemed satisfactory. The aforementioned data indicate that Oro-T may present a viable approach for the management of oral mucositis in cancer patients who are undergoing radiotherapy and chemotherapy.

Way forward

In conclusion, the Oro-T group demonstrated a notable beneficial outcome in both subjective and objective measures when compared to the NS group. This was evidenced by a delay in the onset of symptoms and a less severe manifestation of oral mucositis, ultimately leading to an increase in the quality of life for individuals in the Oro-T group. There were no reported adverse effects that necessitated the termination of the study drug. The participants had a high level of adherence to the study medication.

Journal: Journal of Cancer Research and Therapeutics
Year: 1/7/2021

Sub category: Oral mmucoitis/chemoprotective

A prospective, interventional clinical study to evaluate the safety and efficacy of Liv.52 DS in the management of non-alcoholic fatty liver disease

Company / Institute(Lab)

Himalaya (Division of Gastroenterology-Hepatology, Department of Internal Medicine, Faculty of Medicine, University of Sumatera Utara, Medan, Indonesia; The Himalaya Drug Company, Makali, Bengaluru, India)

Type of Study: Interventional Study

Product: Liv.52 DS tablets

Abstract

The objective of this study is to investigate and analyse the main goal or purpose. This study aims to assess the effectiveness and safety of Liv.52 DS tablets for treating NAFLD. This section provides an overview of the materials and methods used in the study. This study involved 60 patients of various ages and genders who were diagnosed with non-alcoholic fatty liver disease (NAFLD) based on clinical examination, laboratory tests, and ultrasound findings. The patients willingly provided informed consent to participate in the study. In this study, all patients were administered Liv.52 DS, a medication, at a specific dosage of 2 tablets taken twice daily for a duration of 2 months. In this study, patients were assessed at different time points for various health indicators including liver function tests, ultrasound measurements of hepatomegaly, NAFLD Fibrosis Score, lipid profile, and haematology and biochemical investigations.

The findings of the study are presented in this section. The data from the study was analysed using GraphPad Prism Software Version 6.07. The analysis focused on data from patients who finished the study. This study observed a notable improvement in hepatomegaly (enlarged liver) and liver enzymes. The study found that there was no progression of liver fibrosis caused by non-alcoholic fatty liver disease (NAFLD) during the study period, as indicated by the NAFLD fibrosis score. The study did not find any abnormal lab values or report any adverse events.

In conclusion, the findings of this study suggest that further research is needed to fully understand the implications and potential applications of the observed This study examines the safety and benefits of Liv.52 DS in individuals with non-alcoholic fatty liver disease (NAFLD). The findings indicate that Liv.52 DS is both safe and beneficial for individuals with NAFLD.

Way forward

A holistic approach to weight management based on Ayurveda and yoga can be effective and feasible. The data collection process, which required self-tracking and measuring both conventional and Ayurvedic outcomes, was not too burdensome for the participants. The dropout rate observed in this study was similar to that of other weight loss research. The results show a significant weight loss of 3.5 kg right after the intervention, and an additional loss of 5.9 kg at the 6-month follow-up. These findings suggest that long-term weight loss can be achieved through comprehensive lifestyle changes. Moreover, the participants reported improvements in energy, mental health, quality of life, self-awareness, and relationships, indicating the positive impact of these changes. The combination of Weight Stabilisation and Active Lifestyle (WSAY) interventions for obesity shows potential for lasting health benefits and the possibility of preventing or reducing the risk of other chronic diseases related to obesity or its complications.

Journal: European Journal of Clinical and Experimental Medicine 2021; 19 (2): 129–136

Year: 1/6/2021

Sub category: Non alcoholic fatty Liver

Role of Tentex Royal in Erectile Dysfunction of Various Etiologies: A Randomized Double-blind Placebo-controlled Clinical Study

Company / Institute(Lab)

The Himalaya Drug Company

Type of Study: Randomized controlled trial

Product: Tentex Royal

Abstract

The prevalence of erectile dysfunction (ED), characterised by the incapacity to get or sustain a satisfying penile erection, tends to increase as individuals age, leading to a notable decline in patients' overall quality of life. The objective of this study was to evaluate the effectiveness and safety of "Tentex Royal" in individuals with erectile dysfunction (ED). The study was a phase III clinical trial that adhered to ethical norms, employing a prospective, open, and non-comparative design. The study included a cohort of 30 patients with erectile dysfunction (ED) who voluntarily gave informed consent. The selection of participants was based on their responses to a questionnaire regarding their sexual activities. Exclusion criteria were applied to patients with specific medical issues and individuals who declined to provide consent. All participants had comprehensive clinical and biochemical evaluations, and were instructed to consume two capsules of "Tentex Royal" on a daily basis, approximately one hour prior to engaging in sexual activity. The study involved doing weekly assessments and evaluations of erectile function (EF) scores over a period of six weeks.

The main objective of the study was to determine if there was an improvement in EF levels. The study additionally evaluated safety endpoints pertaining to adverse events and patient adherence. The adverse events seen in the study were classified into three categories: "Unrelated," "Possible," or "Probable," based on their association with the study medication.

The statistical analysis employed intent-to-treat principles, with a predetermined significance level of 99% confidence. A p-value of less than 0.001 was deemed statistically significant. The research conducted demonstrated a notable enhancement in the capacity to attain and sustain erections starting from the third week, suggesting a favourable influence of "Tentex Royal" on the sexual function and quality of life of those with erectile dysfunction.

Way forward

In conclusion, seizures commonly manifest in cases of severe hyponatremia, with an observed incidence rate of 4%.

Journal: Indian Journal of Clinical Practice, Vol. 31, No. 12, May 2021

Year: 1/5/2021

Sub category: Seizures

A Randomized, Open label, Comparative Clinical Study to Evaluate the Efficacy and Safety of Cystone Forte Tablet in Urolithiasis

Company / Institute(Lab)

HIMALAYA (1. Department of Urology, Rahee Healthcare, Pune, India, 2.Department of Urology, Ruby Hall Clinic, Pune, India, 3.The Himalaya Drug Company, Makali, Bengaluru, India

Type of Study: Randomized controlled trial

Product: Cystone Forte Tablet

CTRI registration no.: CTRI/2017/12/010914

Abstract

This study aimed to assess the effectiveness and safety of Cystone forte tablet in treating urolithiasis. A clinical study was conducted to compare different treatments for urolithiasis in 62 subjects. The subjects had clinically diagnosed calculi measuring 5 to 12mm and were between the ages of 18 and 50. The study involved 62 participants who were randomly assigned to either the trial group or the comparator group. The trial group was given Cystone forte tablets twice daily for 6 weeks, while the comparator group received Tamsulosin tablets once daily for the same duration. The trial group treated with Cystone forte tablets had similar outcomes to the Tamsulosin group in terms of improving clinical parameters and expelling kidney stones in urolithiasis. The effectiveness and benefits of using Cystone forte tablet in managing urolithiasis were observed in the trial group. In conclusion, both groups experienced mild occasional adverse events that were successfully resolved. This study examines the safety and effectiveness of Cystone forte tablets in treating urolithiasis symptoms when taken orally at the recommended dose.

Way forward

The findings of this study indicate that individuals who received treatment with Cystone forte tablets exhibited positive changes in clinical indicators related to urolithiasis and the removal of kidney stones. These improvements were found to be similar to those observed in individuals who were administered the standard comparator, Tamsulosin tablet. Based on the findings, it can be inferred that the group of participants who received treatment with Cystone forte tablets exhibited similar outcomes to those who were administered the standard comparator Tamsulosin tablet in the management of urolithiasis.

The findings of the study suggest that the poly herbal formulation known as Cystone forte tablet is both safe and effective for treating urolithiasis. The treatment resulted in notable improvements in various clinical symptoms associated with the condition, such as colicky pain at the loin, dysuria, nausea/vomiting, hematuria, as well as the clearance of calculi measuring both less than 7 mm and greater than 7 mm. The general response to the reduction in symptoms related to urolithiasis was determined to be favourable. A small number of mild and sporadic adverse events were observed in certain participants from both groups. However, these incidents were resolved without any lasting clinical consequences by the conclusion of the trial. The effectiveness of Cystone forte pills can be linked to the synergistic actions of the strong herbs and minerals contained in the formulation. The overall adherence to the treatment regimen was satisfactory. Furthermore, it has been observed that this intervention has advantageous effects in the elimination and/or reduction of renal calculi, especially those of larger dimensions exceeding 7mm. Based on the aforementioned discoveries, it may be argued that the polyherbal formulation known as Cystone forte presents a viable alternative to invasive and contemporary therapeutic approaches in addressing the unmet medical requirement of Urolithiasis. Therefore, this clinical investigation provides evidence that the oral administration of Cystone forte tablets is advantageous and efficacious in the treatment of urolithiasis.

Journal: Medical & Surgical Urology (Med Sur Urol, Vol. 9 Iss. 4 No: 235)

Year: 9/1/2020

Sub category: Urolithiasis

An Ayurvedic Herbal Compound to reduce Toxicity to Cancer chemotherapy: A Randomized Controlled Trial

Company / Institute(Lab)

Maharishi Ayurveda

Product: Product: Maharishi Amrit Kalash

Abstract

The background of the study is important to understand the context and rationale behind the research. Maharishi Amrit Kalash (MAK) is an ayurvedic formulation comprising a variety of botanical ingredients that are abundant in antioxidants. The study focused on assessing the impact of a particular intervention in mitigating the adverse effects of chemotherapy in female patients diagnosed with breast cancer.

Methods and Participants: A total of 214 patients diagnosed with breast cancer and undergoing either adjuvant or neo-adjuvant chemotherapy were recruited for this study. The chemotherapy regimens administered to the patients were cyclophosphamide, methotrexate, and 5-fluorouracil (CMF), as well as cyclophosphamide, adriamycin, and 5-fluorouracil (CAF). The evaluation of chemotherapy toxicity was conducted based on the criteria established by the World Health Organisation (WHO). A statistical analysis was conducted using the software Epi-info 6.

In this study, all patients were administered the identical anti-emetic medication consisting of ondansetron using STATA-7 software.

Dexamethasone is a synthetic corticosteroid medication. The findings of the study indicate a noteworthy decrease in toxicities was found in the group receiving MAK throughout the treatment cycles. The concurrent administration of MAK with chemotherapy effectively averted poor performance status.The prevented fraction (PF) in this study was found to be 60.6%, with a 95% confidence range ranging from 22.1 to. This randomised controlled trial investigated the efficacy of an Ayurvedic herbal compound in reducing toxicity associated with cancer chemotherapy.

The Department of Surgery at the All India Institute of Medical Sciences, located in New Delhi, India.

The observed value of 80.1 has a p-value of 0.005. The incidence of vomiting was effectively reduced by the administration of MAK, with a statistically significant decrease seen (PF=40.3%, 95% confidence interval 15.1 to 58.1; p value=0.002). Likewise, the prevalence of anorexia shown a reduction of 35.6% as indicated by the PF statistic. The MAK group had a 95% confidence interval of 17.6 to 49.7, with a p-value of 0.0001. There was no observed improvement in the symptoms of stomatitis, diarrhoea, alopecia, and leucopenia. There was no observed occurrence of tumour overgrowth in the cohort that underwent Neoadjuvant chemotherapy and received MAK treatment.

In conclusion, it is suggested that MAK could serve as a complementary intervention in conjunction with chemotherapeutic medications to mitigate the occurrence of chemotherapy-induced symptoms such as vomiting, anorexia, and overall decline in the health status of patients.

Way forward

In conclusion, it is suggested that MAK could serve as a complementary treatment option in conjunction with chemotherapeutic medications to alleviate symptoms of chemotherapy-induced vomiting, anorexia, and enhance the overall quality of life for patients.

Journal: INDIAN JOURNAL OF MEDICAL & PAEDIATRIC ONCOLOGY

Year: Vol. 29 No 2, 2008

Sub category: Chemoprotective

Effect of Two breathing exercises (Buteyko and pranayama) in asthma: A randomised controlled trial

Company / Institute(Lab)

The National Asthma Campaign, UK

Abstract

The utilisation of breathing exercises by patients with asthma has garnered interest, however their precise impact remains uncertain. A parallel group study was conducted to examine the effects of the Buteyko breathing technique, a device that emulates pranayama (a breathing technique in yoga), and a placebo pranayama device on bronchial reactivity and symptoms over a period of 6 months.

Methods: A total of ninety individuals diagnosed with asthma and currently using an inhaled corticosteroid were selected for this study. Following a two-week run-in period, the participants were randomly assigned to one of three groups: Eucapnic Buteyko breathing, utilisation of a Pink City Lung Exerciser (PCLE) to simulate pranayama, or usage of a PCLE placebo device. Participants engaged in the practise of the techniques in their own residences twice daily over a period of 6 months, subsequently followed by an optional phase involving the gradual reduction of steroid usage. The primary metrics of interest in this study were symptom scores and the change in the dosage of methacholine required to induce a 20% decrease in forced expiratory volume in one second (FEV1), also known as the PD20, during a period of six months.

The trial was completed by 69 patients, which accounted for 78% of the total participants. There was no statistically significant disparity observed in the PD20 values among the three groups at the 3-month and 6-month time points. The symptoms exhibited minimal fluctuations in both the PCLE and placebo cohorts, however a notable decrease in symptoms was observed in the Buteyko intervention group. The median change in symptom scores at the 6-month mark was found to be 0 (with an interquartile range of -1 to 1) in the placebo group, -1 (with an interquartile range of -2 to 0.75) in the PCLE group, and -3 (with an interquartile range of -4 to 0) in the Buteyko group. The p-value for the difference between the groups was determined to be 0.003. The Buteyko group exhibited a decrease in bronchodilator usage by an average of two puffs per day after a period of six months. In contrast, the other two groups did not experience any significant change in bronchodilator use during the same time frame (p=0.005). There was no observed disparity between the groups in terms of forced expiratory volume in one second (FEV1), exacerbations, or the capacity to decrease the usage of inhaled corticosteroids.

Way forward

In conclusion, it can be inferred that the implementation of the Buteyko breathing technique has the potential to ameliorate symptoms and decrease the reliance on bronchodilators among those diagnosed with asthma. However, it does not seem to have a discernible impact on bronchial responsiveness or lung function in this patient population. No discernible advantage was seen for the Pink City Lung Exerciser.

Journal: Thorax
Year: Published Online First: 28 Jul 2003

Sub category: Asthma

Effect of Ayurveda intervention in the integrated management of essential hypertension: A retrospective observational study

Company / Institute(Lab)

Central Council for Research in Ayurvedic Sciences (CCRAS)

Type of Study: A retrospective analysis

CTRI registration no.:
CTRI/2020/06/025592

Abstract

The study titled "Integration of Ayush (Ayurveda) with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)" was conducted in India across three districts in three states: Bhilwara (Rajasthan), Gaya (Bihar), and Surendranagar (Gujarat). The study, which commenced in 2015, aimed to manage various non-communicable diseases (NCDs) through an integrated approach.

Objective: The aim of this study is to assess the impact of Ayurveda medication, lifestyle modification, and Yoga when used in conjunction with standard care for the treatment of essential hypertension.

In this study, we employed a set of materials and methodologies to investigate the research question at hand. A comprehensive examination was conducted on the demographic and clinical records that were accessible from the NPCDCS-Ayush Integration Project. The study included individuals diagnosed with Essential Hypertension (EHTN) who were between the ages of 30 and 60. These participants had undergone a six-month integrated management programme following the treatment protocol of the NPCDCS-Ayush Integration project. Data from these individuals, collected between July 2018 and March 2019, was divided into two groups based on the type of intervention they received. Participants who were recommended to incorporate lifestyle modifications and practise Yoga, in addition to receiving standard care with any of the five medications or combinations (Amlodipine, Atenolol, Amlodipine Atenolol, Losartan, or Telmisartan), were assigned to Group I. On the other hand, participants who were provided with Ayurveda medication, along with lifestyle modifications and Yoga, in addition to standard care, were assigned to Group II. The analysis focused on the alteration in blood pressure, as well as the observation of dose decrease or discontinuation of conventional drugs.

The findings of the study are as follows: The data from a total of 1938 participants who had successfully completed treatment under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases, and Stroke (NPCDCS) was subjected to analysis. In the sixth month, there was a substantial reduction ($P < 0.01$) in both systolic and diastolic blood pressure among all categories of participants in Group I and Group II, compared to their initial measurements. Moreover, it was observed that 33.1% of participants in Group I and 30.4% of participants in Group II had a reduction in the dosage of conventional medicine compared to the initial measurement. Additionally, 15.1% of participants in Group I and 36.7% of participants in Group II completely discontinued the use of conventional medicines.

In conclusion, the utilisation of Ayurveda medication, in conjunction with lifestyle management and Yoga, has proven to be an effective approach in regulating both systolic and diastolic blood pressure. Additionally, this integrated approach has demonstrated the potential to reduce or even eliminate the need for conventional medications in individuals with essential hypertension.

Way forward

Subsequent investigations could be conducted to evaluate additional criteria, such as the impact on participants' quality of life. In order to enhance the comparability of outcomes, it is recommended that future research incorporate a control group receiving solely conventional therapy. Obesity assessment may be incorporated into the analysis while screening hypertension cases.

The combination of Ayurveda medication (M-Sarpagandha Mishran and Praval Pishti), combined with lifestyle control and Yoga, has been found to be beneficial in regulating both systolic and diastolic blood pressure. Additionally, this approach has shown promise in decreasing or discontinuing the use of conventional drugs in those with essential hypertension.

Journal: Journal of Ayurveda and Integrative Medicine
Year: April 2021

Sub category: Hypertension

6.3
Category-III
Infectious Diseases

Infectious diseases pose a significant global health threat, causing widespread morbidity and mortality. Traditional and complementary medicine (TCM) approaches, including Ayurveda, Yoga, Unani, Siddha, and Homeopathy, offer a range of preventive and curative options for managing infectious diseases.

Ayurveda, a traditional healthcare system, emphasizes maintaining a balanced dosha (mind-body constitution) to prevent infections. Ayurvedic practices like herbal remedies, dietary modifications, and lifestyle changes can boost immunity and aid in the body's natural healing process.

Yoga, a mind-body discipline, promotes relaxation, stress reduction, and overall well-being, which can strengthen the immune system and enhance the body's ability to fight infections. Yogic practices like pranayama (breathing exercises) and meditation can help regulate stress hormones, improve sleep quality, and promote overall well-being.

Integrating TCM practices with conventional medicine can offer a more holistic and personalized approach to managing infectious diseases.

Clinical Evaluation for the Thrombopoietic Activity of Platenza Tablet in Cases of Dengue with Thrombocytopenia - Randomized Open Label Comparative Clinical Study

Company / Institute(Lab)

National Institute of Unani Medicine

Type of Study: Randomized controlled trial

Product: Platenza Tablet

Abstract

Dengue, a viral infection transmitted by vectors, is becoming increasingly prevalent in numerous countries. The demand for a safe and effective herbal formulation is high, despite the presence of many therapeutic options.

Objective: This study aims to assess the effectiveness and safety of platenza tablets in improving platelet counts in individuals with dengue fever and low platelet levels. In this study, conducted at Patna Medical College and Hospital in Bihar, the Department of Medicine was involved. This study was conducted to compare the effects of different treatments in a controlled clinical setting. The study involved 40 subjects who were divided into two groups: the platenza group (n=21) and the standard comparator group (n=19). The platenza group received platenza tablets twice daily, while the standard comparator group received Carica papaya leaves extract three times daily. This treatment was administered orally for a duration of 10 days.

Results: Platelet count was assessed at various time points throughout the study, including screening and on multiple days during the treatment period. After a period of 10 days, the platenza group exhibited a significant rise in platelet count from 52905 to 207381 cells/mm3, in comparison to the standard comparator group. The study had a 0% dropout rate. Conclusion: The study found that platenza tablets showed potential in increasing platelet production and reducing symptoms of dengue fever with low platelet count, compared to using Carica papaya leaves extract alone.

Way forward

In conclusion, based on the findings of this study, it can be inferred that the use of platenza tablet shows promise in terms of safety and effectiveness in normalising platelet counts and alleviating the clinical manifestations (such as fever, myalgia, arthralgia, and headache) of dengue fever accompanied by thrombocytopenia, when compared to the standard comparator comprising solely of Carica papaya leaf extracts.

There is strong evidence to support the use of platenza tablets as an adjunctive or supplementary treatment in individuals diagnosed with dengue fever. These tablets have been shown to effectively alleviate the manifestations of dengue fever, particularly those associated with low platelet levels. Furthermore, platenza tablets have been found to expedite the recovery process by facilitating an increase in platelet counts, ultimately leading to a reduction in the duration of hospital stay.

Journal: Annals of Medical and Health Sciences Research
Year: Volume 8 | Issue 2 | March-April 2018

Sub category: Dengue

6.3.1 Sub-category COVID CARE

While modern medicine has made significant strides in managing COVID-19, Traditional and Complimentary Medicine (TCM) offers a complementary approach that can enhance overall well-being and support the body's natural healing mechanisms. Ayush practices, encompassing Ayurveda, Yoga, Naturopathy, Unani, Siddha, Sowa rigpa and Homeopathy, provide a range of modalities that can be effectively integrated into COVID care.

Ayurveda, with its emphasis on personalized medicine and lifestyle adjustments, can help strengthen the immune system and promote overall health. Yoga, with its deep breathing exercises and meditation techniques, can reduce stress, improve respiratory function, and promote emotional well-being. Unani, known for its use of herbal remedies, offers several potential options to alleviate symptoms and support the body's recovery. Siddha, with its focus on metal-based formulations, provides unique therapeutic approaches. Homeopathy, with its principle of "like cures like," offers individualized remedies that address specific symptoms and promote gentle healing.

Integrating TCM practices into COVID care can provide a holistic approach that addresses both the physical and emotional aspects of the disease, empowering individuals to take an active role in their own healing journey.

The role of herbal immunomodulators as adjuvant therapy for asymptomatic and mildly symptomatic covid-19: An exploratory clinical study.

Company / Institute(Lab)

Himalaya (Department of Pharmacology, Bangalore Medical College and Research Institute; Department of General Medicine; Medical College and Research Institute; Department of Dermatology, MVJ Medical College and Research Hospital; Department of Pharmacology; Medical College and Research Institute; Ayurvedic Consultant; Others...

Product: Herbal immunomodulator

Type of Study: Exploratory study

CTRI registration no.: CTRI/2020/06/025801

Abstract

The present research attempts to explore the potential advantages of incorporating herbal immunomodulators (Septilin and Bresol) as supplementary therapy for individuals with asymptomatic or mildly symptomatic COVID-19. This study aimed to evaluate the effectiveness of combining Septilin and Bresol with standard care in comparison to standard care alone. Participants were randomly assigned to either the combination group or the standard care group.

The study found that participants who received herbal immunomodulators experienced decreased levels of inflammation markers, improved interferon levels, decreased D-dimer values, and significant reductions in lactate dehydrogenase and neutrophil-to-lymphocyte ratio. In the post-illness recovery phase, clinical assessments revealed enhancements in fatigue scores and quality of life. The use of herbal immunomodulators alongside standard care may have potential long-term benefits in the management of COVID-19 and post-COVID-19 recovery.

Way forward

In conclusion, the incorporation of this herbal combination as a supplementary treatment to the standard of care (SOC) has the potential to yield further long-term advantages in the management of COVID-19 infection through the mitigation of inflammatory processes. This therapeutic intervention may serve as a valuable adjunct for the management of post-COVID-19 syndrome.

Journal: Asian journal of pharmaceuticals and clinical research (AJPCR)

Year: 3/1/2022

Sub category: Anti-inflammatory

A randomized control study to evaluate the role of herbal immunomodulators in boosting the immunity and overall health of healthcare workers in covid-19 wards: An exploratory, feedback clinical study

Company / Institute(Lab)

Himalaya Wellness Company

Type of Study: Exploratory study

Product: Herbal immunomodulator

Abstract

Research participants were assigned to COVID-19 wards, and the herbal immunomodulators Immusante and Guduchi were tested for their effects on the participants' immunity and general well-being. The study conducted was a clinical trial that followed an open-label, randomised, prospective design. It was carried out in a single-center setting and involved the participation of 100 healthcare workers. The participants were divided into two groups through random assignment. One group received Immusante and Guduchi pills (referred to as Arm I), while the other group followed the treatment protocol established by the institution (referred to as Arm II). The investigation assessed multiple parameters following a 30-day intervention, encompassing respiratory symptoms, an Adapted Immune Status Questionnaire (ISQ), quality of life as measured by the Short Form 12 (SF-12) Health Survey, and safety.

The study was successfully completed by all 100 participants in accordance with the established methodology. It is worth mentioning that the participants in Arm I did not exhibit any respiratory symptoms, however 8% of the persons in Arm II reported experiencing coughing episodes throughout the duration of the study. Arm I exhibited a more significant enhancement in immunological status, as assessed by the modified immunological Status Questionnaire (ISQ), in comparison to Arm II. Furthermore, notable disparities were noted across all eight dimensions of the SF-12 Health Survey, with Arm I exhibiting more favourable outcomes. In a retrospective evaluation of COVID-19 infection, the prevalence of positive test results was found to be 8% among individuals in Arm I, in contrast to 26% among people in Arm II.

In summary, the findings of the study indicate that the utilisation of Immusante and Guduchi in combination yielded advantageous outcomes in enhancing immune response and promoting general well-being among healthcare professionals who face an elevated susceptibility to developing COVID-19. This assertion is substantiated by the favourable patterns identified in the ISQ, SF-12 scores, and reduced incidence of COVID-19 infections within Arm I.

Way forward

Based on the findings of this study, which indicate a favourable correlation between the use of Immusante and Guduchi in healthcare professionals at a heightened risk of COVID-19 infection, it can be concluded that this combination has a favourable impact on enhancing immunity and overall health. This is evidenced by improvements in ISQ, SF-12 scores, and a reduction in COVID-19 infection rates.

Journal: Asian journal of pharmaceuticals and clinical research
Year: August' 2021

Sub category: Immunity booster

Herbal immunomodulators as add on treatment in asymptomatic and mildly symptomatic COVID-19 confirmed cases: Findings from a prospective single centre clinical trial

Company / Institute(Lab)

Sri Sri Tattva (Research and Development-Healthcare, Sriveda Sattva Private Limited (Sri Sri Tattva), Bengaluru, Karnataka, India)

Product: Herbal immunomodulator

Type of Study: Observational study

CTRI registration no.: CTRI/2020/06/025592

Abstract

In this study, the focus was on assessing the safety and efficacy of Sri Sri TattvaTM immunity products, which consist of single and poly-herb formulations, in COVID-19 patients. Over a 14-day oral administration period, these products exhibited significant improvements in clinical symptoms. Notably, patients with fever, cough, and sore throat started responding positively from the third day, with most becoming symptom-free by the seventh day. Early recovery was observed in the majority of patients. The study also revealed improvements in immune markers, including TNF-alfa, IL-6, IFN-beta, D-dimer, ferritin, LDH, and CRP.

Importantly, the results showed that these products reduced the time to clinical recovery and the number of days needed to achieve negative RT-PCR results, signifying early viral clearance and reducing hospitalization duration. Remarkably, 82% of COVID-19 patients cleared the virus within 10-14 days, with no progression to severe COVID-19 or fatalities. These findings underscore the potential of Sri Sri TattvaTM immunity products when administered orally alongside standard care in effectively managing COVID-19 patients.

Way forward

The current investigation revealed that a significant proportion of individuals diagnosed with COVID-19, specifically 82%, exhibited viral clearance during a study period of 10-14 days. This outcome resulted in a notable reduction in the length of hospital stay for these patients. All of the patients remained free from developing significant COVID-19 symptoms and did not have fatal outcomes as a result of the disease. This statement provides convincing evidence that the oral administration of Sri Sri TattvaTM immune products, in conjunction with regular medical therapy, plays a conclusive role in the treatment of individuals with COVID-19.

Journal: International Journal of Basic & Clinical Pharmacology

Year: Received: 31 March 2021 | Revised: 30 April 2021 | Accepted: 01 May 2021

An In-vitro evaluation of a polyherbal formulation, against SARS-Cov-2

Company / Institute(Lab)

Sri Sri Tattva (Research and Development-Healthcare, Sriveda Sattva Private Limited (Sri Sri Tattva), Bengaluru, Karnataka, India)

Product: Poly herbal formulation

Type of Study: Observational study

CTRI registration no.: CTRI/2020/06/025592

Abstract

The study assessed the antiviral efficacy of a novel Ayurvedic polyherbal formulation, NOQ19, comprising 13 well-known herbs, against SARS-CoV-2 in a cell-based setting. Using Vero E6 cells, the study tested various concentrations of NOQ19, ranging from 0.05 mg/ml to 0.9 mg/ml, and employed Remdesivir as a positive control.

The results revealed a notable antiviral effect, with the highest concentration of NOQ19 (0.9 mg/ml) completely eliminating the virus and an IC50 of 0.2 mg/ml. However, it's crucial to recognize the limited data on preclinical efficacy of polyherbal Ayurvedic drugs and the need for further preclinical and clinical trials to validate these findings. While these results suggest the potential of NOQ19 as a therapeutic option against COVID-19, extensive human trials and regulatory assessments are necessary to establish its safety and efficacy conclusively.

Way forward

There is limited data around pre-clinical efficacy of polyherbal Ayurvedic drugs. Ayurvedic and herbal formations need to be tested in a preclinical setting to support the human data. The results of the present study demonstrated viral load reduction using NOQ19 in Vero E6 cell lines infected with SARS-CoV-2 virus. These result along with other preclinical and clinical trials could further evaluate the efficacy of NOQ19 as a potential therapeutic option in the fighting the COVID-19 challenge.

Journal: Journal of Ayurveda and Integrative Medicine

Year: Received 19 February 2022 | Accepted 16 April 2022 | Available online 23 June 2022

Sub category: AntiCovid

Neem (Azadirachta Indica A. Juss) Capsules for Prophylaxis of COVID-19 Infection: A Pilot, Double-Blind, Randomized Controlled Trial

Company / Institute(Lab)

All India Institute of Ayurveda & Nisarga Biotech in Maharashtra, India

Type of Study: Randomized Controlled Trial

Product: Neem Capsules

CTRI registration no.: CTRI/2020/07/026560

Abstract

SARS-CoV-2 is a significant global public-health issue. This study highlights the pressing need for interventions aimed at preventing infection through Ayurvedic medicines. Neem possesses anti-inflammatory and antiviral properties, which suggest its potential as a preventive measure against COVID-19.

This study aimed to assess the preventive effects of neem capsules on individuals who are at a high risk of contracting COVID-19 due to their exposure to COVID-19 positive patients. In this study, the researchers developed a prospective, a randomised, double-blind, placebo-controlled, parallel-design approach.

Setting:
This study took place at a solitary research facility located in India. Participants in this study included 190 healthcare workers from the hospital and relatives of patients diagnosed with COVID-19 infection.

Intervention: The study included a total of 190 participants, with 95 assigned to the intervention group and 95 to the control group. In this study, participants were administered either a 50 mg dose of a neem-leaf extract or a placebo orally in capsules. This administration occurred twice a day for a duration of 28 days.

Outcome Measures: This study aimed to assess the number of individuals who tested positive for COVID-19 during the period between the initial assessment and the follow-up on day 56.

The primary outcome measure was assessed. This study also assessed the safety of neem and its impact on quality of life and biomarkers.

Way forward

The findings of this study indicate that the use of neem capsules significantly reduces the risk of COVID-19 infection, suggesting its potential as a prophylactic treatment for preventing COVID-19. However, further research is needed to confirm these results through a larger randomised, double-blind study. Additionally, considering the potential anti-inflammatory and antiviral properties of neem capsules, they could also be explored as a therapeutic intervention for COVID-19 infection.

Journal: Alternative Therapies In Health And Medicine
Year: April 2021

Sub category: COVID-19 Prophylaxis

Efficacy of two siddha polyherbal decoctions, Nilavembu Kudineer and Kaba Sura Kudineer, along with standard allopathy treatment in the management of mild to moderate symptomatic COVID-19 patients: A double-blind, placebo-controlled, clinical trial

Company / Institute(Lab)

Central Council for Research in Siddha (CCRS), Min. of Ayush, GIMS Greater Noida, Uttar Pradesh, India

Product: Nilavembu Kudineer & Kaba Sura Kudineer

Type of Study: Double-blind RCT, placebo-controlled comparative clinical trial

CTRI registration no.: CTRI/2020/08/027286

Abstract

This paper aims to evaluate the effectiveness of two polyherbal formulations, Nilavembu Kudineer (NVK) and Kaba Sura Kudineer (KSK), in treating mild to moderate COVID-19 symptoms. These formulations are derived from the Siddha system of medicine, a traditional form of healing practiced in India. The paper provides a brief introduction to the Siddha system, its history, culture, and geography. It also reviews the previous studies on the use of NVK and KSK for viral infections such as dengue and chikungunya, and their safety and efficacy profiles.

The paper describes the design and methodology of a randomized controlled trial that compared the effects of NVK and KSK with a placebo in 125 patients diagnosed with COVID-19. The trial was conducted from August 2020 to December 2020, and the participants were assigned to either the treatment group or the control group in a double-blind manner. The clinical outcomes were measured by using specific indicators, such as fever, cough, breathlessness, oxygen saturation, and viral load. The adverse events were monitored and recorded throughout the trial. The paper presents the statistical analysis of the data and the results of the comparison between the treatment and control groups.

The paper concludes that both NVK and KSK showed significant improvement in clinical outcomes compared to the placebo, and no serious adverse events were reported. The paper suggests that these polyherbal formulations may be effective alternatives or adjuncts to conventional therapies for COVID-19, and recommends further research on their mechanisms of action and long-term effects.

Way forward

This study aims to evaluate the efficacy of two traditional Siddha herbal formulations, namely NVK and KSK, in comparison to the usual allopathic treatment for COVID-19. The individuals that were assigned to Arm II of the NVK study, specifically the patient group.

By the sixth day, there was a decrease in both Arms II and III, indicating a negative trend. The duration for achieving asymptomatic status was shorter in the treatment group as compared to the control group receiving a placebo. Among the various treatments available, the Siddha treatments and the KSK arm stand out as noteworthy options.

The experimental arm demonstrated more favourable outcomes compared to the NVK arm, as evidenced by the data. More than 50% of the patients were discharged and tested negative for RT-PCR even on the third day. The patients of KSK had the lowest expenditure.

The duration of hospitalisation among all three experimental groups. The IL6 indicators of the treatment arms in Siddha medicine exhibited a statistically significant disparity when compared to the placebo arm. There were no serious adverse events (SAEs) documented during the duration of the research. The findings of this experiment indicate that NVK and KSK demonstrate both safety and efficacy. The utilisation of pharmaceutical substances in conjunction with allopathic treatment for the management of mild to moderate COVID-19 disease.

The observed effects of these medications were found to be statistically significant, providing evidence for the effectiveness of an integrative approach that combines allopathy in the management of COVID-19. This trial is in accordance with the National Health Policy 2017, which promotes the integration of allopathic medicine with traditional systems of medicine, particularly Siddha medicine. The outcome of this trial serves as a source of encouragement.

Journal: Biomedical central: Part of Springer Nature

Year: 28th August 2021

Sub category: Immunity

In silico evaluation of the compounds of the ayurvedic drug, Ayush-64, for the action against the SARS-CoV-2 main protease

Company / Institute(Lab)

ICMR-National Institute of Epidemiology & Central Council for Research in Ayurvedic Sciences (CCRAS)

Type of Study: LibDock protocol of BIOVIA Discovery Studio and AutoDock Vina

Product: Mproe Akuammicine N-Oxide

Abstract

The emergence of COVID-19 in late 2019 has resulted in a worldwide public health emergency. This study focuses on the lack of approved anti-viral drugs or vaccines for COVID-19 and the ongoing research on repurposing existing drugs for treatment.

This study examines the clinical use of Ayurvedic Sciences in India as a drug for treating malaria, inflammation, and fever. This study aimed to assess the effectiveness of Ayush-64 compounds in treating Severe Acute Respiratory Syndrome-Corona Virus (SARS-CoV-2) Main Protease (Mpro; PDB ID: 6LU7) using computer-based methods. This section describes the materials and methods used in the study. This study utilised molecular docking software, specifically Discovery Studio and AutoDock Vina, to evaluate the potential of drugs derived from selected Ayush-64 compounds in targeting SARS-CoV-2. In this study, molecular dynamics simulations were performed using Desmond software for a duration of 100 nanoseconds. Additionally, the MM/GBSA method was employed to analyse the most favourable interaction between Ayush-64 and Mpro of SARS-CoV-2.

In this study, 36 compounds containing four ingredients of Ayush-64 were screened. Out of these, 35 compounds showed better binding energies compared to a previously published positive co-crystal compound of N3 peptide. This study examines the affinity and interactions of Akuammicine N-Oxide, derived from Alstonia scholaris, with the Mpro protein. The binding energy, as determined by AutoDock Vina, is found to be 8.4 kcal/mol. Additionally, the Libdock score obtained from Discovery studio is 147.92 kcal/mol. This study utilised molecular dynamics simulations with MM-GBSA to investigate the stability and specific interactions between the enzyme Mproe and the ligand Akuammicine N-Oxide in a docked complex. The compound Akuammicine N-Oxide exhibits strong hydrogen bonding interactions with important residues, Cys145 and His164, in the Mpro protein.

Conclusion: The study findings suggest that the presence of Mproe Akuammicine N-Oxide, which exhibits the highest Mpro binding energy, along with 34 other chemical compounds with similar activity found in Ayush-64, could be a potential option for repurposing in the treatment of COVID-19. However, further experimental and clinical studies are needed to validate its effectiveness.

Way forward

To conclude, the present work has demonstrated that many substances derived from an Ayurvedic medication exhibit significant inhibitory effects on the SARS-CoV-2 Mpro enzyme.

By employing two distinct molecular docking techniques and conducting extensive molecular dynamics simulations, it can be elucidated that the Akuammicine N-Oxide molecule exhibits a strong binding affinity. The hydrogen bond is formed between the important residues Cys145 and His164 of the Mpro protein. The stability of the system was seen in both pre- and post-dynamics simulations. The findings suggest that Ayush-64, a medicine that has been authorised and deemed safe, is effective for the intended purpose. The presence of symptoms such as joint aches, fever, and influenza-like illnesses renders it a viable candidate for repurposing in the context of COVID-19. Hence, it is imperative to conduct more experimental and clinical investigations to establish the efficacy of Ayush-64 in inhibiting protease activity against COVID-19.

Journal: Journal of Ayurveda and Integrative Medicine

Year: 25 February 2021

Sub category: Antiviral

Ayush (Indian System of Medicines) Therapeutics for COVID-19: A Living Systematic Review and Meta-Analysis

Company / Institute(Lab)

Institute of Teaching and Research in Ayurveda & World Health Organization Regional Office for South-East Asia, New Delhi, India

Type of Study: Systematic Review

Product: Ayush therapeutics

Abstract

The global outbreak of COVID-19 since late 2019 has led to a significant international public health crisis. This study examines the absence of authorised anti-viral drugs or vaccines for COVID-19 and the current investigations into repurposing existing drugs for therapeutic purposes.

This research paper explores the application of Ayurvedic Sciences in India for the treatment of malaria, inflammation, and fever. This study evaluates the efficacy of Ayush-64 compounds in the treatment of Severe Acute Respiratory Syndrome-Corona Virus (SARS-CoV-2) Main Protease (Mpro; PDB ID: 6LU7) through computer-based methods.

The following section provides a description of the materials and methods employed in the study. In this study, the researchers used molecular docking software, namely Discovery Studio and AutoDock Vina, to assess the effectiveness of drugs derived from specific Ayush-64 compounds in targeting SARS-CoV-2. This study utilised the Desmond software to conduct molecular dynamics simulations lasting 100 nanoseconds. In this study, the MM/GBSA method was used to analyse the optimal interaction between Ayush-64 and Mpro of SARS-CoV-2.

This study involved the screening of 36 compounds that contained four ingredients found in Ayush-64. This study evaluated the binding energies of 35 compounds and compared them to a previously published positive co-crystal compound of N3 peptide. This research paper investigates the relationship between Akuammicine N-Oxide, a compound found in Alstonia scholaris, and its interactions with the Mpro protein. The binding energy of the molecule was calculated using AutoDock Vina and found to be 8.4 kcal/mol. The Libdock score obtained from Discovery Studio is 147.92 kcal/mol. In this study, the stability and specific interactions between the enzyme Mproe and the ligand Akuammicine N-Oxide in a docked complex were investigated using molecular dynamics simulations with MM-GBSA.

In this study, the authors investigate the hydrogen bonding interactions between the compound Akuammicine N-Oxide and two crucial residues, Cys145 and His164, in the Mpro protein.

Way forward

This study indicates that a compound called Mproe Akuammicine N-Oxide, which has a strong binding affinity to Mpro, along with 34 other compounds with similar properties found in Ayush-64, may have potential for repurposing as a treatment for COVID-19. Additional research is required to confirm the efficacy of the intervention through both experimental and clinical investigations.

To conclude, the prudent utilisation of integrated or independent Ayush therapies in individuals with mild-to-moderate COVID-19 is deemed to be a secure approach and has the potential to provide therapeutic advantages. The effect estimates have the potential to be altered as a result of the inclusion of supplementary evidence in forthcoming updates.

Journal: Journal of integrative and complementary medicine

Year: October 11, 2022

Sub category: Covid -19

Randomized, Double Blind, Placebo Controlled, Clinical Trial to Study Ashwagandha Administration in Participants Vaccinated Against COVID-19 on Safety, Immunogenicity, and Protection With COVID-19 Vaccine–A Study Protocol

Company / Institute(Lab)

Central Council for Research in Ayurvedic Sciences(CCRAS)

Type of Study: Randomized, Double Blind, Placebo Controlled, Clinical Trial

Product: Ashwagandha

CTRI registration no.: CTRI/2021/06/034496

Abstract

Vaccines have proven to be highly effective in combating the COVID-19 pandemic. This paper discusses the global implementation of COVID-19 vaccination programmes by governments. The Oxford-AstraZeneca COVID-19 vaccine, known as COVISHIELDTM, is extensively utilised in India. This study examines the prevalence of traditional medicine usage among Indian individuals as a means of enhancing protection against COVID-19 infection. This paper discusses the immunological benefits and potential as a vaccine adjuvant of Withania somnifera (Ashwagandha), as reported in various studies. This study aims to evaluate the safety, immunogenicity, and clinical protection provided by a 6-month regimen of Ashwagandha in individuals who have volunteered to receive the COVID-19 vaccine (COVISHIELDTM) as part of the national vaccination programme.

This section describes the methods and analysis used in the study. In this study, we conducted an exploratory research on healthy volunteers who received the COVISHIELDTM vaccine. The study followed a prospective, randomised, double-blind, parallel-group, placebo-controlled, two-arm design. This study examines the timing of Ashwagandha administration in relation to the initial doses of COVISHIELDTM, with the intervention starting within 7 days. The main focus of this study is to measure the immunogenicity of the SARS-CoV-2 spike (S1) and RBD-specific IgG antibodies. The secondary outcome measures in this study include evaluating safety, assessing the protective immune response, and measuring quality of life. This study will monitor adverse events at regular intervals.

This study aims to recruit 600 participants per arm in order to demonstrate a superiority margin of 7% with a power of 80%. The study lasted for a total of 28 weeks, with an interim analysis conducted at the 12-week mark. This study obtained ethics approval from the Central and Institutional Ethics Committees, ensuring adherence to ethical guidelines. The recruitment of participants began in December 2021. The findings will be shared at conferences and made available in preprint archives before undergoing peer review for publication in medical journals.

Way forward

Ashwagandha has been shown to increase Th-1 activity selectively in previous research.

In infection models, Ashwagandha enhanced antibody titers against pertussis toxins when given with the DPT vaccine (8). Computational models, or in silico networks, have been used to study ethnopharmacology. These studies have suggested that the bioactive compounds in Ashwagandha can modulate immune pathways related to both innate and adaptive immunity.

The references for this are (28, 29). Additionally, the interim efficacy data for the ChAdOx1 nCoV-19 vaccine was evaluated in four clinical trials in the United Kingdom, Brazil, and South Africa.

The study showed a protection rate of 64.1% after a single standard dose (14).

The COVISHIELDTM vaccine has been given in two phases to a large population in India. Our hypothesis is that Ashwagandha could boost antibody levels when taken with the COVISHIELDTM vaccine, especially after the first dose.

A lasting and strong immune response to the vaccine is important for preventing future infections. Therefore, this study will also examine how Ashwagandha affects the persistence of neutralising antibodies for up to four months after the second dose (30). Ashwagandha is known to improve overall mental health.

This work aims to measure the neutralising antibodies against two well-studied variants of concern, namely B1.617.2 and USA-WA1/2020 variants. Recently, a new variant called B.1.1.529 or Omicron has emerged.

Journal: Frontiers in Medicine

Year: Published: 16 February 2022

Sub category: Covid-19

Effect of Prophylactic Use of Intranasal Oil Formulations in the Hamster Model of COVID-19

Company / Institute(Lab)

Translational Health Science and Technology Institute

Type of Study: Experimental Study

Product: Intranasal Oil

Abstract

The aim of this paper is to analyse the global situation of Coronavirus Disease (COVID-19), which emerged in Wuhan in December 2019 and has been declared a pandemic by the World Health Organisation (WHO) due to its rapid spread across the world (Chen and Li, 2020; Wang et al., 2020). This paper presents a summary of the global coronavirus infection cases and related deaths as of September 6, 2021. The total number of infections reached 221,846,104, resulting in approximately 4,586,516 deaths worldwide. India had the highest number of deaths, with 441,075.

This paper emphasises that a large percentage of people infected with the coronavirus do not show any symptoms and do not require intensive medical care. This paper investigates the risk of developing severe COVID-19 symptoms in infected people. About 13.8% of those infected are at risk of suffering from respiratory distress, high fever, loss of taste and smell, and diarrhoea. (Chen and Li, 2020; Wang et al., 2020). This paper explores the occurrence of respiratory failure, cardiovascular complications, and multiple organ failure in about 6% of COVID-19 cases, which is caused by cytokine storm. SARS-CoV2, like other respiratory viruses, first infects the upper respiratory tract and then quickly spreads to the lower respiratory tract (Chen and Li, 2020).

This paper examines the transmission of the virus during an active infection. It discusses how the virus can be transmitted by both symptomatic and asymptomatic individuals through respiratory droplets. The transmission occurs through actions such as coughing, sneezing, or hyperventilation, mainly through the airborne route.

Way forward

The global spread of SARS-CoV2 and the associated COVID-19 disease has been slowed down by the rapid deployment of vaccines that target the original Wuhan strain of the virus (Dong et al., 2020; Poland et al., 2020a, 2020b). However, the emergence of new variants that have higher transmissibility and severity poses a new challenge, especially as some of them can evade the neutralising antibodies induced by vaccination (Garcia-Beltran et al., 2021; Planas et al., 2021; Supasa et al., 2021). Therefore, it is crucial to focus on therapeutic interventions to combat COVID-19.

The existing drugs that have been repurposed for treating COVID-19 patients have limited efficacy. A safer alternative could be the use of herbal medicines or drugs derived from herbal extracts, which have a long history of use in humans and are well tolerated with minimal side effects. The studies by Matveeva et al. (2020), Jan et al. (2021), and Li et al. (2021) support this claim. Recently, Chinese traditional medicine has gained popularity for its antiviral activity against SARS-CoV2 in vitro and in vivo studies (Ling, 2020; Xiong et al., 2020; Yang et al., 2020; Jan et al., 2021; Lee et al., 2021). In India, ayurvedic medicines have been used for thousands of years to treat various diseases, including infectious ones. The word "ayurveda" comes from the Sanskrit words "ayur" meaning life and "veda" meaning knowledge (Subrahmanya et al., 2013; Banerjee et al., 2020; Girija and Sivan, 2020; Golechha, 2020; Joshi and Puthiyedath, 2020; Rastogi et al., 2020).

Journal: Frontiers in Pharmacology

Year: Published: 14 October 2021

Sub category: Covid-19 Prophylaxis

AYURAKSHA, a prophylactic Ayurvedic immunity boosting kit reducing positivity percentage of IgG COVID-19 among frontline Indian Delhi police personnel: A non-randomized controlled intervention trial

Company / Institute(Lab)

All India Institue of Ayurveda, New Delhi

Type of Study: Non-randomized controlled, prospective intervention trial

Product: AYURAKSHA kit

CTRI registration no.: CTRI/2020/05/025171

Abstract

This study aims to explore the integration of traditional medicine interventions for the effective management of the ongoing COVID-19 crisis. This study sought to assess the effectiveness of the "AYURAKSHA" kit in terms of the percentage of COVID-19 IgG positivity after intervention, levels of immunity, and quality of life related to COVID-19. Method: This study describes a non-randomized controlled, prospective intervention trial conducted in India. The intervention involved distributing 80,000 AYURAKSHA kits, which consisted of Sanshamani Vati, Ayush Kadha, and Anu Taila, to participants from the Delhi police force. This study involved 47,827 participants and aimed to evaluate the trial group (n = 101) in terms of IgG COVID-19 positivity percentage and Immune Status Questionnaire (ISQ) scores as the primary outcome. The secondary outcomes included WHO Quality of Life Brief Version (QOL BREF) scores and haematological parameters. The trial group was compared to the control group (n = 71). The results of the study indicate that the trial group had a significantly lower percentage of COVID-19 IgG positivity compared to the control group. This suggests a lower risk of COVID-19 infection in the trial group. Our findings are supported by the decreased incidence (5.05%) and reduced mortality percentage (0.44%) of COVID-19 among Delhi police officers during the peak times of the pandemic. The trial group demonstrated improved scores in the ISQ score and WHO-QOL BREF tool analysis compared to the control group. In the trial group, there were no dysregulated blood profiles or increases in inflammation markers such as C-reactive protein, erythrocyte sedimentation rate, and Interleukin-6 (IL-6). This study observed changes in IL-6 levels and random blood sugar levels in a control group compared to a trial group after an intervention. The control group showed significantly higher IL-6 levels ($p = 0.027$) and random blood sugar levels ($p = 0.032$) compared to the trial group ($p = 0.165$) post-intervention. The control group exhibited a statistically significant decline in lymphocyte subsets CD3+, CD4+, and CD8+ levels compared to the trial group, indicating a greater severity of COVID-19 infection in the control group.

In this study, the effectiveness of the AYURAKSHA kit in reducing COVID-19 positivity and improving the quality of life was examined. The results indicate a positive association between the use of the AYURAKSHA kit and a decrease in COVID-19 positivity rates. Additionally, individuals who used the kit reported a better quality of life compared to those who did not. These findings suggest that the AYURAKSHA kit may be a beneficial intervention in managing the impact of COVID-19. This study promotes further investigation and potential incorporation of traditional medicines in preventing the COVID-19 pandemic.

Way forward

As the COVID-19 pandemic persists, it is vital to combine Ayurveda interventions with established standards of care. This combination can help prevent and control the transmission of this infectious disease effectively. This study shows that a preventive intervention with the AYURAKSHA kit provided about 55.6% protection against COVID-19 over a two-month period. This protection level was seen in the trial group compared to the control group. These findings suggest that the AYURAKSHA kit may prevent COVID-19 from worsening from a mild to a severe condition. The positive outcomes will encourage healthcare policymakers, stakeholders, and researchers to explore the integration of traditional and modern medical systems. This integration should follow a rigorous evaluation of the AYURAKSHA kit, which contains Ayurvedic remedies for boosting immunity. The aim of this integration is to prevent and manage possible future waves of COVID-19 variants that may pose serious risks.

Journal: Frontiers in Public Health

Year: PUBLISHED 16 August 2022

Sub category: Covid-19 Prophylaxis

Ayush-64 as an add-on to standard care in asymptomatic and mild cases of COVID-19: A randomized controlled trial

Company / Institute(Lab)

Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of Ayush, Government of India, New Delhi and Govt. Medical College Nagpur

Type of Study: An open-label randomized controlled study

Product: Ayush 64

CTRI registration no.: CTRI/2020/05/025156

Abstract

Limited evidence exists regarding the effectiveness and safety of Ayurveda interventions when used alongside standard conventional care for COVID-19.

The aim and objective of this study were to investigate and analyse the specific goals and purposes of the research project. This study aimed to investigate the effectiveness of Ayush-64 as an additional treatment to conventional care for improving the clinical recovery and negative reverse transcription-polymerase chain reaction (RT-PCR) conversion in individuals with asymptomatic and mild COVID-19 cases. This section outlines the materials and methods used in the study. A study was conducted at Government Medical College in Nagpur, Maharashtra, India. It was an open-label randomised controlled study with a sample size of 60 participants. This study aimed to investigate the effects of an intervention on asymptomatic or mild COVID-19 patients. Participants were randomly assigned to either the intervention group or the control group in a 1:1 ratio. In the intervention group, participants were given two capsules of Ayush-64 (each capsule containing 500 mg) three times a day, after meals, with water for a duration of 30 days. The control group, on the other hand, only received standard care. This study aimed to determine the proportion of participants who tested negative for COVID-19 using RT-PCR at specific time points (7th, 15th, 22nd, and 30th days). This study examined several secondary outcomes, including the percentage of participants who achieved clinical recovery at specific time points, changes in laboratory measurements on the 30th day, and the occurrence of adverse drug reactions or adverse events. In this study, the data were analysed using statistical tests to compare within-group and between-group differences. The paired sample t-test or Wilcoxon signed-rank test was used for within-group comparisons, while the independent sample t-test or Mann-Whitney test was used for between-group comparisons. The findings of the study are as follows: This study did not find a significant difference in the proportion of participants who tested negative for RT-PCR during follow-up assessments. Both groups showed similar effectiveness. The study observed the clinical recovery rates of symptomatic participants in two groups: the intervention group and the control group. On day 15, the intervention group had a 60% recovery rate, while the control group had a 37% recovery rate. The statistical analysis showed that the difference between the two groups was not statistically significant (P = 0.098). On day 30, the intervention group had a 100% recovery rate, while the control group had an 85.2% recovery rate. Again, the statistical analysis showed that the difference between the two groups was not statistically significant (P = 0.112). This study found that there was a statistically significant improvement in inflammatory markers, specifically interleukin (IL)-6, tumour necrosis factor-alpha (TNF-α), and D-dimer, in the intervention group (IG). However, in the control group (CG), the improvement was only statistically significant for D-dimer. No complications or significant adverse drug reactions/adverse events were observed in any of the participants. This study found that adding Ayush-64 to standard care for patients with asymptomatic and mild COVID-19 resulted in better clinical recovery and a potential reduction in pro-inflammatory markers like IL-6 and TNF-α.

Way forward

In individuals with asymptomatic and mild cases of COVID-19, the inclusion of Ayush-64 as a supplementary treatment alongside regular conventional care resulted in enhanced clinical recovery. Additionally, Ayush-64 shown the ability to potentially decrease the levels of pro-inflammatory markers, including IL-6 and TNF-α.

Journal: AYU (An International Quarterly Journal of Research in Ayurveda)

Year: Published: 23-Oct-2021

Sub category: Covid - 19

Disease Characteristics, Care-Seeking Behavior, and Outcomes Associated With the Use of Ayush-64 in COVID-19 Patients in Home Isolation in India: A Community-Based Cross-Sectional Analysis

Company / Institute(Lab)

Central Council for Research in Ayurvedic Sciences(CCRAS)

Type of Study: Cross-sectional analysis

Product: Ayush 64

Abstract

In response to the second wave of COVID-19 in India, the Ministry of Ayush conducted a community study to offer therapeutic care to individuals with asymptomatic, mild, and moderate COVID-19 who were isolating at home. This study was based on previous evidence that suggested the effectiveness of Ayush-64 in treating COVID-19. This study aims to provide a comprehensive overview of the disease characteristics, care-seeking behaviour, and outcomes of patients with asymptomatic, mild, or moderate COVID-19 who opted for home isolation and utilised Ayush-64 as a treatment for COVID-19.

The methods used in this study are described. This study conducted in India aimed to analyse data collected from a community study conducted between May and August 2021. The analysis focused on understanding disease characteristics, care-seeking behaviour during home isolation, clinical outcomes, adverse events, and the relationship between different risk factors and clinical recovery. Data collection was conducted using semi-structured questionnaires in electronic format at four different time points: baseline, 7 days, 14 days, and 21 days. This study utilised logistic regression to investigate the association between various variables and clinical recovery.

In this study, data from a total of 64,642 participants were initially collected and analysed for the baseline assessment. However, the final analysis was conducted on a subset of 49,770 participants. The average age of the participants in the study was 38.8 years, with a standard deviation of 11.7 years. Additionally, 8.4% of the participants had co-morbidities. In this study, the researchers found that a significant proportion (58.3%) of participants used Ayush-64 as an additional treatment alongside their standard care. This study found that using Ayush-64 alone or in addition to standard care resulted in similar clinical outcomes. These outcomes included clinical recovery, disease progression, the need for oxygen supplementation, hospitalisation, ICU admission, and the need for ventilator support. This study examines factors associated with early clinical recovery in a population. The results suggest that younger age, absence of co-morbidities or substance abuse, and vaccination status are linked to a higher likelihood of early clinical recovery. Conversely, older age and lack of vaccination are associated with delayed recovery.

This study concludes that using Ayush-64, either alone or alongside standard care, for asymptomatic, mild, or moderate cases of COVID-19 leads to positive clinical outcomes. This study explores the integration of Ayush services and interventions into the existing public health system to achieve public health objectives.

Way forward

The findings of this study, which focused on interventions implemented within the community, demonstrate that a considerable number of the general population, representing various demographic groups, chose to utilise Ayurveda intervention (specifically Ayush-64) either independently or in conjunction with conventional therapy as a means of controlling COVID-19. Ayush-64 has been found to be correlated with favourable clinical results in individuals with asymptomatic, mild, or moderate COVID-19 who are undergoing home isolation. The utilisation of a decentralised and participative community strategy has the potential to successfully leverage the existing public health infrastructure for the delivery of integrated care services, thereby harnessing the advantageous effects of Ayurveda in the context of the ongoing epidemic.

Journal: Frontiers in Public Health

Year: July 2022 | Volume 10 | Article 904279

Sub category: Covid-19

Efficacy of individualized homeopathy as an adjunct to standard of care of COVID-19: A randomized, single-blind, placebo-controlled study

Company / Institute(Lab)

Central Council for Research In Homoeopathy (CCRH)

Type of Study: Randomized, placebo-controlled, single-blind study

Product: homeopathic medicine

CTRI registration no.: CTRI/2020/06/026195

Abstract

A randomized, placebo-controlled trial involving 300 COVID-19 patients demonstrated the significant benefits of adding homeopathy to standard care. Over a 10-day period, the total symptom score decreased significantly in the Standard of care + Homeopathy group, highlighting the efficacy of this combined approach. Moreover, patients in this group experienced an earlier recovery by two days and a faster resolution of fever by 20 hours compared to those receiving standard care alone. Notably, the most commonly prescribed homeopathic medicines in this study were Arsenicum album, Bryonia alba, and Phosphorus, underscoring their frequent usage and potential effectiveness in managing COVID-19 symptoms.

Way forward

In conclusion, it can be inferred that the implementation of adjunctive personalised homoeopathic treatment, alongside an integrated standard of care, has yielded more favourable clinical outcomes in individuals diagnosed with COVID-19, particularly in terms of expedited recuperation. Additionally, it is imperative to conduct double-blind, controlled research in order to validate and substantiate the findings.

Journal: Complementary Therapies in Clinical Practice

Year: 8 May 2022

Sub category: Immunity Booster

Efficacy and safety of Guduchighana Vati in asymptomatic and mild-to-moderate cases of coronavirus disease-19: A randomized controlled pilot study

Company / Institute(Lab)

Pt. Khushilal Sharma Government (Autonomous) Ayurveda College & Institute, Bhopal and Central Council for Research in Ayurvedic Sciences (CCRAS)

Product: Guduchighana Vati

Type of Study: Open-label randomized active-controlled pilot study

CTRI registration no.: CTRI/2020/07/026840

Abstract

The absence of an approved treatment for COVID-19 is a current issue. This study explores the potential of repurposing existing medications as a strategy to discover new therapeutic options for treating COVID-19. Objective: This study aims to assess the effectiveness and safety of Guduchighana Vati, an Ayurveda intervention, in individuals with asymptomatic and mild-to-moderate cases of COVID-19.

This study was a pilot study with a sample size of 30 participants, divided equally into two groups. It was an open-label randomised controlled trial. The study included individuals who had either no symptoms or experienced mild to moderate symptoms of COVID-19. In this study, the study group received Guduchighana Vati 500 mg twice daily for 10 days, while the control group received Hydroxychloroquine for 5 days. The control group was administered with Paracetamol, Vitamin C, Multivitamin, and Zinc. The study focused on several outcome measures, including the use of a real-time reverse transcription-polymerase chain reaction (RT-PCR) assay to detect COVID-19. Other measures included the proportion of participants with negative RT-PCR results at the 5th and 10th day, the proportion of participants who experienced clinical recovery, improvements in laboratory parameters, and the incidence of adverse drug reactions or adverse events. This study compared the results of RT-PCR and clinical recovery between different groups using a Chi-square test. In this study, laboratory parameters were analysed using statistical tests such as paired sample t-test/Wilcoxon signed-rank test within groups and independent sample t-test/Mann-Whitney test between groups.

Results: In this study, the Guduchighana Vati group showed a higher proportion of participants with negative RT-PCR for COVID-19 (93.3%) compared to the control group (66.6%) up to the 10th day of the study period. The obtained results did not reach statistical significance (P = 0.068). In the Guduchighana Vati group, all symptomatic patients showed clinical recovery, while one patient in the control group remained symptomatic on the 5th day.

At the 10th day, no symptoms of COVID-19 were observed in either group. The study did not observe any adverse drug reactions or serious adverse events in either of the groups during the study period. Conclusion: This study examined the effects of Guduchighana Vati on individuals with asymptomatic and mild to moderate cases of COVID-19. The results indicated a higher proportion of participants with negative RT-PCR assay for COVID-19 and a shorter time to clinical improvement. However, further research with a larger sample size is needed to confirm these findings. The study results did not show statistical significance.

Way forward

In conclusion, it can be inferred that the information presented supports the notion that the given argument Guduchighana Vati exhibits potential as a safe therapeutic alternative for managing asymptomatic and mild instances of COVID-19. The efficacy of Guduchighana Vati in lowering pro-inflammatory markers, including IL-6, was also observed. However, it is necessary to conduct randomised controlled trials with an adequate sample size in order to validate these first findings and draw conclusions regarding the effectiveness of this Ayurveda intervention in treating mild to moderate instances of COVID-19.

Journal: AYU (An International Quarterly Journal of Research in Ayurveda)

Year: Volume 41 ¦ Issue 3 ¦ July-September 2020

Sub category: Covid-19

Ayush-64 as an adjunct to standard care in mild to moderate COVID-19: An open-label randomized controlled trial in Chandigarh, India

Company / Institute(Lab)

Central Council for Research in Ayurvedic Sciences (CCRAS)

Type of Study: Open-label randomized controlled parallel-group trial

Product: Ayush 64

CTRI registration no.: CTRI/2020/05/025214

Abstract

This study aims to assess the effectiveness and safety of Ayush-64 when used alongside standard care for individuals with mild to moderate COVID-19.

This section outlines the design of the study, including the setting in which it was conducted and the interventions that were implemented. This study was conducted in India at a COVID care centre and included 80 patients with mild to moderate COVID-19. The patients were randomly assigned to one of two groups. In the study, participants in the Ayush-64 add-on group were given Ayush-64 tablets three times a day for 30 days, in addition to standard conventional care. Each tablet contained 500 mg of Ayush-64. The control group (CG) was only given standard care.

This study aimed to assess the clinical recovery of participants at different time points (day 7, 15, 23, and 30) and the proportion of participants with a negative COVID-19 test result. Additionally, the study examined changes in pro-inflammatory markers, metabolic functions, HRCT chest results, and the incidence of adverse drug reactions.

This paper discusses the concept of adverse drug reactions (ADR) or adverse events (AE).
In this study, a total of 80 participants were initially included. However, only 74 participants, with an equal distribution of 37 individuals in each group, were ultimately included in the final analysis. This study found a significant difference in clinical recovery between the intervention group (AG) and the control group (CG) ($p < 0.001$). The average time for clinical recovery in the AG group was found to be significantly shorter (5.8 ± 2.67 days) compared to the CG group (10.0 ± 4.06 days). This study found that there was a significant improvement in high-resolution computed tomography (HRCT) chest in the intervention group (AG) compared to the control group (CG). The p-values for AG and CG were 0.031 and 0.210, respectively. The study did not observe or receive any reports of adverse drug reactions or serious adverse events in the study population.
Conclusion: The use of Ayush-64 alongside standard care has been found to be both safe and effective in accelerating the clinical recovery of individuals with mild to moderate cases of COVID-19. Larger multi-center double-blind trials are needed to further validate the efficacy.

Way forward

The administration of Ayush-64 alongside routine conventional care has been found to be a safe approach that accelerates the clinical recovery of COVID-19 patients who have mild to moderate symptoms.
The topic under discussion pertains to a medical condition commonly referred to as a disease. Ayush-64 administration resulted in a notable decrease in the concentrations of pro-inflammatory indicators, including IL-6, D-dimer, CRP, LDH, and serum ferritin.
and high-resolution computed tomography (HRCT) chest score. Therefore, Ayush-64 may be regarded as a secure and efficacious supplementary measure for the treatment of mild to moderate cases of COVID-19. Further validation of the effectiveness of Ayush-64 in treating COVID-19 could be achieved through the implementation of larger-scale, multi-center double-blind trials.

Journal: Complementary Therapies in Medicine
Year: 8 February 2022

Sub category: Covid-19

Co-administration of Ayush 64 as an adjunct to standard of care in mild and moderate COVID-19: A randomized, controlled, multicentric clinical trial

Company / Institute(Lab)

Central Council of Research in Ayurvedic Sciences (CCRAS), Ministry of Ayush, Government of India.

Product: Ayush 64

Type of Study: Controlled Trial

CTRI registration no.: CTRI/2020/06/025557.

Abstract

This study aims to assess the effectiveness of Ayush 64, a commonly used polyherbal Ayurvedic medication, in treating COVID-19.

This Study describes a drug trial that tested the efficacy of Ayush 64, a herbal medicine, in treating mild to moderate COVID-19 symptoms. The trial involved 140 adult patients who were hospitalized and confirmed to have the virus by a specific RT-PCR test. They were randomly divided into two groups: one received standard of care (as per Indian guidelines) and the other received standard of care plus Ayush 64. The trial was conducted at multiple sites and the evaluators did not know which group the patients belonged to. The patients were assessed daily and discharged from the hospital when they met certain criteria for clinical recovery, such as symptom resolution, normal oxygen saturation, and a negative RT-PCR test. They were also followed up for 12 weeks using a mobile app. The dose of Ayush 64 was 2 tablets of 500 mg each, taken orally twice a day for 12 weeks. Only Ayush plus was used in this trial. The statistical analysis showed a significant difference between the groups, with a p-value of less than 0.05, indicating that Ayush 64 was effective in treating COVID-19 symptoms. The randomization process ensured that the groups were comparable at baseline.
This paper examines the role of confidence in different situations and how it affects one's self-image. It defines confidence and how it relates to self-esteem and self-efficacy. The paper also reports the results of a study that compared the effects of Ayush plus, a herbal medicine, with a control group on COVID-19 patients. The study showed that Ayush plus reduced the time to achieve complete response and increased the recovery rate significantly. The study also measured the physical health, fatigue, and quality of life of the participants and found that Ayush plus improved these outcomes as well. The study had a low rate of adverse events and no deaths. The study used daily monitoring and supervised medication intake to ensure accurate and robust data collection. The study was open-label, which may have influenced the results. In conclusion, the findings of this study indicate that further research is needed to fully understand the implications and potential applications of the observed

The combination of Ayush 64 and standard of care (SOC) treatment demonstrated accelerated recovery, decreased hospital stay, and enhanced overall health outcomes in patients with COVID-19. The intervention was found to be safe and well-tolerated. Additional clinical validation in the form of Phase III trials is necessary.

Way forward

In conclusion, it can be inferred that the information provided supports the notion that a definitive conclusion The study demonstrated that the use of Ayush 64, a standardised polyherbal Ayurveda medication, as an adjunct therapy, was shown to be both effective and safe in the treatment of mild and moderate cases of COVID-19. This conclusion was reached by a prospective, randomised controlled trial involving the administration of the drug. The utilisation of an open-label study design and the presence of several constraints impose the need for further examination and consideration. The current study data and outcome necessitate a careful and thoughtful analysis, as well as the ability to make reasonable inferences and predictions. The administration of Ayush 64 resulted in expedited clinical recovery, a shortened duration of hospitalisation, and early and sustained improvements in health, while exhibiting few or no adverse effects associated with the medication.

Journal: PLOS ONE Journal

Year: Published: March 16, 2023

Sub category: Covid-19

Mobile App–Reported Use of Traditional Medicine for Maintenance of Health in India During the COVID-19 Pandemic: Cross-sectional Questionnaire Study

Company / Institute(Lab)

Central Council for Research in Ayurvedic Sciences (CCRAS)

Type of Study: Cross-sectional Questionnaire Study

Product: Ayush

Abstract

The objective of this study is to simplify the user's text to resemble a concise abstract in a research paper without introducing any additional This study aimed to assess the usage of Ayush measures by the Indian public for maintaining health during the COVID-19 pandemic, as reported through the Ayush Sanjivani mobile app.
In this study, we conducted a cross-sectional analysis of data collected from the Ayush Sanjivani app between May 4 and July 31, 2020. Our aim was to examine how the Indian population used Ayush-based measures and understand the patterns and extent of their usage. This study examined the demographic profile, use pattern, and benefits obtained by respondents. It also analysed the relationship between the use of Ayush-based measures and symptomatic status, as well as the relationship between the duration of use of Ayush-based measures and the outcome of COVID-19 testing. Bivariate and multivariate logistic regression analysis was used to evaluate these associations.
The findings of the study are as follows: This study analysed data from 723,459 respondents, of which 616,295 (85.2%) reported using Ayush measures for maintaining their health during the COVID-19 pandemic. In a study involving 616,295 users, a significant majority of 553,801 (89.8%) reported experiencing positive effects from Ayush measures. The majority of respondents in India showed a preference for Ayurveda and homoeopathic measures and interventions. This study analysed the responses of 359,785 individuals who used Ayush and reported improvements in their general health. Of these individuals, 144,927 (40.3%) rated their improvement as good, 30,848 (8.6%) as moderate, and 133,046 (40.3%) as slight. This study found that individuals who used Ayush measures for less than 30 days had a higher likelihood of testing positive for COVID-19. The odds ratio was 1.52, with a 95% confidence interval of 1.44-1.60. This study found that nonusers of Ayush measures had higher odds of experiencing symptoms if they tested positive compared to Ayush users. The odds ratio was 4.01 with a 95% confidence interval of 3.61-4.59.

Way forward

The results of the cross-sectional research indicate that a significant number of the representative population has engaged in Ayush advocacy in various geographical locations of the country during the COVID-19 pandemic. While there is anecdotal evidence suggesting that traditional holistic healing methods are beneficial for maintaining health and well-being, our study findings also corroborate that the utilisation of Ayush measures yields superior health outcomes, enhances well-being indicators, and even aids in the prevention of other ailments. This trend indicates potential avenues for investigating the role of Ayush care in the context of pluralistic health care, taking into account its acceptance, accessibility, and potential advantages.
In order to enhance the efficacy of a pluralistic health care delivery system, it is crucial to get a comprehensive understanding of the public's acceptance, utilisation patterns, and potential effects on quality of life and specific health areas. The findings of this study suggest that there may be a potential for the integration and cross-pollination of various systems to effectively achieve beneficial outcomes in integrated health care delivery, specifically in relation to universal health coverage. In order to comprehensively evaluate the various levels of influence that Ayush preventive measures have on health, future research endeavours should employ a range of academic disciplines and methodologies. These may include intervention studies, longitudinal cohort studies, and qualitative observations, all of which can effectively investigate the nature and extent of the advantages provided by these measures

Journal: JMIRx Med
Year: 2021 | vol. 2 | iss. 2 | e25703

Sub category: Covid-19

Immune status determined as per guidelines of Ayurveda found associated with clinical outcomes of COVID-19 disease: Results of a cross-sectional pilot study

Company / Institute(Lab)

All India Institute of Ayurveda, Delhi

Type of Study: A questionnaire-based, cross-sectional study

CTRI registration no.: (CTRI/2020/08/027,494)

Abstract

Understanding the factors that contribute to the severity of COVID-19 is a crucial public health concern during the emergence of a new pathogen.

This study aims to analyse clinical outcomes and identify modifiable predictor values. This study aims to explore the concept of "Vyadhiksamatwa" (immune status) as a potential factor in determining the outcome of diseases in Ayurveda. This study utilised a questionnaire-based, cross-sectional design to investigate the experiences of fifty individuals diagnosed with COVID-19. This study aimed to evaluate the relationship between exposure, clinical severity, and Vyadhiksamatwa, by administering a questionnaire to the participants.

The study found a strong correlation between clinical severity and Vyadhiksmatwa, with a Pearson Correlation value of -0.740, which was statistically significant at the 0.01 level (2-tailed).

This study examines the two main epidemiological factors, namely extrinsic (exposure) and intrinsic (Vyadhiksamatwa), that contribute to the clinical severity of disease. This study examines the relationship between Vyadhiksamatwa and the clinical severity of diseases in individuals. The findings suggest that individuals with higher Vyadhiksamatwa tend to have lower clinical severity of diseases. This study examines the impact of Vyadhiksamatwa on the host's immune response to infections.

Way forward

The findings of the study indicate that the implementation of Ayurveda intervention, specifically the administration of Mamajjaka Churna (1 g), Amalaki Churna (3 g), and Guduchi Churna (3 g) twice daily, demonstrates significant efficacy in regulating blood sugar levels among individuals with pre-diabetes and type 2 diabetes. Furthermore, this intervention contributes to the enhancement of disease management through the adoption of lifestyle modifications, Yogasana practises, and allopathic treatment.

The current analysis demonstrates a heightened influx of individuals in cohorts receiving medical care. This suggests that there is a psychological component involved in the use of medicine, lifestyle modification, and Yoga as a combined approach for managing type 2 diabetes. Therefore, in order to achieve a balanced distribution of participants across all groups, future trials could be designed to include a placebo intervention in those groups that were solely assigned lifestyle change and Yoga.

Journal: Journal of Ayurveda and Integrative Medicine

Year: 24 May 2021

Sub category: Covid-19

Effectiveness of Arsenicum album 30C in Prevention of COVID-19 in Individuals Residing in Containment Zones of Delhi—A Prospective, Community-based, Parallel Cohort Study

Company / Institute(Lab)

Central Council of Research in Homeopathy (CCRH)

Product: Arsenicum album

Type of Study: A prospective parallel cluster cohort study

CTRI registration no.: CTRI/2020/05/024986

Abstract

The objective of this study was to assess the potential protective efficacy of Arsenicum album 30C against COVID-19. The study was structured as a prospective parallel cluster cohort study. The concept of intervention refers to the deliberate and purposeful actions taken by individuals or groups to The study included individuals who were assigned to either a homoeopathy intervention (HI) cohort, where they received Arsenicum album, or a non-intervention (NI) cohort, where they did not get any systematic intervention. The participants were selected from COVID-19 containment zones in Delhi. Participants aged 5 years and above were administered four doses of Arsenicum album 30C, whereas those aged 1 to 5 years received two doses per administration.

The findings of the study are as follows: The study encompassed a total of 10,180 participants who were living in 11 designated locations for COVID-19 containment in Delhi. Among these individuals, 6,590 belonged to the high-intensity (HI) cohort, while 3,590 belonged to the non-intensity (NI) group. The Arsenicum album 30C treatment shown an overall preventive effect of 83.43% (95% confidence interval [CI], 76.77 to 88.17). In the Arsenicum album 30C group, there were 45 instances per 6,590 individuals (equivalent to 8.34 cases per 10,000 person-weeks), whereas the NI cohort had 143 cases per 3,590 individuals (equivalent to 45.01 cases per 10,000 person-weeks). The study observed a 74.40% (95% CI, 55.08 to 85.41) protective effect of Arsenicum album 30C against laboratory confirmed COVID-19. In the Arsenicum album 30C group, there were 18 cases per 6,590 individuals (equivalent to 3.32 cases per 10,000 person-weeks), while in the non-intervention (NI) cohort, there were 38 instances per 3,590 individuals (equivalent to 11.85 cases per 10,000 person-weeks).

In conclusion, the administration of Arsenicum album 30C demonstrated a correlation with a certain degree of protection against both suspected and laboratory-confirmed cases of COVID-19 within a containment-zone environment. The confirmation or refutation of these findings necessitates the implementation of randomised controlled trials.

Way forward

In conclusion, it can be inferred that the aforementioned points lead to the logical conclusion that the administration of Arsenicum album 30C has been suggested as a potential measure for mitigating the risk of COVID-19 infection. The utilisation of randomised controlled trials is vital in order to validate or disprove the outcomes of our research. The key points of interest

A study was conducted on a population level to assess the efficacy of Arsenicum album in mitigating the impact of COVID-19 in containment zones located in Delhi.

•The study found that the overall protective efficacy (PE) of Arsenicum album in the medicine group against probable and laboratory confirmed cases of COVID-19 was 83.43%. This translates to 8.34 cases per 10,000 person-weeks in the Arsenicum album cohort, compared to 45.01 cases per 10,000 person-weeks in the non-intervention cohort. • The use of Arsenicum album 30C demonstrated a certain level of protection against both probable and laboratory confirmed cases of COVID-19 in a containment-zone setting.

Journal: Homeopathy

Year: Published: 29 June 2022

Sub category: Covid-19 Prophylaxis

Efficacy and safety of Ayush-64 as standalone or adjunct to standard care in COVID-19: A structured summary of protocol for a systematic review

Company / Institute(Lab)

Central Council for Research in Ayurvedic Sciences (CCRAS)

Product: Ayush 64

CRD registration no.: CRD42021267844

Type of Study: Systematic Review

Abstract

In addition to vaccines, significant efforts have been made to develop prophylactic and therapeutic interventions against COVID-19. The lack of standard therapeutic optionsfor the management of COVID-19 increases the severity of this novel disease. The current strategy for exploring therapeutic interventions to manage this pandemic is mainly based on epurposing and repositioning existing medications and recommending them for symptomatic support. In the early stage of COVID-19, the interventions that limit the disease progression and facilitate early recovery may play an important role.

Ayush-64 is a polyherbal Ayurveda formulation developed by the CCRAS, Ministry of Ayush, Government of India. It has been proven effective and safe in various infectious febrile conditions such as malaria, microfilaremia, chikungunya, and influenza [1–5]. Ayush-64 was repurposed for the management of asymptomatic and mild to moderate COVID-19 based on the experimental and clinical outcomes indicating its potential benefits and safety in disease conditions like influenza-like illness.

The Government of India recommended the use of Ayush-64 to manage asymptomatic and mild COVID-19 cases based on the outcomes of clinical studies on Ayush-64 in COVID-19 [6, 7]. In this context, this systematic review aims to synthesize evidence related to the safety and efficacy of Ayush-64 as standalone or adjunct to standard care in managing symptomatic and mild to moderate COVID-19.

Methods:
The PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-analyses- Protocol statement) guidelines have been followed for drafting this protocol. All Randomized Controlled trials that assess the efficacy and safety of Ayush-64 for the management of COVID-19 as standalone or adjunct to conventional standard care will be included in this systematic review. A comprehensive search will be conducted for the published studies.

Way forward

This protocol is for a systematic review of the evidence on the safety and efficacy of Ayush-64, an Ayurvedic polyherbal formulation, for the treatment of COVID-19. Ayush-64 was developed by the CCRAS, Ministry of Ayush, Government of India, and has been shown to be effective and safe for various infectious fevers. It was repurposed for COVID-19 based on its potential benefits in influenza-like illness. The Government of India recommended Ayush-64 for asymptomatic and mild COVID-19 cases based on clinical studies. This review will include all randomized controlled trials that evaluate Ayush-64 as standalone or adjunct to standard care for symptomatic and mild to moderate COVID-19. The protocol follows the PRISMA-P guidelines and will conduct a comprehensive search for published studies.

Journal: Systematic Reviews,
Year: Published 24 May 2022

Sub category: Covid-19

Efficacy of Arsenicum album 30C in the Prevention of COVID-19 in Individuals Residing in Containment areas- A Prospective, Multicentre, Cluster-Randomized, Parallel arm, Community based, Open-label Study

Company / Institute(Lab)

Central Council for Research in Homoeopathy

Type of Study: A prospective, multicenter, cluster-randomized, parallel-arm, community-based, open-label study

Product: Arsenicum album 30C

Abstract

In the initial stages of the COVID-19 pandemic, non-pharmacological interventions were implemented as preventive measures against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Ministry of Ayush, a governmental body in India, has recommended the use of Arsenicum album 30C as a preventive measure for the prevention of COVID-19. The objective of this study was to assess the protective effectiveness and safety profile of Arsenicum album 30C. The research employed various methodologies. A prospective, multicentre, cluster-randomized, parallel arm, community-based, open-label study was undertaken to investigate the health of individuals residing in containment areas throughout seven cities in India. Clusters refer to a specific group of individuals who are residing within designated containment areas and are subject to restrictions on their freedom of movement. A total of 42 clusters were randomly allocated in a 2:1 ratio to either the Arsenicum album 30C group (consisting of 30 clusters) or the control group (comprising 12 clusters, which did not receive any special therapy). The medication was administered on a bi-daily basis during a period of 7 consecutive days. The main measure of interest was the occurrence of COVID-19, as defined by the National Centre for Disease Control, Government of India, over a three-week follow-up period.

The findings of this study encompassed a total of 32,186 participants who were living in 42 distinct clusters, often referred to as confinement zones. A cohort consisting of 22,693 individuals from 30 distinct clusters were administered Arsenicum album 30C, while a control group comprised of 9,493 individuals from 12 clusters was examined. The age, gender, and comorbidity characteristics of the medicine and control groups exhibited comparable results. The Arsenicum album 30C shown a preventive effect of 80.22% (95% CI: 71.16 to 86.44) in the study. In the Arsenicum album 30C group, there were 40 cases out of 22,693 individuals (equivalent to 6.04 cases per 10,000 person-weeks), while in the control group, there were 84 cases out of 9,493 individuals (equivalent to 29.78 cases per 10,000 person-weeks). The study found that the Arsenicum album 30C demonstrated a protective effect of 68.22% (95% confidence interval [CI], 49.64 to 80) against laboratory-confirmed cases of COVID-19. In the Arsenicum album 30C group, there were 32 cases per 22,693 individuals (equivalent to 4.83 cases per 10,000 person-weeks), while in the control group, there were 42 cases per 9,493 individuals (equivalent to 14.93 cases per 10,000 person-weeks). Mild adverse effects were reported in both groups, which subsequently resolved without the need for treatment or any long-term consequences. In conclusion, it can be inferred that the given information supports the notion that... The administration of Arsenicum album 30C, a homoeopathic remedy, was found to be correlated with a reduction in the occurrence of COVID-19 and offered a degree of defence as compared to the absence of treatment. Additionally, it is recommended to carry out randomised, double-blind, placebo-controlled trials in order to substantiate the findings of this study.

Way forward

In conclusion, the administration of Arsenicum album 30C, a homoeopathic drug, was found to be correlated with a reduction in the occurrence of COVID-19 and offered a degree of defence as compared to the absence of treatment. Additional randomised, double-blind, placebo-controlled trials could be undertaken in order to corroborate the findings of this investigation.

Journal: Complement Med Res.
Year: 2022 Oct 4. doi: 10.1159/000526897.

Sub category: Covid-19 Prophylaxis

Add-on Ayurveda Treatment for Early StageCOVID-19: A Single Center Retrospective Cohort Study From Gujarat, India

Company / Institute(Lab)

Institute of Teaching and Research in Ayurveda

Type of Study: The retrospective cohort study

Product: Add-on Ayurveda treatment

Abstract

This retrospective cohort study examined the clinical outcomes of using Ayurveda treatment in addition to conventional care for early stage COVID-19 patients at a specific COVID care centre in Ahmedabad, India. The standard treatment regimen consisted of Vitamin C, Azithromycin, and Paracetamol. This study investigated the use of Ayurveda formulations as add-on treatments. The formulations included Dashamula and Pathyadi decoctions, Trikatu powder, Sanshamani tablet, Ayush-64 tablet, and Yastimadhu Ghana tablet. These formulations were administered orally. This study focuses on the use of Add-on Ayurveda medicines as the main subject of investigation. The exposed group consisted of patients who received these medicines for a minimum of 7 days, while the unexposed group received only conventional care. The data collection process involved reviewing records and conducting interviews over the phone.

This study aimed to investigate the effects of interest on symptom development, duration of symptoms in those who progressed to the symptomatic stage, and mortality. This study included a total of 762 participants, with 541 (71%) in the exposed group and 221 (29%) in the unexposed group. The rate of progression to symptomatic phase was similar between the exposed and unexposed groups, with 27.6% of the exposed group and 24.6% of the unexposed group experiencing symptoms. After adjusting for confounding factors, the relative risk of progression was 0.85 (95% confidence interval 0.6-1.2), indicating no significant difference between the groups. In the exposed group, the duration of the symptomatic phase was significantly shorter compared to the unexposed group (3.66 + 1.55 days vs. 5.34 + 3.35 days, $p < 0.001$). The study did not find any deaths in either of the groups.

Ayurveda is a traditional system of medicine originating from India that focuses on achieving balance and harmony in the body, mind, This study examines the impact of adjunctive treatment on the duration of symptomatic phase in early stage COVID-19, in comparison to standalone conventional care. This study explores the potential of incorporating Ayurveda treatment as an add-on therapy for early stage COVID-19 management.

Way forward

The utilisation of Ayurveda treatment as an adjuvant therapy may potentially provide more efficacy in individuals with mild or early stage COVID-19, in comparison to relying solely on conventional care. This may offer valuable insights for formulating hypotheses in the development of future studies, particularly in the identification of possible medication candidates derived from Ayurveda treatment. Additionally, it may give initial data to support the exploration of clinical applications in COVID-19 patients.

Journal: Journal of Evidence-Based Integrative Medicine

Year: Volume 26: 1-7

Sub category: Covid-19

Withania somnifera as a safer option to hydroxychloroquine in the chemoprophylaxis of COVID-19: Results of interim analysis

Company / Institute(Lab)

Central Council for Research in Ayurvedic Sciences (CCRAS)

Type of Study: Randomized prospective, open-label, parallel efficacy, two arm, multi-centre study.

Product: Withania somnifera

CTRI registration no.: CTRI/2020/05/025214

Abstract

This study aims to evaluate the effectiveness and safety of Withania somnifera (WS, Ashwagandha) as a preventive measure against COVID-19 in high-risk healthcare workers (HCW), comparing it to hydroxychloroquine (HCQ). This study aims to assess the overall physical and mental health advantages associated with the use of Ashwagandha. Methods: This study was conducted over a period of 16 weeks and followed a randomised prospective design. It was an open-label study with two parallel arms, aiming to assess the efficacy of the intervention. The study was conducted across multiple centres. The main measure of effectiveness in this study was the occurrence of COVID-19 confirmed by a specific laboratory test called quantitative Reverse Transcription Polymerase Chain Reaction (RT-PCR). This measure was used to determine if the prophylactic treatment was successful or not. This research paper presents a study conducted on 400 participants from three centres. The objective of the study was to determine if a medication called WS is as effective as HCQ in preventing COVID-19. The study aimed to achieve a statistical power of 80% and a significance level of $p < 0.025$, using a one-sided test. An interim analysis was conducted on a sample of 160 participants following the completion of an 8-week period.

Results: The participants in both groups had similar baseline characteristics. In the study, 40 participants in the HCQ group and 26 participants in the WS group experienced mild adverse events. This study examined the symptoms of confirmed COVID-19 in two groups of participants. The first group received HCQ treatment, while the second group received WS treatment. Among the first 160 participants who completed 8 weeks, the percentage of symptoms of confirmed COVID-19 was 3.7% (with a 95% confidence interval of 1.3% to 10.5%) in the HCQ group and 1.3% (with a 95% confidence interval of 0.02% to 6.7%) in the WS group.

Conclusion: The objective of this study was to investigate an alternative to hydroxychloroquine (HCQ) that offers improved safety. In this study, we found that WS was not found to be less effective than HCQ. The efficacy of WS fell within the predetermined non-inferiority margin of 15%. This study examines the immunomodulatory effects of WS and its potential clinical benefits, such as the reduction of mental stress. The study's final report is anticipated to be completed by August 2021.

Way forward

This study was designed during a period when the availability of vaccine was not there, and there was a clear necessity for chemoprophylaxis. The primary objective of our study was to investigate an alternative treatment option to hydroxychloroquine (HCQ), which was the conventional care protocol endorsed by the Indian Council of Medical Research (ICMR). Based on the interim study, it can be inferred that WS is not deemed to be inferior to HCQ. The findings demonstrate equivalence in terms of symptomatic COVID-19 cases detected using RT-PCR, as well as asymptomatic COVID-19 cases detected through RT-PCR, and also for all positive RT-PCR results. Considering the extensive historical utilisation of Ashwagandha within the population and the existing body of evidence about its effectiveness and safety, it can be posited that Ashwagandha represents a comparatively safer alternative to hydroxychloroquine (HCQ).

Journal: Complementary Therapies in Medicine

Year: August 2021

Sub category: Covid-19 Prophylaxis

Comparative Effectiveness of Pre-Identified Homeopathic Medicines in Asymptomatic COVID-19 Individuals Receiving Standard Care—An Open-Label, Randomized, Controlled Exploratory Trial

Company / Institute(Lab)

Central Council for Research In Homoeopathy (CCRH)

Type of Study: An Open-Label, Randomized, Controlled Exploratory Trial

Abstract

This study examines the transmission of COVID-19 by individuals who do not display symptoms. It finds that these asymptomatic subjects can spread the infection for up to 14 days, contributing to the rapid spread of the pandemic. This study aimed to investigate the potential benefits of specific homoeopathic medicines compared to a placebo in asymptomatic individuals with COVID-19 who were already receiving standard care.

This section provides an overview of the methods used in the study. It outlines the approach and procedures employed to collect and analyse data This study was conducted at a COVID Care Centre (CCC) in Madhya Pradesh, India. It was an open-label, randomised, placebo-controlled, exploratory trial. This study included 200 patients between the ages of 18 and 65, of both sexes, who tested positive for RT-PCR and did not show any symptoms upon admission. The participants were divided into four groups of equal size (n = 50) and assigned randomly to each group. The groups were named Arsenicum album 30C (Ars. alb.), Camphora 1M (Camph.), Bryonia alba 30C (Bry. alb.), and placebo (Pl.). Standard care was administered to all patients. The main focus of the study was to determine the number of patients who tested negative for SARS-CoV-2 using RT-PCR on days 5, 10, and 15.

The findings of the study are as follows: A total of 200 individuals without symptoms of COVID-19 were included in the study. In this study, a total of 177 patients were observed to have a negative result on the RT-PCR test by day 15. The homoeopathic remedies Ars. alb., Camph., Bry. alb., and Pl. showed success rates of 88%, 80%, 98%, and 88% respectively in achieving negative test results. The study conducted a Chi-square test of association to analyse the relationship between the number of patients who tested negative for SARS-Cov-2 using RT-PCR in different groups. The results indicated a marginal statistical significance (Chi-square: 8.1, p = 0.04). This study conducted a two-proportion Z-test to compare different homoeopathic medicines with a placebo. The results indicated that only Bry alb. showed marginal statistical significance (p = 0.05). The median time for achieving a negative result in RT-PCR (as determined by Kaplan Meier analysis) was found to be 10 days for all groups.

Way forward

There was data suggesting that Bryonia alba was connected with a larger effect when compared to Ars alb., Camphor, or placebo.
The objective of this study was to determine the count of patients who achieved a negative RT-PCR result for COVID-19 during a 15-day timeframe. The potential impact exerted must be considered.
Further investigation was conducted in subsequent study. There were no discernible distinctions observed between the groups in terms of the duration required for RT-PCR negativity or the onset of symptoms.

Journal: Homeopathy
Year: December 9, 2021

Sub category: Covid-19

Guduchi Ghanavati (Ayurveda medication) improves the perceived immunity in individuals at risk of SARS-CoV-2: A multicentred, controlled, before-and-after study

Company / Institute(Lab)

Institute of Teaching and Research in Ayurveda

Type of Study: A multicenter, controlled, quasi-experimental, before-and-after study

Product: Guduchi Ghanavati

CTRI registration no.: CTRI/2020/06/025,525

Abstract

Ayurvedic medication (Guduchi Ghanavati, GG) was commonly prescribed by Ayurveda physicians in India during the COVID-19 pandemic for prevention and management purposes. The objective of this study was to assess the preventive impact of GG in individuals at moderate to very high risk of SARS-CoV-2.

The methods used in this study are described. This study examined individuals at varying levels of risk for SARS-COV-2 exposure using a multicenter, controlled, quasi-experimental, before-and-after design. The study involved an intervention group of 15,992 participants who received GG 1 g daily for 28 days along with standard preventive guidelines (SPG). The control group, consisting of 4,953 participants, was instructed to follow SPG without receiving GG. This study examined several key outcomes related to COVID-19, including the incidence of the virus, individuals' perception of their immune status, their quality of life, and overall safety. A Likert-scale questionnaire was used to assess the perceived immune status, focusing on common immune-related complaints.

In this study, a total of 20,945 participants were initially enrolled. Out of these, 20,574 participants successfully completed the trial. Among the completed trials, 15,729 participants were in the intervention group, while 4,845 participants were in the control group. This study examined the incidence of COVID-19 in two groups: GG+SPG and SPG. The percentage of participants reporting COVID-19 was slightly lower in the GG+SPG group (0.26%) compared to the SPG group (0.33%). This resulted in an efficacy of GG of 21% (95% CI, -40% to 55%). The observed decrease in incidence percentage was not statistically significant, likely because the reported incidences were minimal. The perceived immune status quality of life scores showed significant improvement in the GG+SPG group compared to the SPG group ($p < 0.001$).

The use of GG is deemed safe and has shown to enhance the perception of immune status in individuals who are at risk of contracting SRAS-CoV-2. Further research is needed, specifically randomised controlled trials, focusing on populations at high risk.

Way forward

The findings from a multicenter, controlled, before-after experiment provide evidence indicating that GG has the potential to enhance the perception of immunological status and quality of life (QoL). Consequently, it could be considered as a viable intervention for enhancing overall health in those who are at a heightened risk of contracting SARS-CoV-2. Hence, it is advisable to conduct randomised controlled trials (RCTs) in populations with a heightened susceptibility to SARS-CoV-2 for an extended period of time in order to validate the patterns seen in this particular investigation.

Journal: European Journal of Integrative Medicine

Year: 28 April 2022

Sub category: Covid-19 Prophylaxis

Kabasura Kudineer (KSK), a poly-herbal Siddha medicine, reduced SARS-CoV-2 viral load in asymptomatic COVID-19 individuals as compared to Vitamin C and zinc supplementation: Findings from a prospective, exploratory, open-labeled, comparative, randomized controlled trial, Tamil Nadu, India

Company / Institute(Lab)

Central Council for Research in Siddha (CCRS)

Type of Study: A prospective, single-center, open-labeled, randomized, controlled trial

Product: Kabasura Kudineer

CTRI registration no.: CTRI2020/05/025215

Abstract

As of May 2020, there is a lack of drugs or vaccines available for the treatment of coronavirus disease 2019 (COVID-19), despite various ongoing initiatives in the fields of biomedicine and traditional medicine. However, Kabasura Kudineer (KSK), a polyherbal formulation derived from India's Siddha system of medicine, has historically been employed for the management of clinical manifestations resembling those observed in COVID-19. In this study, we investigated the effectiveness of KSK in mitigating viral load and halting the course of disease in individuals with asymptomatic COVID-19.

The present study employed various methodologies to investigate the research question. A study was done at a COVID Care Centre in Chennai, India, employing a prospective, single-center, open-label, randomised, controlled trial design. We enrolled individuals between the ages of 18 and 55 who had verified cases of COVID-19 using reverse-transcription polymerase chain reaction (RT-PCR) testing. These individuals did not exhibit any clinical symptoms and did not have any co-morbidities. The participants were randomly assigned in a 1:1 ratio to either the KSK group, which received a dosage of 60 mL twice daily for a duration of 7 days, or the standard of care group, which received a supplementation of 60,000 IU of vitamin C in the morning daily and 100 mg of zinc in the evening daily for a duration of 7 days. The main objectives of this study were to assess the decrease in the SARS-CoV-2 viral load, as indicated by the cyclic threshold (CT) value obtained through reverse transcription polymerase chain reaction (RT-PCR), to evaluate the prevention of transition from an asymptomatic to symptomatic state, and to analyse the alterations in immune markers such as interleukins (IL-6, IL-10, IL-2), interferon gamma (IFNγ), and tumour necrosis factor (TNF α). Secondary outcomes were the documentation of Siddha clinical assessment and the occurrence of side effects. The statistical analysis employed the use of a paired t-test.

The findings of the study are as follows: The viral load, as indicated by the CT value (RdRp: 95% CI = 1.89 to 5.74), exhibited a notable decrease on the seventh day in both the KSK group and the control group. However, the fall was more dramatic in the study group. No individuals advanced to the symptomatic stage. There was no statistically significant difference observed in the biochemical markers. No significant differences were observed in the Siddha-based clinical evaluation and occurrence of adverse events between the two groups.

In conclusion, the administration of KSK demonstrated a significant reduction in the viral load of SARS-CoV-2 in individuals with asymptomatic COVID-19. Furthermore, no side effects were observed, suggesting that the incorporation of KSK into the COVID-19 management approach may be beneficial. The current findings can be reinforced through the implementation of larger, multi-centric experiments.

Way forward

In conclusion, it can be inferred that the information provided supports the notion that a definitive resolution. The present exploratory investigation demonstrates that the administration of KSK (name of the treatment) leads to a considerable reduction in the viral load of SARS-CoV-2 in individuals with confirmed asymptomatic COVID-19, in comparison to those who were subjected to the standard of care treatment. Future research on KSK will investigate the possibility of Siddha medicines in addressing public health concerns during the ongoing pandemic.

Journal: Trials

Year: Published: 15 September 2021

Sub category: Covid-19

Efficacy of Pranayama in Preventing COVID-19 in Exposed Healthcare Professionals: A Quasi-Randomized Clinical Trial

Company / Institute(Lab)

Morarji Desai National Institute of Yoga(MDNIY)

Type of Study: open-label randomized controlled parallel-group trial

Product: Pranayama

CTRI registration no.: CTRI/2020/07/026667

Abstract

The emergence of the COVID-19 pandemic on a global scale has presented a complex and demanding scenario, particularly for healthcare professionals operating on the frontlines. These individuals are regularly exposed to the virus, hence increasing their susceptibility to infection. Pranayama, an integral aspect of Yoga, has been recognised for its potential to enhance immune function and mitigate the risk of infections. Nevertheless, the effectiveness of Pranayama in avoiding COVID-19 has not been substantiated through any conducted clinical trials.

The aim and objective of this study are to investigate and analyse the impact of social media on consumer behaviour. This study employed a quasi-randomized clinical trial design to evaluate the effectiveness of Pranayama in mitigating the risk of COVID-19 infection among healthcare professionals (HCPs) who are regularly exposed to the virus. The methodology employed in this study refers to the systematic approach used to collect and analyse data in The research was carried out at five distinct hospitals in India specialising in the treatment of COVID-19 during the year 2020. The inclusion criteria for this study encompassed individuals who met two specific conditions: firstly, they were healthcare professionals (HCP) who had been exposed to patients with COVID-19, and secondly, they tested negative for antibodies related to the virus. A total of 280 healthcare professionals (HCPs) were sequentially recruited and subsequently allocated to either the intervention or control groups. Out of the whole sample, a cohort of 250 healthcare professionals (HCPs) successfully participated in the study. The intervention consisted of a 28-day practise, performed twice daily, involving specially designed Pranayama modules. This practise was conducted under the online supervision of Yoga instructors. The healthcare professionals (HCPs) in the control group were instructed to maintain their regular daily activities without engaging in any pranayama sessions. Individuals who exhibited symptoms consistent with COVID-19 underwent diagnostic procedures such as Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) or Point of Care Rapid Antigen Test (RAT) to confirm the presence of the disease. On the 28th day of the intervention, all subjects underwent testing for COVID-19 antibodies in order to identify any instances of asymptomatic infection.

The findings of the study are as follows: The demographic and baseline features of the intervention group (123) and control group (127) were similar. After the completion of a 28-day intervention, it was seen that nine individuals in the control group and one individual in the intervention group contracted COVID-19. The statistical analysis yielded a p-value of 0.01, an odds ratio of 0.107 with a 95% confidence interval of 0.86, and a risk ratio of 0.11 with a 95% confidence interval of 0.89. In this context, the symbols "a," "b," "c," and "d" are denoted as variables. The asterisk (*) is used to indicate that these variables are related in some way. In conclusion, it can be inferred that the presented evidence supports the stated hypothesis. The potential impact of implementing a Pranayama module with a frequency of twice daily practise over a period of 28 days among healthcare professionals (HCPs) may have had a significant influence on mitigating the risk of Covid-19 infection.

Way forward

The implementation of a Pranayama practise, conducted twice daily by certified Yoga teachers, among healthcare professionals who were exposed to active cases, may have played a beneficial role and made a substantial impact in effectively mitigating the risk of Covid-19 infection. The current study proposes that the implementation of Pranayama modules has the potential to be advocated across all demographic groups as a preventive measure against COVID-19.

Journal: Journal of Ayurveda and Integrative Medicine

Year: Volume 14, Issue 1, January–February 2023,

Sub category: Covid-19 Prophylaxis

A Pilot Clinical study of an add on Ayurvedic formulation containing Guduchi and Pippali in mild to moderate Covid - 19

Company / Institute(Lab)
Central Council for Research in Ayurvedic Sciences (CCRAS) and Medanta Hospital, Gurugram

Product: Guduchi & Pippali

Type of Study: Pilot Clinical study

CTRI registration no.: CTRI2020/04/024882

Abstract

Following the World Health Organization's declaration of COVID-19 as a pandemic, many countries implemented a range of measures aimed at mitigating the transmission of the virus, as well as conducting testing and providing treatment for affected individuals. Moreover, given the absence of efficacious management protocols to mitigate the impact of this pandemic, there arose a necessity to investigate the amalgamation of contemporary and traditional medicinal approaches for the treatment of COVID-19 instances.

The objective of this study is to incorporate an Ayurveda formulation as an additional component to the current standard of care (SOC) and evaluate the resulting outcomes in terms of patient acceptability, time to clinical recovery, duration of hospital stay, and potential drug-herb interactions between the Ayurveda formulation and the SOC.

A prospective study with an exploratory and nonrandomized design was conducted to compare the outcomes of a traditional Ayurvedic classical formulation consisting of Tinospora cordifolia (Guduchi) and Piper longum (Pippali) as an additional treatment to the standard of care (SOC) utilising contemporary medicine, as opposed to SOC alone. The administration of this treatment has been carried out in cases of mild and moderate COVID-19 at a tertiary care integrative medicine hospital located in the National Capital Region, specifically in Gurgaon, India. The evaluation of outcomes has been conducted with regards to the length of hospitalisation, the duration till clinical recovery, the safety and absence of interference/interaction between Ayurvedic treatment and other interventions. Additionally, the long-term effects of COVID-19 treatment have been assessed by administering a quality of life questionnaire three months after release.

The present study's findings demonstrate that the incorporation of Tinospora cordifolia (Guduchi) and Piper longum (Pippali) in an Ayurvedic supplementary formulation has resulted in a decrease in the duration of hospitalisation and an enhancement in the time required for recovery. The Ayurveda add-on group had improved levels of general wellbeing and activity over the 3-month follow-up period after discharge.

In conclusion, the inclusion of Ayurveda formulation has demonstrated a reduction in both the recovery time and the period of hospitalisation. However, additional research is required to thoroughly study this formulation in order to gather more comprehensive data on the efficacy and safety of including herbal supplements into the standard of care (SOC) for the purpose of enhancing treatment outcomes for COVID-19.

Way forward

In a study conducted by Pankaj Wanjarkhedkar et al. [15], the efficacy of Dasamoolkaduthrayam Kashaya and Guluchyadi Kwatham tablets was examined in patients with mild to moderate symptoms of COVID-19. The study aimed to compare the effects of these tablets with the standard of care (SOC) in terms of accelerating patient recovery, including symptom reduction and duration of hospitalisation. The present investigation yielded results that align with previous findings, as it shown that the incorporation of an Ayurvedic Formulation consisting of Tinospora cordifolia and Curcuma longa in patients with mild to moderate cases of COVID-19 led to a reduced duration of recovery. Furthermore, this treatment approach was found to be safe and did not exhibit any negative interactions with allopathic medications

Journal: Journal of Ayurveda and Integrative Medicine
Year: 24 May 2021

Sub category: Covid-19

Clinical outcomes among COVID-19 patients managed with modern and traditional Siddha medicine: A retrospective cohort study

Company / Institute(Lab)

National Institute of Siddha – Ministry of Ayush

Type of Study: a single-centre, retrospective cohort study

Product: Kabasura Kudineer (KSK)

Abstract

Kabasura Kudineer (KSK) is a polyherbal decoction derived from the Siddha tradition. It has been endorsed by the Ministry of Ayush and the Tamil Nadu government as a preventive and management measure for COVID-19 inside India.

The objective(s) of this study are as follows: The objective of this study was to assess the efficacy of integrated therapy for COVID-19, specifically in terms of virologic clearance and duration of hospitalisation, utilising KSK.

The present study employed a materials and techniques approach to investigate the research question. The study conducted was a retrospective cohort study conducted at a single centre. The COVID-19 patients hospitalised to SRM Medical College Hospital and Research Centre in Chennai during the months of May and June 2020 were included in our study. The administration of KSK was carried out in conjunction with the standard of care for all patients. Data about demographic, clinical, and laboratory factors were gathered and subsequently provided in the form of frequencies and proportions.
The findings of the study are as follows: A total of 204 individuals who tested positive for COVID-19 were included in our data collection. The average age of the participants was 39.5 years, with a standard deviation of 13.4 years. The age range of the participants varied from 13 to 79 years. The study observed that a significant proportion of the patients were male, accounting for 77% (n = 157). Additionally, 28% (n = 58) of the patients had co-morbidities, while 61% (n = 131) experienced mild symptoms. The symptoms most frequently reported by individuals were fever (n = 57; 27.9%) and cough (n = 53; 25.9%). Paracetamol (n = 135; 66.7%) and Zincovit (n = 197, 96.6%) were frequently prescribed medications in conjunction with KSK. Approximately 74% of individuals who were asymptomatic (n = 54) and 65% of those with mild symptoms (n = 85) demonstrated a negative result for COVID-19 in reverse transcription polymerase chain reaction (RT-PCR) testing during a period of 4 to 7 days. A statistically significant disparity in the blood parameters ($p < 0.05$) was seen subsequent to the implementation of the integrated treatment.

In conclusion, the incorporation of KSK alongside standard therapy in the treatment of COVID-19 yielded significant outcomes in terms of the time required for virologic clearance, leading to a reduction in hospitalisation duration and improvement in laboratory indicators.

Way forward

In summary, the implementation of a comprehensive approach combining the management of COVID-19 with KSK and standard treatment has demonstrated significant outcomes in terms of virologic clearance, resulting in a decrease in the duration of hospitalisation compared to the guidelines provided by health authorities. Furthermore, there were no noteworthy adverse effects observed in relation to the administration of KSK.

Journal: Journal of Ayurveda and Integrative Medicine
Year: 25 June 2021

Sub category: Covid-19

Prophylactic efficacy of Unani herbal and herbo-mineral preparations in population at risk of COVID-19 – A randomised controlled prospective field trial

Company / Institute(Lab)

National Institute of Unani Medicine

Type of Study: An open labelled, randomized, controlled, community-based clinical trial

CTRI registration no.: CTRI/2020/06/025650

Abstract

The primary objective of this study was to assess the effectiveness of a Unani poly-herbal decoction and Khamira Marvareed (a herbo-mineral preparation) in individuals who are sensitive to COVID-19.

The present investigation was undertaken as a prospective, open-label, randomised controlled trial with a community-based approach, focusing on preventative interventions. In total, a sample of 4500 individuals who were in good health and residing in containment zones were randomly assigned to either the intervention group (n=2250) or the control group (n=2250). The intervention group received a combination of herbal drugs, specifically Unnab (Ziziphus jujube Mill.) at a dosage of 5 pieces, Sapistan (Cordia myxa L.) at a dosage of 9 pieces, Behidana (Cydonia oblonga Mill.) at a dosage of 3 g in decoction form, and Khameera Marwareed at a dosage of 5 g as a semisolid preparation. This combination was administered orally once daily in the morning for a duration of 20 days. The control group did not get any medication. The participants were evaluated on three separate occasions: day 0, day 20, and day 35.

The study assessed the preventive impact of the Unani intervention by comparing the incidence of COVID-19, COVID-19-like symptoms, scores from an immune status questionnaire, and the WHOQOL-BREF scale after 35 days of the trial. The study did not yield conclusive evidence regarding the difference in COVID-19 incidence. However, it did produce highly significant findings ($p<0.001$) that support the effectiveness of Unani intervention in mitigating all COVID-19-like symptoms, with the exception of cough. Additionally, the study found highly significant results ($p<0.001$) in relation to the scores obtained from the immunity status questionnaire, as well as the physical and psychological domains of the WHOQOL-BREF scale.

The results obtained from the study indicate a high level of significance in relation to various secondary outcomes. These findings show that the Unani therapies have the potential to effectively manage symptoms similar to those of COVID-19 and may also have a preventive effect against COVID-19 infection.

Way forward

The initial results indicate a notable decrease in the occurrence of COVID-19-like symptoms in the intervention group. This is supported by a considerable enhancement in both immune status and quality of life. These data suggest that the Unani intervention may be effective as a preventive measure against COVID-19. The observed beneficial outcomes in this study pertaining to symptoms resembling those of COVID-19, the questionnaire assessing immune status, and the WHOQOL-BREF scale can be related to the immunomodulatory, antioxidant, antibacterial, and antiviral properties of the Unani decoction and Khamira Marwareed. Nevertheless, the constraints in the study could potentially be mitigated by formulating additional

Journal: Indian Journal of Traditional Knowledge
Year: Vol 21(1), January 2022, pp 97-105

Sub category: Immunity Booster

A pilot, prospective, interventional study assessing safety and efficacy of hfim – 01 in improving respiratory immunity

Company / Institute(Lab)

BAIDYANATH (1 Director, Siddhayu Ayurvedic Research Foundation Pvt. Ltd, Nagpur, Maharashtra, India.
Pharmacology and Clinical Research, Siddhayu Ayurvedic Research Foundation Pvt. Ltd, Nagpur, Maharashtra, India.
Managing Director, Mprex Healthcare Pvt Limited, Wakad, Pune, Maharashtra, India.)

Product: Respiratory immunity

Type of Study: Randomized controlled trial

CTRI registration no.: CTRI/2021/02/031425

Abstract

The COVID-19 pandemic is characterised by its unique and unprecedented nature. The global health care systems have been faced with a significant challenge. The focus of global attention has shifted to the immune system in light of the coronavirus pandemic, which serves as the body's defence mechanism against disease-causing agents. This study emphasises the significance of enhancing respiratory immunity in Ayurveda through the use of a carefully formulated and standardised product containing a distinct combination of ingredients. The integration of this product into an individual's daily routine is crucial for achieving optimal results. The HFIM-01 decoction has been developed by Siddhayu Ayurvedic Research Foundation Pvt. Ltd.

This study investigates the fermentation process of bitter herbs, specifically Woodfordia flower nectar and Munakka raisins, over a period of 6 weeks. The resulting blend is designed to have therapeutic properties and a mildly sweet taste, making it a potential ingredient for HFIM-01. This study aimed to assess the safety and effectiveness of HFIM-01 in enhancing immune function in individuals without any health issues. In this study, a treatment regimen was administered to a group of healthy individuals for a duration of 30 days. The treatment resulted in enhancements in B cell-mediated humoral immunity, as indicated by increased IgG levels, and T cell-mediated acquired immunity, as demonstrated by an elevated CD4 count. This suggests that overall immune system regulation may be effective in combating various stressors, as well as viral and bacterial infections.

The study findings suggest that HFIM-01 treatment leads to positive changes in overall health and well-being, as evidenced by improvements in GHQ-28 score and a decrease in fatigue severity score. The safety and effectiveness of HFIM-01 in managing general wellbeing, immunity, and gut health are discussed.

Way forward

Enhancing immune function has emerged as a fundamental aspect of maintaining good health, particularly in the context of the ongoing Covid-19 pandemic. HFIM-01 is a meticulously crafted Ayurvedic preparation that incorporates a distinctive notion of fermenting bitters to enhance the potency of the formulation through the development of a powerful sweet component. The administration of a 30-day formulation treatment to persons who were in good health resulted in enhancements in B cell-mediated humoral immunity, specifically in IgG levels, as well as improvements in T cell-mediated acquired immunity, specifically in CD4 count. This, in turn, suggests a comprehensive immunomodulation approach to address many stresses, as well as viral and bacterial diseases. The formulation HFIM-01 has been found to exhibit digestive properties due to its distinctive manufacturing process and careful selection of ingredients. In the current study, all participants reported an amelioration of gastrointestinal problems. The HFIM-01 exhibits advantageous properties in enhancing gastrointestinal well-being, hence contributing to the establishment of immune system homeostasis. The findings suggest that there is a notable enhancement in overall health and well-being following the administration of HFIM-01 therapy, as evidenced by a significant improvement in GHQ-28 scores and a reduction in tiredness severity scores. The safety and efficacy of HFIM-01 in the management of overall wellbeing, immunity, and gut health can be deemed noteworthy.

Journal: EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

Year:

Sub category: Daily Immunity

A pilot, prospective, interventional study assessing safety and efficacy of HFIMJ in improving respiratory immunity in children.

Company / Institute(Lab)

BAIDYANATH (1 Head Clinical Research, Siddhayu Ayurvedic Research Foundation Pvt. Ltd, Nagpur, Maharashtra, India 2 Siddhayu Ayurvedic Research Foundation Pvt. Ltd, Nagpur, Maharashtra, India 3 Mprex Healthcare, Wakad, Pune, Maharashtra, India 4 Consultant, Global Hospital, Kalewadi phata, Wakad, Pune Maharashtra, India)

Product: Painquit Tablet

CTRI registration no.: CTRI/2020/07/026655

Type of Study: RCT

Abstract

This study examines the availability of immunity boosters for adults in the market and the specific needs of parents in finding a safe, time-tested, and effective formula for their children to enhance their immunity. The study also considers the importance of taste in these formulas.

On average, young children experience approximately four to eight respiratory infections per year.This study examines various factors that contribute to an individual's susceptibility to allergies, including exposure to allergens, having school-aged siblings, and exposure to pollution. The user's input consists of two numbers, 2 and 3.

The importance of enhancing the respiratory system has become crucial due to the ongoing COVID-19 pandemic. Siddhayu Ayurved has created a liquid blend called HFIMJ, which consists of Ayurvedic herbs and phytoactives infused with warm honey. This blend is intended to be taken daily by children as a means of boosting their immune system. The ingredients in the formulation have been shown to enhance immunity, promote vitality, and prevent common infections and allergies like the common cold and cough. This study examines the potential benefits of the ingredients used in HFIMJ for allergies, viral infections, and seasonal cough and cold in children, with the aim of improving their overall well-being. In this study, the authors investigate the numerical values [5, 6] and their implications. The purpose of this research is to analyse the significance and potential applications

This Study aims to provide a rationale for the development of HFIMJ decoction by Siddhayu Ayurvedic Research Fdn. Pvt. Ltd. It examines the effects of the product HFIMJ on the respiratory immunity of children. The product contains specific ingredients that have the ability to regulate respiratory immunity.

Way forward

The current study observed a notable enhancement in the levels of immunoglobulin IgG and IgM, as well as an increase in the counts of immune cells such as CD3, CD4, and CD8, following the administration of HFIMJ therapy in children. No statistically significant alterations in the haematological markers were observed following the treatment. No instances of illness were seen among the child participants during the course of the 30-day treatment session. The level of conformity with HFIMJ was observed to be 100%. A notable enhancement in digestive health was observed by mitigating symptoms such as bloating, constipation, and diminished appetite. The current study provides evidence supporting the safety and effectiveness of HFIMJ therapy in enhancing immune function in paediatric patients. However, it is necessary to conduct a large-scale multi-centric investigation with a bigger sample size.

Protocol No: MHC/CT/21-22/002 (Version 1.0, dated 1st April 2021)

Sub category: Kids Immunity

6.4
Category-IV
Women Wellness

Ayush practices, encompassing Ayurveda, Yoga, Unani, Siddha, and Homeopathy, offer a holistic approach to women's healthcare throughout their various life stages. Ayurveda aids in addressing menstrual irregularities, promoting healthy pregnancies, and supporting postpartum recovery. Yoga provides gentle exercise, stress reduction, and hormonal balance, beneficial for conditions such as PCOS and menopausal symptoms. Unani medicine offers remedies for gynecological issues, while Siddha focuses on strengthening the female reproductive system. Homeopathy provides individualized treatments for a range of women's health concerns. By integrating these traditional systems with modern medicine, women can explore complementary approaches to managing their physical and emotional well-being.

Studies are investigating the efficacy and safety of traditional herbs and therapies for gynecological conditions like fertility, menstrual disorders, pregnancy, and menopause. This research aims to validate Ayush knowledge with scientific evidence.

Effect of Lucronil® Tablets in the Patients with Leucorrhea: An Open Clinical Trial

Company / Institute(Lab)

Central Ayurveda Research Institute (CARI)

Product: Lucronil Tablet

Type of Study: Open clinical trial

CTRI registration no.: CTRI/2015/02/005515

Abstract

Leucorrhoea is a prevalent issue in gynaecology that can cause discomfort and disrupt women's daily activities. This study aimed to assess the effectiveness and safety of Tab. Lucronil® in treating the clinical signs and symptoms of Leucorrhea, considering the lack of specific treatment options available for this condition.

This study involved recruiting 31 patients after obtaining permission from the Ethics Committee and obtaining their written informed consent. The study assessed the characteristics of vaginal discharge in patients before and after treatment. Inflammatory changes were evaluated using cervical smear collection. In this study, the participants were given Tab. Lucronil® in the form of two tablets (500 mg) twice daily after meals, accompanied by water. This administration continued for a duration of one month.

In this study, we examined the effects of Tab. Lucronil® on Leucorrhoea symptoms in a group of 8 patients over a period of 15 days. Our findings indicate that Tab. Lucronil® was effective in reducing the symptoms of Leucorrhoea in these patients. In the study, 23 patients experienced a significant reduction ($p < 0.001$) in their condition.

The study found a significant correlation between the amount of cervical discharge and inflammation ($p<0.01$). No negative effects were observed during the study. This paper discusses the effectiveness of Tab. Lucronil® in treating a specific condition.
The treatment was well tolerated by all patients, as indicated by their high compliance. This study examines the effectiveness and safety of Tab. Lucronil in treating leucorrhoea.

Way forward

The current study aimed to assess the impact of Tab. Lucronil®, a herbomineral formulation, on patients with Leucorrhoea. A cohort of 31 individuals received the pharmaceutical intervention of Tab. Lucronil®. The study involved the observation of the effects of Tab. Lucronil® on the symptoms of Leucorrhoea in a group of 8 patients over a period of 15 days. It was found that Tab. Lucronil® resulted in a reduction of symptoms in all patients within the specified timeframe. Among the cohort of 23 patients who successfully completed a 30-day treatment regimen, notable reductions were observed in both the severity of cervical discharge ($p < 0.0001$) and inflammation ($p < .01$). Furthermore, there was seen improvement in the other symptoms as well. The results of the study demonstrate the effectiveness of Tab. Lucronil in treating leucorrhoea.

Journal: International Journal of Science and Research (IJSR)
Year: Volume 5 Issue 10, October 2016

Sub category: Leucorrhea

The effect of YOCAS© ® yoga for musculoskeletal symptoms among breast cancer survivors on hormonal therapy

Company / Institute(Lab)

Department of Surgery, University of Rochester, Rochester, NY, USA

Abstract

Musculoskeletal symptoms, including joint and muscular pain, are frequently reported by around 50% of breast cancer survivors undergoing aromatase inhibitor therapy. These symptoms have a substantial impact on the adherence to treatment and the rates at which patients discontinue therapy. A secondary data analysis was performed on a nationwide, multi-site, phase II/III randomised controlled clinical trial that investigated the effectiveness of yoga in enhancing musculoskeletal symptoms in breast cancer survivors who were undergoing hormone therapy, specifically aromatase inhibitors (AI) or tamoxifen (TAM). The study included a total of 167 breast cancer survivors who were currently undergoing treatment with either AI (N = 95) or TAM (N = 72) and had not participated in yoga for the past 3 months. These participants were randomly assigned to one of two groups: (1) standard care monitoring or (2) standard care with the addition of a 4-week yoga intervention. The yoga intervention consisted of two sessions per week, each lasting 75 minutes. All participants in both groups were included in the analysis. The yoga intervention employed the UR Yoga for Cancer Survivors (YOCAS©®) programme, which included breathing exercises, 18 gentle Hatha and restorative yoga postures, and meditation techniques. The evaluation of musculoskeletal symptoms was conducted prior to and during the implementation of the intervention. Initially, individuals who utilised AI technology reported experiencing elevated degrees of general pain, muscle pains, and overall physical discomfort compared to individuals who used TAM technology (all $P < 0.05$). In the cohort of breast cancer survivors on hormonal therapy, those assigned to the yoga intervention had more significant decreases in musculoskeletal symptoms, including general pain, muscle aches, and overall physical discomfort, compared to the control group. These findings were statistically significant, with all values of P being less than or equal to 0.05. The musculoskeletal complaints exhibited by individuals using artificial intelligence (AI) were found to be more severe in comparison to those using traditional automation methods (TAM). The YOCAS©® intervention, implemented within a community setting, demonstrated a significant reduction in general pain, muscular pains, and physical discomfort among breast cancer survivors undergoing hormone therapy.

Way forward

In summary, this study suggests that yoga, particularly the Gentle Hatha and Restorative yoga components within the YOCAS program, could be an effective intervention for alleviating musculoskeletal symptoms in breast cancer survivors undergoing endocrine therapy. To confirm these findings, future clinical trials with a primary focus on musculoskeletal symptoms like arthralgias and myalgias are warranted. The YOCAS yoga program used in this study is designed for reproducibility and can be employed in future trials. Moreover, subsequent research should explore the sustainability of benefits observed during the intervention and investigate the biological mechanisms through which yoga mitigates musculoskeletal symptoms.

Journal: Journal of Clinical Oncology
Year: Published: 27 March 2015

Randomized, Controlled Trial of Yoga in women with Breast Cancer undergoing radiotherapy

Company / Institute(Lab)

University of Texas M. D. Anderson Cancer Center, Houston, TX; Swami Vivekananda Yoga Anusandhana Samsthana, Bangalore, India

Abstract

Previous studies have demonstrated that the integration of yoga (YG) into radiotherapy (XRT) for women diagnosed with breast cancer leads to notable enhancements in their overall quality of life (QOL). Nevertheless, the research is constrained by some limitations, which ultimately restrict the generalizability of the findings.

This study employed a patient-centered approach in its methodology. The study enrolled patients diagnosed with breast cancer in stages 0 to III prior to initiating XRT. These patients were then randomly divided into three groups: YG (n = 53), ST (n = 56), or WL control (n = 54). The YG and ST groups engaged in their respective interventions three times a week for a duration of 6 weeks, along with XRT. At baseline, the completion of therapy, and 1, 3, and 6 months thereafter, various self-report measures were utilised to assess the quality of life (using the Medical Outcomes Study 36-item short-form survey as the major endpoint), fatigue, depression, and sleep quality. Additionally, five saliva samples were obtained per day for a duration of three consecutive days.

The YG group exhibited statistically significant higher gains in physical component scale scores in comparison to the WL group at both 1 and 3 months following XRT ($P = .01$ and $P = .01$). The YG group exhibited significantly higher improvements in physical functioning at 1, 3, and 6 months compared to both the ST and WL groups ($P < .05$). However, the differences between the ST and WL groups were only significant at the 3-month mark ($P < .02$). The observed disparities in general health reports exhibited comparable patterns across different groups. At the conclusion of the XRT intervention, both the YG and ST groups exhibited a statistically significant decrease in fatigue ($P < .05$). No significant differences were seen across the groups in terms of mental health and sleep quality. The cortisol slope exhibited the highest degree of steepness in the YG group in comparison to the ST and WL groups at the conclusion of the study ($P = .023$ and $P = .008$) as well as one month following XRT ($P = .05$ and $P = .04$).

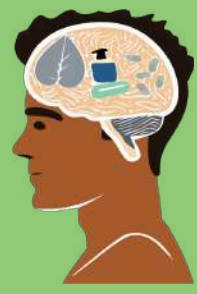
Way forward

In conclusion, the implementation of YG interventions has been found to enhance the quality of life (QOL) and induce physiological changes related to XRT that surpass the advantages offered by basic strength training (ST) exercises. Furthermore, these benefits have demonstrated long-term sustainability

Journal: Journal of Clinical Oncology
Year: 1 April 2014

Sub category: Breast Cancer

6.5
Category-V
Mental Health



Mental health is an essential aspect of overall well-being, and Traditional and Complementary Medicine (TCM) offers a range of practices that can enhance mental health and promote emotional balance. Ayush encompasses a rich tapestry of traditional healthcare systems that have been practiced for centuries. These practices emphasize a holistic approach to health, focusing on the mind-body connection and addressing the root causes of mental health challenges.

Ayurveda, an ancient Indian system of medicine, emphasizes the balance of three doshas – Vata, Pitta, and Kapha. Ayurvedic practices such as herbal remedies, dietary modifications, and lifestyle changes can help alleviate stress, anxiety, and depression by restoring balance to the mind and body.

The integration of Ayush practices into mental health care can provide individuals with a comprehensive and personalized approach to managing their mental well-being. AYUSH systems emphasize a holistic perspective, recognizing the deep connection between the mind, body, and spirit in addressing mental health.

Mindfulness significantly reduces self-reported levels of anxiety and depression. Results of a randomised controlled trial among 336 Danish women treated for stage I-III breast cancer.

Company / Institute(Lab)

Danish Cancer Society Research Center, Denmark

Type of Study: open-label randomized controlled parallel-group trial

Abstract

Given the increasing prevalence of breast cancer and improvements in survival rates, there is a growing demand for therapies aimed at mitigating anxiety and depression throughout the various stages of therapy. Prior research has documented favourable outcomes associated with the implementation of an organised eight-week collective intervention known as the mindfulness-based stress reduction programme (MBSR) in individuals diagnosed with cancer and other medical ailments.

In order to assess the impact of a specific intervention on levels of anxiety and depression in women diagnosed with breast cancer, a population-based randomised controlled research was conducted.

The study employed a randomised controlled trial design to investigate the effects of Mindfulness-Based Stress Reduction (MBSR) in addition to usual care on a sample of 336 women who had undergone surgery for breast cancer at stages I-III. The participants were randomly assigned to either the usual care group or the MBSR + usual care group. Prior to randomization, questionnaires were presented to participants. These questionnaires included the Symptom Checklist-90r anxiety and depression subscales, as well as the Centre for Epidemiological Studies-Depression scale. The same questionnaires were then administered immediately after the intervention, as well as at 6 and 12 months post-intervention.

The findings of the study are as follows:
The intention-to-treat analyses revealed significant differences between the groups in terms of anxiety levels ($p = 0.0002$) and depression levels as measured by the SCL-90r ($p < 0.0001$) and CES-D ($p = 0.0367$) scales after a duration of 12 months. The graphical analysis revealed that those with higher levels of anxiety and depression at the beginning of the study saw a considerably bigger reduction in symptoms over the course of the intervention. In contrast, there were no notable differences observed among participants with lower levels of anxiety and depression. Significant impacts were observed in the intervention group for all outcomes when analysing the change scores following a 12-month follow-up period.

Way forward

The intervention of the 8-week group-based Mindfulness-Based Stress Reduction (MBSR) programme yielded substantial clinical improvements in depression and anxiety, as evidenced by statistically significant results and effect sizes ranging from medium to large, even after a 12-month follow-up period. The results of our study provide evidence in favour of promoting the implementation of Mindfulness-Based Stress Reduction (MBSR) programmes among women diagnosed with breast cancer. The clinical trial with the identifier NCT00990977 is registered on Clintrials.gov.

Journal: European Journal of Cancer
Year: Volume 49, Issue 6, April 2013

Sub category: Depression in Breast cancer patients

Adjunctive yoga vs. health education for persistent major depression: A randomized controlled trial

Company / Institute(Lab)

Sri Sri Tattva (Research and Development-Healthcare, Sriveda Sattva Private Limited (Sri Sri Tattva), Bengaluru, Karnataka, India)

Type of Study: open-label randomized controlled parallel-group trial

Product: Yoga Protocol

Abstract

The primary objective of this research was to assess the effectiveness of hatha yoga as a supplementary intervention for persons who experience persistent depressive symptoms after receiving treatment with antidepressant medication.

The method employed in this study was carefully designed and executed to ensure accurate and reliable results. A randomised controlled trial was done to compare the effects of weekly yoga sessions (n = 63) and health education workshops (Healthy Living Workshop; HLW; n = 59) on adults with higher depressive symptoms and antidepressant drug use. The High-Level Writing (HLW) group was utilised as an attention-control group. The duration of the intervention phase spanned a total of 10 weeks, followed by subsequent assessments conducted at 3 and 6 months post-intervention. The main measure of interest in this study was the severity of depression symptoms, which was evaluated by a rater who was unaware of the treatment conditions, at the 10-week mark. The secondary outcomes encompassed many factors such as depression symptoms during the entire intervention and follow-up periods, social and role functioning, general health perceptions, pain, and physical functioning.

The findings of the study are as follows:
At the 10-week mark, no statistically significant distinction was observed between the groups in terms of depression symptoms (b = −0.82, S.E. = 0.88, p = 0.36). Nevertheless, during the entirety of the intervention and subsequent monitoring period, after accounting for baseline differences, those who engaged in yoga demonstrated reduced levels of depression compared to participants in the health and wellness (HLW) group (b = −1.38, S.E. = 0.57, p = 0.02). At the 6-month follow-up, it was seen that 51% of individuals who participated in yoga exhibited a response, characterised by a reduction of at least 50% in symptoms of depression. In comparison, only 31% of participants in the healthy living workshop (HLW) indicated a similar reaction. The odds ratio between the two groups was calculated to be 2.31, indicating that the odds of achieving a response were 2.31 times higher in the yoga group compared to the HLW group. This difference was found to be statistically significant, with a p-value of 0.04. The study findings indicate that those who engaged in yoga had notable improvements in their social and role functioning, as well as in general health perceptions, as time progressed.

Way forward

Despite the absence of discernible disparities in depression symptoms at the conclusion of the intervention phase, individuals engaged in yoga exhibited a reduced prevalence of depressive symptoms for the entirety of the subsequent monitoring period. The potential advantages of doing yoga may gradually increase as time progresses.

Journal: Psychol Med.
Year: September 2017

Sub category: Depression

Antidepressant efficacy of Sudarshankriya Yoga (SKY) in melancholia: A randomized comparison with electroconvulsive therapy (ECT) and imipramine

Company / Institute(Lab)

A. Department of Psychiatry, National Institute of Mental Health and Neuro Sciences, Bangalore 560 029, India | B. Department of Psychiatry, Research assistants NIMHANS research project on SKY, National Institute of Mental Health and Neuro Sciences, Bangalore 560 029, India | C.Department of Psychiatry, Yoga Teacher, National Institute of Mental Health and Neuro Sciences, Bangalore 560 029, India

Type of Study: open-label randomized controlled parallel-group trial

Abstract

Sudarshan Kriya Yoga (SKY) is a technique that encompasses the practise of rhythmic hyperventilation at varying breathing rates. The prospective, open clinical trial provided evidence of the antidepressant effectiveness of SKY in individuals with dysthymia.

The objective of this study was to assess and compare the effectiveness of SKY, electroconvulsive therapy (ECT), and imipramine (IMN) as therapies for melancholia, a kind of depression. The present study employed various methodologies to investigate the research question. A total of 45 individuals diagnosed with melancholic depression, who provided informed consent, were admitted to a hospital setting and subsequently randomly assigned to one of three therapy groups in equal proportions. Participants underwent an initial assessment at the time of recruitment, followed by subsequent weekly assessments for a duration of four weeks.

The findings of the study are as follows: Substantial decreases in the overall scores on the Beck Depression Inventory (BDI) and Hamilton Rating Scale for Depression (HRSD) were observed on consecutive instances within each of the three groups. However, there were no significant differences observed across the groups. A notable level of engagement was seen between the groups and the specific assessment occasion. During the third week, the SKY group exhibited superior results compared to the ECT group, while no significant differences were observed between the SKY group and the IMN group. The rates of remission, defined as a total Hamilton Rating Scale for Depression (HRSD) score of seven or below, at the conclusion of the trial were 93%, 73%, and 67% in the electroconvulsive therapy (ECT), intramuscular ketamine (IMN), and synchronised Kundalini yoga (SKY) groups, respectively. There were no observed clinically significant adverse effects.

Discussion: Given the constraints of the study design, including the absence of double-blind conditions, it may be inferred that, while not as effective as electroconvulsive therapy (ECT), SKY may serve as a viable alternative to pharmacological interventions for melancholia, particularly as an initial treatment option.

Way forward

Within the limitations of the design (lack of double blind conditions), it can be concluded that, although inferior to ECT, SKY can be a potential alternative to drugs in melancholia as a first linetreatment.

Journal: Journal of Affective disorders
Year: March 2000

Sub category: Depression

Effect of Sudarshan Kriya on male prisoners with non- psychotic psychiatric disorders: A randomized control trial.

Company / Institute(Lab)

Central Jail Hospital (CJH)

Type of Study: RCT

Abstract

The objective of this study is to examine the potential impact of Sudarshan Kriya and related practises (SK&P) on the enhancement of global assessment of functioning (GAF) and overall sense of well-being in male prisoners diagnosed with a non-psychotic psychiatric condition.

The methodology employed in this study encompasses a systematic approach to investigate and analyse the research question at

The present study is a six-month parallel randomised controlled trial including a sample of 230 incarcerated males. Participants who met the predetermined criteria for inclusion and exclusion were assigned to either the study group or the control group by a process of simple random allocation. This allocation was determined by generating a random allocation sequence using a random number table. Every individual study participant was engaged in a daily regimen of Skill-building and Practise (SK&P) for a duration of six weeks. Each control participant was given instructions to assume a seated position in an armchair, close their eyes, and maintain a mild focus on their breath for a period of six weeks. In order to be eligible for participation in this study, individuals must meet the following criteria: they must be male prisoners who have been diagnosed with a psychiatric disease, excluding psychosis and bipolar affective disorder (BPAD), according to the International Classification of Diseases, 10th edition (Diagnostic Criteria for Research). Additionally, participants must be between the ages of 18 and 65 years.

The majority of participants in the study were married adults who were unemployed. Their educational attainment was limited to undermatric level, and they did not possess occupational skills beyond the level of unskilled labour. The implementation of Skills, Knowledge, and Practises (SK&P) over a period of six weeks resulted in a statistically significant enhancement in the average ± standard deviation (SD) scores of the individuals participating in the study across many domains, including Global Assessment of Functioning (GAF), anxiety (ANX), depressive mood (DEP), positive well-being (PWB), general health (GH), self-control (SC), vitality (VT), and overall positive general well-being (PGWB). The statistical analysis revealed a significant difference in the mean ± standard deviation (SD) scores between the research participants and the control participants in relation to the Global Assessment of Functioning (GAF), anxiety (ANX), depression (DEP), psychological well-being (PWB), general health (GH), and positive global well-being (PGWB). The observed changes in SC and VT scores did not reach statistical significance when compared to the scores of control participants.

Way forward

In conclusion, the practise of self-kindness and compassion positively contributes to the enhancement of general affective functioning, psychological well-being, overall mental health, and total psychological general well-being in individuals. The administration of SK&P has been found to result in a notable decrease in levels of anxiety and depression. The impact of SK&P on SC and VT is deemed to be statistically insignificant.

Journal: Asian Journal of Psychiatry
Year: 20 June 2014

Sub category: Psychiatric disorder

Sleep quality, depression state, and heath sttatus of older adults after silver yoga exercise: cluster randomized trial.

Company / Institute(Lab)

A. School of Nursing, Fooyin University; 151 Chin-Hsueh Rd., Taliao Township, Kaohsiung 831 Taiwan| B. Social Affairs Bureau of Kaohsiung City Government, Kaohsiung, Taiwan | C. Kaohsiung Veterans General Hospital, Taiwan | D. Department of Nursing, Meiho Institute of Technology, Taiwan | E. School of Nursing, Fooyin University, Taiwan | F. Department of Nursing, Yuhing Junior College of Health Care and Management, Taiwan

Type of Study: Cluster Randomised Trial

Abstract

Sleep problems, depression, and a diminished impression of health status are frequently observed among the aged population. Nevertheless, healthcare professionals often underestimate or fail to recognise the existence of these symptoms, attributing them to the natural process of ageing. It is imperative to conduct research on non-pharmacological interventions that facilitate a synergistic relationship between the mind and body in order to improve the mental well-being of elderly individuals.

The objective of this study is to examine and analyse the impact of various factors on the outcome The objective of this study is to examine the impact of a 6-month intervention using silver yoga exercises on the mental health of older individuals residing in senior activity centres. Specifically, this research aims to assess the effects of the intervention on sleep quality, depression levels, and self-perceived health status among the participants.

Way forward

The administration of Ayush-64 alongside routine conventional care has been found to be a safe approach that accelerates the clinical recovery of COVID-19 patients who have mild to moderate symptoms.

The topic under discussion pertains to a medical condition commonly referred to as a disease. Ayush-64 administration resulted in a notable decrease in the concentrations of pro-inflammatory indicators, including IL-6, D-dimer, CRP, LDH, and serum ferritin.

and high-resolution computed tomography (HRCT) chest score. Therefore, Ayush-64 may be regarded as a secure and efficacious supplementary measure for the treatment of mild to moderate cases of COVID-19. Further validation of the effectiveness of Ayush-64 in treating COVID-19 could be achieved through the implementation of larger-scale, multi-center double-blind trials.

Journal: International Journal of nursing studies
Year: October 2008

Sub category: Elderly mental health

The effect of the Maharishi Student Rasayana food supplement on non-verbal intelligence

Company / Institute(Lab)

MAHARISHI AYURVEDA (Departments of 'Science of Creative Intelligence and Education and Physiological and Biological Sciences, Maharishi International University, Fairfield, IA 52556and 'College of Medicine, The Ohio State University, Columbus, OH, U.S.A.)

Abstract

Empirical evidence suggests that intelligence quotient (IQ) exhibits a robust correlation with student academic achievement. Prior research has indicated that augmenting the consumption of vitamins and minerals has a positive impact on non-verbal intelligence. The objective of this research was to assess the impact of a herbal dietary supplement, specifically Maharishi Ayur-Ved Student Rasayana (MA-SR), on non-verbal cognitive abilities. The study, which spanned a duration of 5 months, used a sample of 34 third-grade students who were assigned in a random manner to either an experimental group or a placebo group. The experimental group receiving the MA-SR treatment had a significant improvement of 9.83 points in IQ scores, whereas the placebo group only experienced a modest rise of 4.88 points. The data analysis revealed that a notable percentage of children in the MA-SR group (78%) exhibited a greater improvement in IQ compared to the placebo group (50%), surpassing the influence of the test-retest effect. Further statistical research revealed that the administration of MA-SR has a positive impact on IQ. The potential mechanisms are deliberated upon.

Way forward

The MA-SR herbal food supplement resulted in a mean change score of 18.75 for the four students with an IQ below 105. This study serves as a valuable addition to previous research on nutrition, providing further evidence to support the assertion that the inclusion of vitamins and minerals in the dietary intake of students can enhance cognitive performance. According to Eysenck's (1991) theory regarding the correlation between nutrition and brain function, it is possible that MA-SR offers supplementary nutrients to the brain, hence influencing information processing. In a prior study conducted by Schoenthaler et al. (1991a), the presence of anomalies in the brain, as observed using EEG brain mapping, was significantly reduced with the administration of vitamin-mineral supplements. Subsequent investigations pertaining to MA-SR ought to incorporate an evaluation of alterations in cerebral functioning as a means of establishing the mediation mechanisms between enhanced nutrition and heightened intelligence quotient (IQ).

Journal: Personality and Individual Differences
Year: Volume 15, Issue 5, November 1993

Sub category: IQ level enhancer

Randomized controlled trial of yoga and exercise in multiple sclerosis

Company / Institute(Lab)

American Academy of Neurology

Abstract

The objective of this study is to assess the impact of yoga and aerobic exercise on cognitive function, fatigue, mood, and quality of life in individuals diagnosed with multiple sclerosis (MS).
The research employed various methodologies. Participants diagnosed with clinically definite multiple sclerosis (MS) and an Expanded Disability Status Score (EDSS) of 6.0 or lower were assigned randomly to one of three intervention groups, each lasting for a duration of 6 months. The groups included a weekly Iyengar yoga class combined with home practise, a weekly exercise class utilising a stationary bicycle along with home exercise, and a control group placed on a waiting list. Baseline and post-intervention outcome assessments encompassed a comprehensive set of cognitive measures targeting attention, physiological measures gauging alertness, Profile of Mood States, State-Trait Anxiety Inventory, Multi-Dimensional Fatigue Inventory (MFI), and Short Form (SF)-36 health-related quality of life.

The study recruited a total of sixty-nine participants who were then randomly assigned to different groups. A total of twelve individuals did not complete the six-month intervention. No adverse effects were seen in relation to the intervention. Neither of the active interventions had any effects on the primary outcome measures of attention or alertness. Both active therapies resulted in a significant improvement in secondary measures of fatigue as compared to the control group. These measures include Energy and Fatigue (Vitality) on the SF-36 questionnaire and general fatigue on the Multidimensional Fatigue Inventory (MFI). No discernible alterations in mood were observed in relation to the practise of yoga or engagement in physical exercise.

Way forward

In conclusion, individuals diagnosed with Multiple Sclerosis (MS) who engaged in a 6-month yoga programme or fitness programme demonstrated notable enhancements in fatigue-related indicators when compared to a control group that was placed on a waiting list. There was a lack of significant enhancement in cognitive function observed in both intervention groups.

Journal: Journal of clinical medicine
Year: June 08, 2004

Sub category: Multiple Sclerosis (MS)

Yoga therapy as an add-on treatment in the management of patients with schizophrenia a randomized controlled Trial

Company / Institute(Lab)

Department of Psychiatry, National Institute of Mental Health and NeuroSciences, Bangalore 560029, India.

Abstract

Despite the existence of antipsychotic medications, the treatment of schizophrenia has proven to be inadequate. The present study investigated the effectiveness of including yoga therapy (YT) as a supplementary intervention alongside continued antipsychotic treatment.

Methodology: A total of sixty-one schizophrenia patients with moderate illness were selected at random and divided into two groups: YT (n = 31) and physical exercise treatment (PT; n = 30). The duration of the intervention was four months. The participants underwent baseline assessment and were re-evaluated four months after the intervention commenced. The assessments were conducted by an impartial rater who was unaware of the participants' group assignment.

The results of the study indicate that a total of forty-one patients (YT = 21; PT = 20) were included in the final assessment after a period of four months. At the conclusion of the 4-month period, it was observed that those belonging to the YT group had a notably lower prevalence of psychopathological symptoms compared to those in the PT group. Additionally, they exhibited notably higher levels of social and vocational performance, as well as an enhanced quality of life.

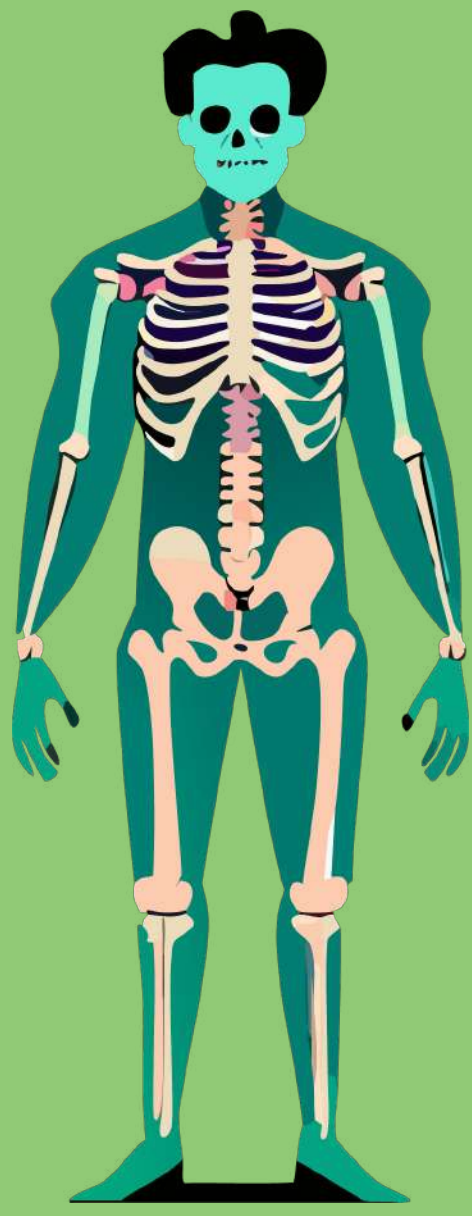
Way forward

In conclusion, it can be observed that both non-pharmacological therapies play a role in symptom reduction, with Yoga Therapy (YT) demonstrating superior efficacy.

Journal: Acta Psychiatr Scand

Sub category: Schizophrenia

6.6
Category-VI
Bone and Joint Support



Traditional and complementary medicine (TCM) offers a comprehensive approach to bone and joint health, encompassing a range of practices that aim to prevent and treat various musculoskeletal conditions. These practices, deeply rooted in ancient healthcare systems, work by addressing the underlying imbalances in the body, to restore harmony and promote overall well-being.

Yoga, a mind-body discipline, offers a holistic approach to bone and joint health. Through its gentle postures, controlled breathing exercises, and meditative practices, yoga enhances flexibility, strengthens muscles, and improves balance, thereby reducing pain, enhancing joint mobility, and preventing falls.

Ayurvedic therapies include herbal supplements to strengthen bones and reduce inflammation, massage therapy to improve circulation and relieve muscle tension, and panchakarma, a detoxification process to restore balance and promote healing.

These Ayush therapies personalized approach to bone and joint health, providing Holistic healthcare.

Clinical evaluation of efficacy and safety of tab hf-b1 in osteopenia and osteoporosis: an observational study

Company / Institute(Lab)

BAIDYANATH (1 Samshodhanam Healthcare Research Services, Pune, Maharashtra, India 2 Siddhayu Ayurvedic Research Foundation Pvt. Ltd, Nagpur, Maharashtra, India)

Product: Calciactiv tablet

Type of Study: Observational study

CTRI registration no.: CTRI/2017/08/009259

Abstract

This study examines the relationship between frequent fractures and inflammatory conditions, and their impact on the likelihood of debility. This study examines the limitations of conventional medications that use synthetic calcium supplementation. These medications are only a temporary solution and may have adverse effects on the gastrointestinal and cardiovascular systems.

This study aims to investigate effective treatment options. Herbal medicines have been effective in treating bone disorders for a long time. In this study, we examined the effectiveness of Tab HF-B1, an Ayurvedic formulation made from herbs and minerals, for treating osteopenia and osteoporosis. The study was conducted in an open-label, observational clinical setting. The study found a decrease in the average severity of symptoms like bone pain and joint pain. The T-Score and BQI experienced a notable increase.

The study found no negative effects, indicating that the participants were able to follow the treatment and tolerate it well. The safety and effectiveness of Tab HF-B1 were evaluated in patients with Osteopenia and Osteoporosis, and positive outcomes were observed.

Way forward

In conclusion, the study indicates that Tab HF-B1 may have a possible anti-osteoporotic effect in individuals with osteopenia and osteoporosis. The medicine exhibited a high level of tolerability among the patients, suggesting that the formulation is safe.

Journal: Omkar et al / Int. J. Res. Ayurveda Pharm. 10 (2), 2019

Year: 2019

Sub category: Osteoporosis

A Randomized, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of HFPM-01 in Improving Pain, Stiffness, and Inflammation in Patients Suffering from Knee Osteoarthritis

Company / Institute(Lab)

BAIDYANATH (1. Head Clinical Research, Siddhayu Ayurvedic Research Foundation Pvt. Ltd, Nagpur, Maharashtra, India | 2. Siddhayu Ayurvedic Research Foundation Pvt. Ltd, Nagpur, Maharashtra, India | 3. Mprex Healthcare, Wakad, Pune, Maharashtra, India | 4. Consultant, Global Hospital, Kalewadi phata, Wakad, Pune Maharashtra, India)

Product: Painquit Tablet

Type of Study: Randomized Controlled Trial

CTRI registration no.: CTRI/2020/07/026655

Abstract

This study aims to investigate the impact of osteoarthritis, a prevalent chronic joint condition, on mobility, muscle tone, and overall physical fitness. The various challenges discussed in this study have a negative impact on individuals' daily activities, overall quality of life, and potentially their mental well-being. This study examines the prevalence of symptomatic osteoarthritis among individuals aged over 60 years globally.

The findings indicate that approximately 9.6% of men and 18.0% of women in this age group experience this condition. It focuses on a prevalent joint disease in India, which ranks as the second most common rheumatologic problem. With a prevalence ranging from 22% to 39%, this disease holds significant importance in the population. It focuses on evaluating the effectiveness of a new treatment called HFPM-01 for individuals with knee osteoarthritis. The goal is to provide clinical evidence for its use as an alternative to traditional treatments, which have certain limitations. In this study, a total of 90 participants were included and assigned randomly to one of three treatment groups. The participants were being assessed through a clinical examination. The vital signs of the subject were documented. Blood samples were obtained to measure C-reactive protein (CRP) levels.

The evaluation of subjective questionnaire scores was conducted using the SF-36 health survey score, VAS scale, and WOMAC questionnaire. It observed variations in the severity of symptoms such as morning stiffness, tiredness, tenderness, and muscle spasms, while also evaluating gastrointestinal symptoms. It observed significant improvements in various measures. The WOMAC score showed a 33% change, indicating a positive outcome. The SF-36 score increased by 308%, suggesting an overall improvement in quality of life. The VAS score decreased by 60.44%, indicating a reduction in pain levels. CRP levels also decreased by 52%, suggesting a decrease in inflammation. Additionally, GI symptoms were reduced by 40%. These findings demonstrate the effectiveness of the intervention in improving multiple aspects of health. The severity of swelling, inflammation, and pain decreased from moderate to mild and eventually resolved completely.

Way forward

In conclusion, it may be inferred that the HFPM-01 pill demonstrates a notable efficacy in enhancing the SF36 score, WOMAC score, and VAS scale score. The intervention demonstrates efficacy in mitigating pain, inflammation, and rigidity of knee articulations, while concurrently enhancing their range of motion. Additionally, it confers gastroprotective benefits, so effectively addressing pain and stiffness. The HFPM-01tablet has been found to be both safe and effective in the management of Osteoarthritis.

Journal: International Journal of Research and Review

Year: Vol.8; Issue: 4; April 2021

Sub category: Osteoarthritis

Efficacy and Safety Evaluation of Myostaal Forte, a Polyherbal Formulation, in Treatment of Knee Osteoarthritis: A Randomised Controlled Pilot Study

Company / Institute(Lab)

Dhootapapeshwar

Product: Myostaal Forte

Type of Study: RCT

CTRI registration no.: CTRI:REF/2016/03/010991

Abstract

This study focuses on Myostaal Forte, a unique blend of nine herbal plant extracts known for their pain-relieving, anti-inflammatory, and joint-protective qualities.

The aim of this study is to investigate and analyse the research topic. This study aimed to assess the effectiveness and safety of Myostaal Forte in patients with knee osteoarthritis. It was a planned study with two groups, randomly assigned and compared. The study was designed to be unbiased, with assessors blinded to the treatment. This section describes the materials and methods used in the study. The study recruited individuals with idiopathic knee osteoarthritis based on the clinical criteria established by the American College of Rheumatology (ACR). In this study, sixty patients were divided into two groups: one group received Myostaal Forte TDS and the other group received Paracetamol 650 mg TDS. The treatment period lasted for six weeks. The effectiveness of naproxen as a rescue analgesic was evaluated. This study utilised the Modified Western Ontario and McMaster Universities Arthritis Index (WOMAC), Visual Analogue Scale (VAS), and global assessment scores to evaluate the progress of patients. These assessments were conducted by an orthopaedic physician at various time points throughout the study.

This study evaluated safety by conducting laboratory investigations at the beginning and after six weeks, as well as monitoring adverse events and tolerability. The data were presented as the mean value plus or minus the standard deviation. Statistical analysis was performed using the Chi-square test and unpaired t-test. A significance level of $p<0.05$ was deemed as statistically significant.

Results: The study found that both Myostaal Forte and Paracetamol were effective in reducing the activity of osteoarthritis disease. The study found that Myostaal Forte showed significant improvement in pain, stiffness, and physical function compared to Paracetamol after eight weeks ($p<0.05$). The study observed a notable decrease in WOMAC pain scores after two weeks in the Myostaal Forte group ($p<0.05$), while no such reduction was observed in the Paracetamol group. The study observed a reduction in pain severity in all patients who took Myostaal Forte for two weeks, compared to only half of the patients who took Paracetamol. The study observed the effects of two treatments, Myostaal Forte and Paracetamol, on symptomatic relief after six weeks. The Myostaal Forte group showed sustained relief for two weeks, while the Paracetamol group experienced a relapse of pain and physical disability within two weeks. The statistical analysis did not show a significant difference between the two groups ($p>0.05$). Both groups did not experience any significant negative effects, changes in laboratory measurements, and showed excellent adherence to the treatment. Conclusion: Myostaal Forte is a safe and effective alternative for treating knee osteoarthritis due to its ability to provide pain relief and protect the cartilage, even after treatment is stopped.

Way forward

In conclusion, the administration of Myostaal Forte demonstrates a prompt analgesic impact and long-term chondroprotective properties even after discontinuation of treatment. This indicates that Myostaal Forte can be considered a viable and reliable therapeutic option for managing knee osteoarthritis, ensuring both safety and efficacy.

Journal: Journal of Clinical and Diagnostic Research

Year: October 2017

Sub category: Osteoarthiritis

Ayurveda in Knee Osteoarthritis- secondary analysis of a Randomized Trial

Company / Institute(Lab)

1.Institute of Social Medicine, Epidemiology and Health Economics, Charité—Universitätsmedizin Berlin, Corporate Member of Freie Universität Berlin and Humboldt-Universität zu Berlin, 10117 Berlin, Germany | 2. Department for Complementary and Integrative Medicine, Immanuel Hospital Berlin, 14109 Berlin, Germany | 3. Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University, Varanasi 221005, India | 4. Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University, Jodhpur 342037, India | 5. Department of Psychology and Psychotherapy, University of Witten Herdecke, 58455 Witten, Germany | 6.European Academy of Ayurveda, 95018 Birstein, Germany | 7.Department of Kaya Cikitsa, J.S. Ayurveda College & P.D. Patel Ayurveda Hospital, Nadiad 387001, India | 8. Ayurvedic Point, School of Ayurvedic Medicine, 20149 Milan, Italy | 9. Department of Religious Sciences, University of Frankfurt, 60323 Frankfurt, Germany |10. Institute for Complementary and Integrative Medicine, University Hospital and University of Zurich, 8091 Zurich, Switzerland

Abstract

Ayurveda, a traditional medical system, is extensively utilised in South Asia for the management of osteoarthritis (OA). The primary objective of these secondary data analysis was to ascertain the most pertinent characteristics pertaining to treatment response and group disparities between Ayurvedic therapy and conventional therapy in patients with knee osteoarthritis.

In this randomised controlled study, a total of 151 patients were included in the analysis. The patients were divided into two groups: Ayurveda (n = 77) and conventional treatment (n = 74). The analysis was conducted following the intention-to-treat principle. Various statistical methodologies were utilised in this study, such as generalised linear models, a radial basis function (RBF) network, exhausted CHAID, classification and regression trees (CART), and C5.0 with adaptive boosting. The results of the study suggest that the therapy arm and the baseline values of the WOMAC Index subscales are potentially significant variables in explaining the observed variations between the treatment groups in terms of the WOMAC Index scores throughout the 12-week period, with Ayurveda showing more favourable outcomes. The consumption of dietary supplements within the Ayurveda cohort did not appear to exert a substantial influence on the alterations observed in the WOMAC Index. The individuals who participated in the Ayurveda treatment and had functional limits over 60 points, as well as pain levels surpassing 25 points at the beginning of the study, demonstrated the most significant enhancements in their WOMAC Index scores over the course of 12 weeks. The average value of these improvements was recorded as 107.8 ± 27.4. The C5.0 model, consisting of nine predictors, demonstrated a predictive accuracy of 89.4% in forecasting the change in the WOMAC Index after a duration of 12 weeks, when the change exceeded 10. By employing adaptive boosting, the accuracy of the system increased to 98%. Findings: The results of these additional studies indicate that the therapeutic effects observed cannot be solely attributed to the therapies themselves, despite being the primary components in the models used.

Way forward

The findings of these additional analyses indicate that the therapeutic effects observed cannot be solely attributed to the therapies themselves, despite their significant influence in the models. The rationale behind this can be elucidated in light of various potential factors that may impact the outcomes of clinical research, including the present one. The aforementioned characteristic is not exclusive to CIM studies, but rather represents a universal element of clinical research, particularly within the realm of whole medical system (WMS) research. Having an understanding of this concept can be a crucial asset for developing future clinical trials using complicated interventions of Complementary and Integrative Medicine (CIM) and Ayurveda. Therefore, in the context of research conducted by the World Medical Society (WMS) on Ayurveda and other traditional medical systems (TMS), there is potential for future investigation into the specific individual factors that play a crucial role in determining the effectiveness of these therapeutic approaches. This exploration could lead to the systematic enhancement of study interventions and the subsequent expansion of treatment options by incorporating elements from Ayurvedic medicine [15].

Journal: JAMA network

Year: Published: 28 May 2022

Sub category: Osteoarthiritis

A Randomized Trial Comparing Yoga, Stretching and a Self- care Book for Chronic back pain

Company / Institute(Lab)

Group Health Research Institute, Seattle, Washington (Drs Sherman, Cherkin, and Cook, Mr Wellman, and Mss Hawkes and Delaney); Departments of Epidemiology (Dr Sherman), Family Medicine and Health Services (Dr Cherkin), and Biostatistics (Dr Cook), University of Washington, Seattle; and Department of Family Medicine, Oregon Health and Science University, Portland (Dr Deyo).

Type of Study: Cluster Randomised Trial

Abstract

Chronic low back pain is a prevalent issue that currently lacks extremely efficacious therapeutic alternatives. Preliminary studies indicate that yoga may offer potential advantages for individuals with this particular ailment. The objective of this study was to ascertain the comparative effectiveness of yoga, conventional stretching exercises, and a self-care book in managing persistent low back pain among primary care patients.

The present study aims to investigate the methods employed in the research. A cohort of 228 individuals experiencing persistent low back pain were subjected to randomization, with 92 participants assigned to 12 weekly sessions of yoga, 91 participants assigned to conventional stretching exercises, and 45 participants assigned to a self-care book intervention. The primary objectives of this study were the back-related functional status, assessed using the modified Roland Disability Questionnaire, which is a 23-point scale, and the bothersomeness of pain, measured on an 11-point numerical scale, at the 12-week mark. The assessment of outcomes occurred at four time points: baseline, 6 weeks, 12 weeks, and 26 weeks. The interviewers conducting the assessments were blinded to the treatment group.

The findings of the study are as follows: following the adjustment for baseline values, the 12-week results demonstrated that the yoga group exhibited improved outcomes compared to the self-care group. Specifically, there was a mean difference of -2.5 (95% CI, -3.7 to -1.3; P < .001) for function and a mean difference of -1.1 (95% CI, -1.7 to -0.4; P < .001) for symptoms. At the 26-week mark, the yoga group exhibited continued superiority in terms of function, with a mean difference of -1.8 (95% CI, -3.1 to -0.5; P < .001). At no point in time did yoga demonstrate superiority over conventional stretching exercises.

Way forward

In conclusion, it can be inferred that the aforementioned points lead to the logical conclusion that the efficacy of yoga courses in comparison to a self-care book, as well as stretching classes, was found to be superior in enhancing functionality and alleviating symptoms associated with persistent low back pain. These positive effects were observed to persist for a minimum duration of several months.

Journal: Journal of the International Society of sports nutrition

Year: October 2008

Sub category: Back pain

Efficacy & safety evaluation of Ayurvedic treatment (Ashwagandha powder & Sidh Makardhwaj) in rheumatoid arthritis patients: a pilot prospective study.

Company / Institute(Lab)

All India Institute of Medical Sciences(AIIMS)

Type of Study: ACR parameters

Product: Ashwagandha Powder & Sidh Makardhwaj

CTRI registration no.: CTRI- 2009 000699

Abstract

Ashwagandha powder and Sidh Makardhwaj have been historically employed within the traditional medical framework of India for the therapeutic management of rheumatoid arthritis. Nevertheless, the safety and efficacy of this medication have yet to be assessed.

The present study aims to investigate the effectiveness and safety of Ayurvedic treatment involving the use of Ashwagandha powder and Sidh Makardhwaj in individuals diagnosed with rheumatoid arthritis.
A total of 125 individuals experiencing joint discomfort were selected for screening at an Ayurvedic hospital.A total of 86 patients who met the specified inclusion criteria were deemed eligible and subsequently included in the trial. The medical history and physical examination were documented. The participants ingested a dosage of 5 grammes of Ashwagandha powder.

The recommended frequency for consumption is twice daily for a period of three weeks, using either lukewarm water or milk. The administration of Sidh Makardhwaj (100 mg) in combination with honey was observed.
The intervention was implemented on a daily basis over a period of four consecutive weeks. The patients were monitored at biweekly intervals.

The key measure of effectiveness was determined by evaluating the American College of Rheumatology (ACR) 20 response.The secondary endpoints assessed in this study included ACR50 and ACR70 responses, as well as the change in disease activity score from baseline.
The study examines the relationship between the 28 score and ACR factors. The safety evaluations encompassed liver function, namely alanine aminotransferase.The variables measured in this study include ALT (alanine aminotransferase), AST (aspartate aminotransferase), ALP (alkaline phosphatase), bilirubin, and β2 microglobulin.

The assessment of renal function commonly involves the measurement of urea, creatinine, and NGAL levels, as well as the determination of urine mercury levels.

Way forward

The results of the current study indicate that the Ayurvedic medication consisting of Ashwagandha powder and Sidh Makardhwaj exhibits promising potential for the management of rheumatoid arthritis. Nevertheless, it is imperative to acknowledge that the findings of this study should be interpreted with caution due to several limitations.

Journal: Indian J Med Res
Year: 2012

Sub category: Rheumatoid Arthritis

Effectiveness of an Ayurveda treatment approach in knee osteoarthritis: A randomized controlled trial

Company / Institute(Lab)
Central Council for Research in Ayurvedic Sciences (CCRAS) and Charite University,, Germany

Product: Ayush 64

Type of Study: A Randomized Controlled trial

Trial registration no.: NCT01225133

Abstract

Objective: The utilisation of Ayurveda as a therapeutic approach for the management of knee osteoarthritis (OA) is prevalent in South Asia. The objective of this study was to assess the efficacy of Ayurvedic treatment in comparison to conventional conservative care for individuals diagnosed with knee osteoarthritis.

The method involved the inclusion of knee osteoarthritis (OA) patients based on the criteria established by the American College of Rheumatology (ACR). These patients were enrolled in a multicenter randomised, controlled, open-label trial, which took place in two hospital clinics and two private outpatient clinics located in Germany. The participants were assigned to receive either a multi-modal Ayurvedic treatment or a multi-modal conventional care, with a total of 15 treatments administered over a period of 12 weeks. The primary end measure assessed in this study was the alteration observed in the Western Ontario and McMaster University Osteoarthritis (WOMAC) Index over a period of 12 weeks. The secondary objectives encompassed many measures, such as the subscales of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the pain disability index, a pain experience scale, numeric rating scales for pain intensity and sleep quality, assessments of quality-of-life and mood, utilisation of rescue medication, and considerations related to safety.
Results: A total of 151 people were involved in the study, with 77 receiving Ayurveda treatment and 74 receiving conventional care. The Ayurveda group exhibited more substantial changes in the WOMAC Index from baseline to 12 weeks compared to the conventional group. The mean difference in the Ayurveda group was 61.0 (95%CI: 52.4;69.6), whereas in the conventional group it was 32.0 (95%CI: 21.4;42.6). This resulted in a significant difference between the two groups ($p < 0.001$) and a clinically relevant effect size, as indicated by Cohen's d of 0.68 (95% CI: 0.35;1.01). Consistent patterns were noted for all secondary outcomes at the 12-week mark. The effects demonstrated durability during the 6-month and 12-month follow-up periods.

In conclusion, the findings of this study indicate that Ayurvedic treatment exhibits potential benefits in mitigating symptoms associated with knee osteoarthritis. Additional research is warranted to validate the extent of the impact and to elucidate the contributions of distinct treatment components and non-specific factors.

Way forward

The findings of the study indicated that Ayurveda treatment resulted in notable and medically significant enhancements in the decrease of symptoms unique to the disease. This improvement was observed after a duration of 12 weeks and was found to be superior to conventional care. Furthermore, the positive effects of Ayurveda treatment were observed to persist for a period exceeding 12 months. However, additional research should be undertaken to validate the extent of the impact and to elucidate the contributions of various treatment components and non-specific effects. The implementation of an individualised Ayurvedic approach has the potential to enhance the integration and personalization of care for individuals with osteoarthritis (OA).

Journal: Osteoarthritis

Year: 2018

Sub category: Knee osteoarthritis

Double-Blind, Randomized, Controlled, Pilot Study Comparing Classic Ayurvedic Medicine, Methotrexate, and Their Combination in Rheumatoid Arthritis

Company / Institute(Lab)

Geffen School of Medicine, University of California Los Angeles, CA; University of Washington, Seattle, WA; Ayurvedic Trust, Coimbatore, India; and Department of Gastroenterology, Seth GS Medical College & KEM Hospital, Mumbai, India

Type of Study: Double-Blind, Randomized, Controlled, Pilot Study

Abstract

Objective: The aim of this study is to conduct a double-blind, randomised, double-dummy, pilot experiment over a period of 36 weeks to examine the effectiveness of classic Ayurveda, methotrexate (MTX), and their combination in the treatment of rheumatoid arthritis (RA).

The present study employed various methodologies to investigate the research question. A total of forty-three rheumatoid arthritis (RA) patients who tested positive for antibodies were included in the study based on the diagnostic criteria established by the American College of Rheumatology (ACR). These patients had a disease duration of less than seven years. They were divided into three treatment groups: one group received methotrexate (MTX) together with a placebo for Ayurvedic treatment (n = 14), another group received Ayurvedic treatment along with a placebo for MTX (n = 12), and the third group received both Ayurvedic treatment and MTX (n = 17). The measured outcomes encompassed the Disease Activity Score (DAS28-CRP), American College of Rheumatology (ACR) 20/50/70 response criteria, and the Health Assessment Questionnaire (HAQ) Disability Index. Measurements were collected at 12-week intervals during a period of 36 weeks. The analyses conducted in this study encompassed many statistical methods, such as descriptive statistics, analysis of variance (ANOVA), chi-square test ($\chi 2$), or Student's t-test. This study distinguished itself by undertaking the creation of placebos specific to each Ayurvedic pharmacological dosage form, as well as using a personalised approach to Ayurvedic therapy.

The results indicate that there were no significant differences between the groups at the beginning of the study in terms of demographics and illness characteristics. There were no statistically significant differences observed among the three groups in terms of the efficacy measures. The ACR20 outcomes demonstrated an 86% response rate for MTX, 100% for Ayurveda, and 82% for the combination therapy. Additionally, the DAS28-CRP responses were j2.4 for MTX, j1.7 for Ayurveda, and j2.4 for the combination therapy. The observed differences in adverse events across the groups did not reach statistical significance. However, it is worth noting that the MTX groups reported a higher number of adverse events (174 for MTX, 112 for Ayurveda, and 176 for the combination group). There were no fatalities recorded.

In conclusion, In this inaugural pilot trial, a double-blind, randomised, placebo-controlled design was employed to compare the efficacy of Ayurveda, MTX, and their combination. The findings suggest that all three therapy modalities exhibited comparable levels of effectiveness, albeit within the constraints inherent to a pilot study. The Ayurveda-only group exhibited a lower numerical incidence of adverse events. This study provides evidence that it is feasible to conduct double-blind, placebo-controlled, randomised trials that compare individualised classic Ayurvedic treatment with allopathic treatment, in a manner that adheres to both western scientific norms and the principles of Ayurvedic medicine. Furthermore, it provides a rationale for conducting more extensive investigations.

Way forward

This study provided evidence that complementary and alternative medicine (CAM) can be evaluated in a manner that allows for comparison with allopathic therapy. The evaluation was conducted through a placebo-controlled, double-blind, randomised trial. The thorough and continuous documentation of Ayurvedic treatment facilitated the potential for future analysis. This study conducted a comparative analysis between classic Ayurveda and allopathic medicine, as well as a novel combination of the two, which has not been previously explored. This has significance as it pertains to the apprehensions surrounding potential interaction effects that may arise from the combination of herbal medicines and allopathic drugs.

Journal: Journal of Clinical Rheumatology:
Year: June 2011

Sub category: Rheumatoid Arthritis

Examining the effect of withania somnifera supplementation on muscle strength and recovery: a randomized controlled trial.

Company / Institute(Lab)

1. Sports Medicine, SrimatiKashibaiNavale Medical College, Pune, India. 2. Department of Pharmacology, BVDU Dental College & Hospital, Navi Mumbai, India. 2. Department of Pharmacology, BharatiVidyapeeth Medical College & Hospital, Sangli, India. 4. Department of Clinical Pharmacology, Grant Government Medical College, SirJamshedjeeJeejeebhoy Group of Hospitals, Mumbai, India. 5. Department of Pharmaceutical Technology, NSHM Knowledge Campus, 124 B.L. Saha Road, Kolkata, 700053 India.

Abstract

Withania somnifera, commonly known as ashwagandha, holds a significant position as a herbal remedy in the traditional Indian system of medicine known as Ayurveda. The objective of this investigation was to assess the potential impacts of consuming ashwagandha root extract on muscle mass and strength in physically fit young males participating in resistance training.

In this study, which spanned a duration of 8 weeks, a randomised and prospective design was employed. The study aimed to investigate the effects of a specific therapy on a group of 57 young male participants, aged between 18 and 50 years, who possessed limited prior experience in resistance training. These participants were randomly assigned to either the treatment group, consisting of 29 subjects, or the placebo group, consisting of 28 subjects. To ensure the integrity of the study, a double-blind methodology was implemented, wherein both the participants and the researchers involved were unaware of the treatment assignments. The participants in the treatment group were administered a dosage of 300 mg of ashwagandha root extract twice daily, whereas the control group received starch placebos. After doing baseline measures, both groups of participants engaged in an 8-week resistance training programme, and measurements were then taken again at the conclusion of week 8. The main measure of effectiveness was the assessment of muscle strength. The secondary efficacy measures encompassed assessments of muscle size, body composition, serum testosterone levels, and muscle recovery. The assessment of muscle strength involved the determination of the one-repetition maximum (1-RM) load for the bench press and leg extension movements. The assessment of muscle recovery involved the utilisation of serum creatine kinase level as an indicator of muscle damage resulting from the impact of physical activity. In comparison to the subjects who received a placebo, the group that was treated with ashwagandha demonstrated significantly greater increases in muscle strength during the bench-press exercise (Placebo: 26.4 kg, 95% CI, 19.5, 33.3 vs. Ashwagandha: 46.0 kg, 95% CI 36.6, 55.5; $p = 0.001$) and the leg-extension exercise (Placebo: 9.8 kg, 95% CI, 7.2, 12.3 vs. Ashwagandha: 14.5 kg, 95% CI, 10.8, 18.2; $p = 0.04$). Additionally, the group treated with ashwagandha experienced a significantly greater increase in muscle size at the arms (Placebo: 5.3 cm2, 95% CI, 3.3, 7.2 vs. Ashwagandha: 8.6 cm2, 95% CI, 6.9, 10.8; $p = 0.01$) and chest (Placebo: 1.4 cm, 95% CI, 0.8, 2.0 vs. Ashwagandha: 3.3 cm, 95% CI, 2.6, 4.1; $p < 0.001$). In comparison to the subjects who received a placebo, the subjects who were administered ashwagandha experienced a significantly greater reduction in exercise-induced muscle damage, as evidenced by the stabilisation of serum creatine kinase levels (Placebo: 1307.5 U/L, 95 % CI, 1202.8, 1412.1, vs. Ashwagandha: 1462.6 U/L, 95 % CI, 1366.2, 1559.1; $p = 0.03$). Additionally, the ashwagandha group exhibited a significantly greater increase in testosterone levels (Placebo: 18.0 ng/dL, 95 % CI, -15.8, 51.8 vs. Ashwagandha: 96.2 ng/dL, 95 % CI, 54.7, 137.5; $p = 0.004$), as well as a significantly greater decrease in body fat percentage (Placebo: 1.5 %, 95 % CI, 0.4 %, 2.6 % vs. Ashwagandha: 3.5 %, 95 % CI, 2.0 %, 4.9 %; $p = 0.03$).

Way forward

The present study presents findings indicating a positive correlation between the consumption of ashwagandha supplements and notable enhancements in both muscle mass and strength. These results suggest that incorporating ashwagandha supplementation into a resistance training regimen could potentially provide beneficial outcomes.

Journal: J Gerontol A Biol Sci Med Sci.

Year: 1-April-22

Sub category: Muscle Strength and Recovery

6.7
Category-VII
Others

Ayush products and practices, derived from traditional Indian systems of medicine (Ayurveda, Yoga, Unani, Siddha, Naturopathy and Homeopathy), offer a holistic approach to addressing toxicity and promoting overall health and well-being. Ayurvedic herbs and formulations can act as powerful detoxifiers, aiding the body in eliminating harmful substances and reducing oxidative stress. These natural remedies may also support healthy liver and kidney function, which are crucial for detoxification processes. Additionally, Ayurvedic practices like Panchakarma can provide deep cleansing therapies. In cosmetology, Ayush principles emphasize the use of natural ingredients for skin and hair care, promoting nourishment and radiance without harsh chemicals. Yogic practices such as pranayama (breathing exercises) and meditation can reduce stress, a major contributor to skin problems and imbalances, leading to a healthier, more glowing complexion.

Evaluation of “yak001” for safety profile: acute oral toxicity study

Company / Institute(Lab)

Sri Sri Tattva (1R & D, Sri Sri Ayurveda trust, 21ST km, Kanakapura road, Udayapura, Bangalore, Karnataka, India, 2. Pharmacology Laboratory, SDM Centre for Research in Ayurveda and allied sciences, Kuthpady, Udupi, Karnataka, India)

Type of Study: Invivo study

Abstract

This study investigates the short-term harmful effects of a drug called "YAK001" when administered orally to rats. The drug is prepared as a suspension using gum acacia. The acute toxicity of a single dose was evaluated using OECD guidelines 425 and AOT software. In this study, rats were given varying doses and observed for 14 days. The observations included general appearance, behaviour changes such as increased or decreased motor activity, convulsions, muscle spasms, and other related symptoms. The study also looked at mortality rates and conducted autopsies on deceased animals. The test drug was found to be non-lethal at a maximum oral dose of 2000 mg/kg, which is equivalent to a total dose of 22.4g for a 70 kg human.

Way forward

The absence of toxicity in the coded medication YAK001 is apparent based on the results of the acute oral toxicity study done in accordance with the recommendations established by the Organisation for Economic Cooperation and Development (OECD). The observed behaviour and mortality rates of the test animals over a 14-day duration indicate the absence of toxicity associated with the treatment. Therefore, it may be inferred that the experimental medicine does not possess any hazardous properties, even when administered at a dosage of 2000 mg/kg in animal subjects, which is comparable to 22.4 g in humans. The dosage in human subjects is 7.4 times greater than the standard human dosage of 3 grammes per day.

Journal: INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
Year: 2015

Sub category: Cytotoxicity Analysis

A pilot randomized controlled trial of the Yoga of Awareness program in the management of fibromyalgia.

Company / Institute(Lab)

A. Department of Anesthesiology and Peri-operative Medicine, Oregon Health & Science University, Portland, OR, USA, B. School of Nursing, Oregon Health & Science University, Portland, OR, USA, C. Department of Medicine, Division of Arthritis & Rheumatic Diseases, Oregon Health & Science University, Portland, Oregon, USA

Abstract

An increasing body of scholarly evidence suggests that the comprehensive management of fibromyalgia (FM) should include a combination of pharmacological interventions, physical exercise, and the enhancement of coping strategies. Nevertheless, there exists a notable deficiency in identifying a viable alternative to medication that integrates both exercise and coping mechanisms. The primary objective of this randomised controlled experiment was to assess the impact of a comprehensive yoga intervention on symptoms and coping mechanisms related to fibromyalgia. A cohort of 53 female patients diagnosed with fibromyalgia (FM) were subjected to randomization, with half of them assigned to an 8-week programme called Yoga of Awareness. This programme involved moderate yoga poses, meditation, breathing exercises, coping advice based on yoga principles, and group discussions. The other half of the patients were placed on a wait-list for normal care. The data were subjected to intention-to-treat analysis. Following the completion of the treatment, it was seen that women who were allocated to participate in the yoga programme exhibited notable enhancements in standardised assessments of fibromyalgia (FM) symptoms and overall functioning. These gains were particularly evident in areas such as pain, exhaustion, mood, as well as pain catastrophizing, acceptance, and the utilisation of various coping mechanisms. This preliminary investigation offers encouraging evidence for the potential advantages of implementing a yoga intervention for women diagnosed with fibromyalgia.

Way forward

In summary, this pilot study provides initial support for the positive effects of yoga in managing fibromyalgia symptoms. While encouraging, the study has limitations, and further research is needed to confirm and expand upon these findings. Future studies should explore the mechanisms behind yoga's therapeutic effects, consider moderating factors, and determine optimal yoga practices for symptom relief. The observed improvements highlight the potential of yoga as a valuable tool in fibromyalgia management, calling for more comprehensive research in this area.

Journal: International Association for the Study of Pain

Sub category: Pain

Year: Received 27 April 2010, Revised 24 June 2010, Accepted 16 August 2010, Available online 12 October 2010.

Assessment of Cumulative Irritation and Sensitization Potential of Himalaya's Baby Skin Care Products in Adult Healthy Volunteers by Human Repeat Insult Patch Test (HRIPT)

Company / Institute(Lab)

Himalaya (Head of Medical Services & Clinical Development,HWC, Bengaluru 2-Head of Department & Consultant Dermatologist Dermatology, Manipal Hospital, Bengaluru, Medical Director of MS Clinical Research (MSCR), Bengaluru 3-Senior Consultant Dermatologist, Manipal Hospital,Consultant, MSCR, Bengaluru 4-Clinical Team Lead – Personal Care, Himalaya Wellness Company (HWC), Bengaluru 5-Head-Research & Development (R &D), Himalaya Wellness Company (HWC), Bengaluru)

Product: Winostress Capsule

Type of Study: Observational study

CTRI registration no.: CTRI/2020/03/023725 || CTRI/2020/06/026085

Abstract

The objective of this study was to evaluate the mildness, gentleness, and allergenic potential of 18 baby skin care products available in the market. This study was conducted in a single centre and followed the BIS 4011:2018 guidelines. It consisted of two studies and used an open-label and controlled design. The study involved 200 healthy participants between the ages of 18 and 65, of both genders. Two separate studies were conducted to evaluate a total of 10 products in study 1 and 8 products in study 2. The evaluation of these products took place in different phases. During the induction phase of the study, the products were applied multiple times on the backs of the participants. This was done by using occlusive patches that were left on for 24 hours, three times a week, for a total of three weeks. Reactions were evaluated 48 hours post-patch application. After a 2-week rest period, the subjects underwent a 24-hour challenge where a patch was applied to the untreated area.

The study assessed the reactions observed at three different time points after applying the patch: 48, 72, and 96 hours. In the first study, six products were found to have no cumulative irritation score, while four products (gentle baby soap, refreshing baby soap, nourishing baby soap, extra moisturising baby soap) had cumulative irritation scores ranging from 137.0 to 326.0, suggesting they may cause mild irritation when used normally. In the second study, six products were found to have a mild cumulative irritation score of 0. Two specific products, gentle baby shampoo and extra moisturising baby wash, had cumulative irritation scores of 375.12 and 215.92, respectively. These scores suggest that these products are mild when used normally.

The study found that all 18 baby skin care products were determined to be hypoallergenic and non-irritating. This suggests that the products are safe, mild, and gentle for the babies in the study.

Way forward

A series of clinical trials were conducted to assess the safety and suitability of 8 baby skin care products for Indian adults. The products included baby lotion, baby cream, baby oil, baby shampoo, baby soap, baby powder, baby wipes and diaper rash cream. The trials used two methods: the Cumulative Irritation Test (CIT) and the Human Repeat Insult Patch Test (HRIPT). The CIT measured the skin irritation potential of the products after repeated applications on the forearm. The HRIPT measured the skin sensitization potential of the products after repeated applications on the back. The trials involved a total of 200 healthy volunteers who completed the tests without any adverse reactions.

The findings of the trials showed that none of the products caused any allergic or irritant responses in the volunteers. Therefore, the products were deemed to be safe and suitable for Indian adults.

Journal: International Journal of Toxicological and Pharmacological Research

Year: 2022; 12 (6); 174-184

Sub category: Skincare

Hepatoprotective effect of polyherbal formulations on paracetamol induced liver toxicity in rats

Company / Institute(Lab)

Sri Sri Tattva (1R & D, Sri Sri Ayurveda trust, 21st km, Kanakapura road, Udayapura, Bangalore, Karnataka, India
2Department of Pharmacology, Acharya & B.M Reddy College of Pharmacy, Bangalore, Karnataka, India)

Type of Study: Invivo study

Product: Poly herbal formulation

Abstract

This study aimed to assess the protective effect of a polyherbal formulation called YAK samples on liver damage caused by paracetamol in rats. This study was conducted on albino rats, which were divided into six groups, each containing twelve animals. It involved dividing participants into two groups: one focused on prevention and the other on treatment. Group I was designated as the healthy control group in the study. In this study, different groups of subjects were given different substances orally. Group II received paracetamol, while Groups III, IV, V, and VI received Silymarin, YAK-001, YAK-PVX002, and YAK-PVZ003 respectively. The duration of administration was 15 days. In this study, a group of animals received a dose of paracetamol and were evaluated for its preventive effects after 48 hours. In this study, animals in different groups were given a single dose of paracetamol on the first day, followed by the respective drug treatment for 15 days to assess its curative effect.

This study evaluated the levels of serum biomarkers and examined the histopathology of the liver. This study found that rats treated with a high dose of paracetamol showed a notable increase in certain enzymes in their blood, including SGOT, SGPT, ALP, GGT, and ACP. The increase was statistically significant with a p-value of less than 0.01. The study investigated the effects of YAK-001, YAK-PVX002, and YAK-PVZ003 treatments on paracetamol-induced liver damage.

The results showed that these treatments were able to reduce the levels of liver enzymes in both preventive and curative approaches, suggesting their potential in countering paracetamol-induced hepatotoxicity. In this study, the researchers compared the effectiveness of three different compounds, namely YAK-001, YAK-PVX002, and YAK-PVZ003, in preventing and treating liver damage in rats. The results indicated that YAK-001 exhibited superior preventive and curative effects compared to YAK-PVX002 and YAK-PVZ003 in albino rats. The curative effect of hepatoprotection is found to be more effective than its preventive effect.

Way forward

The findings of this study suggest that YAK-001 exhibits the most pronounced therapeutic impact on hepatotoxicity caused in rats, as compared to Silymarin, YAK-PVX002, and YAK-PVZ003. This is evidenced by its ability to reduce increased hepatic enzymes, as well as the biochemical parameters of blood and liver, in albino rats. The therapeutic effect of hepatoprotection is shown to be more pronounced than its preventive effect, as seen by the reduction in biochemical indicators, liver injury, and hepatic toxicity.

Journal: International Journal of Research in Ayurveda and Pharmacy

Sub category: Hepatoprotective

Year: Received on: 27/10/15 Revised on: 18/12/15 Accepted on: 29/12/15

Effectiveness of novel herbal dentifrice in control of plaque, gingivitis, and halitosis: Randomized controlled trial

Company / Institute(Lab)

Sri Sri Tattva (a Department of Public Health Dentistry, Manipal College of Dental Sciences, Manipal, Manipal Academy of Higher Education, Manipal, India b. Department of Periodontology, Manipal College of Dental Sciences, Manipal, Manipal Academy of Higher Education, Manipal, Indiac Manager (R and D for Cosmetics), Sriveda Sattva Pvt. Ltd, Bangalore, India)

Type of Study: Randomized controlled trial

CTRI registration no.: CTRI/2018/05/014049

Abstract

The study is focussed to assess the effectiveness of a novel herbal dentifrice in controlling plaque, gingivitis, and halitosis, compared to a control dentifrice. Plaque serves as a common factor contributing to oral health issues such as gingivitis, periodontitis, dental caries, and halitosis.

In a randomized controlled, double-blinded clinical trial, participants were randomly assigned to use either the novel herbal dentifrice or the control dentifrice. Assessments of plaque, gingivitis, halitosis, and unstimulated saliva pH were conducted at baseline and one month later by a trained periodontist. All participants received new toothbrushes one week before the study and were instructed to brush with their designated dentifrices for 2-4 minutes, twice daily for one month.

The study included 79 participants, with 75 completing the follow-up. Initial comparisons between the test and control groups revealed no significant differences in mean plaque index, gingival index, halitosis, and pH. However, intra-group comparisons showed a significant decrease in mean plaque, gingival issues, and halitosis at the follow-up compared to baseline for both the test and control groups. After adjusting for baseline scores, no significant differences were observed between the test and control groups in terms of plaque index, gingival index, halitosis, and pH at the follow-up.

In conclusion, the novel herbal dentifrice appears to be a viable alternative for controlling plaque, gingivitis, and halitosis when compared to the control dentifrice. These findings suggest that this herbal dentifrice may offer effective oral hygiene benefits, potentially making it a suitable choice for individuals seeking to address these common oral health issues.

Way forward

The study recruited a total of 79 participants, of whom 75 successfully completed the follow-up phase. There were no statistically significant differences observed in the mean plaque index, gingival index, halitosis, and pH between the test and control groups at baseline, as determined through inter-group comparisons of all variables. The results of intra-group comparisons revealed a statistically significant reduction in the average levels of plaque, gingival inflammation, and halitosis at the follow-up assessment compared to the initial assessment for both the test and control groups. There were no statistically significant changes seen between the test and control groups in terms of the average plaque index (P = 0.792), gingival index (P = 0.292), halitosis (P = 0.266), and pH (P = 0.742) over the follow-up period, after correcting for the corresponding baseline values. The unique herbal dentifrice may serve as a viable alternative for the management of plaque, gingivitis, and halitosis.

Journal: Journal of Traditional and Complementary Medicine

Sub category: Gingivitis

Year: Received 12 February 2019 | 29 May 2019 | Accepted 25 June 2019 | Online 25 June 2019

KEY TAKEAWAYS

India's extensive history of traditional medicine, which includes Ayurveda, Yoga, Naturopathy Unani, Siddha, and Homoeopathy, has experienced a remarkable comeback in recent years, becoming well-known throughout the world for its all-encompassing approach to health and wellness. This comeback is driven by growing awareness among people due to Covid-19 spread and the need of immunity to fightback.

As of 2020, the market size of the Indian Ayush industry was estimated to be around $18.1 billion USD. The key contributors are as growing consumer awareness of the advantages of Ayush practises, government backing and initiatives, and rising industry awakening. It is anticipated that the sector would maintain its current growth trajectory and reach a projected value of US$ 66 billion by 2025 according to Invest India. By 2031, it is anticipated that the worldwide Ayush market would be worth US$14,095.8 billion.

Innovation and investment in the Ayush sector have surged as a result of the growing demand for its goods and services. The researchers and academicians are contributing to verify the effectiveness of ancient practises by generating scientific data and clinical Trial data whereas Ayush businesses are creating new and improved products and government is building legislative frameworks and funding R&D projects in advancing Ayush.

It is crucial to guarantee the sustainability and calibre of Ayush goods and services as the sector grows. This entails carrying out thorough scientific study, building strong regulatory frameworks, and encouraging the sustainable collection and development of therapeutic plants. The Ayush sector can grow and support global healthcare and wellness by tackling these issues and maintaining the highest standards of quality and safety.

Research on the traditional healthcare systems of Ayurveda, Yoga, Unani, Siddha, and Homoeopathy, or Ayush, is crucial because it has the ability to provide a wealth of information and therapeutic potential. Researchers have been able to determine the mechanism of action of Ayush practises, validate their effectiveness, and create standardised protocols for their use by carrying out thorough scientific investigations. These investigations have produced a number of noteworthy advantages:

1. Evidence-based Ayush: The medical community and the general public is more acceptable towards scientifically validated Ayush practices.
2. Enhanced safety and efficacy: Research aids in the improvement of Ayush procedures, maximising their positive effects.
3. Integration with contemporary medicine: Research can pinpoint areas in which Ayush practises can strengthen or supplement conventional medicine, resulting in more thorough and individualised health care.

KEY TAKEAWAYS

As said by WHO Director-General Dr. Tedros Adhanom Ghebreyesus: "Ayurveda is a traditional medicine system that has been used for centuries to promote health and well-being. WHO is committed to supporting the integration of traditional medicine into national health systems, and we believe that Ayurveda has the potential to make a significant contribution to global health."
4. Drug discovery: Ayush research has the potential to find new pharmaceutical molecules derived from natural sources, which could provide innovative ways to treat a range of illnesses.
5. Knowledge exchange and cultural preservation: Research can support the rich knowledge base of Ayush systems and help keep it alive, ensuring their continuous applicability in contemporary healthcare.

To sum up, Ayush research is essential to maximising the benefits of these age-old healing modalities and strengthening their influence on global health and well-being. Ayush has the potential to significantly contribute to the promotion of preventive healthcare, enhancement of treatment outcomes, and preservation of cultural heritage through the rigorous validation of their efficacy, refinement of their practises, and integration with modern medicine. As said by Shri Shripad Yesso Naik, former Minister of Ayush: "Ayurveda is a holistic system of medicine that has been practiced in India for thousands of years. It is based on the principle of maintaining a balance between the body, mind, and spirit. Ayurveda is a valuable resource for modern medicine, and we are committed to promoting its use around the world." Also Dr. Harsh Vardhan, former Minister of Health and Family Welfare said: "Ayurveda is a science of life that has the potential to make a significant contribution to global health. We are working to integrate Ayurveda into the modern healthcare system, and we believe that it has the potential to revolutionize the way we treat disease."

In addition to being a useful tool for contemporary medicine, Ayurveda holds great promise for improving world health. We can use Ayurveda to create novel and efficient therapies for the diseases that afflict the modern world as we continue to learn more about it.

ABOUT AYUSHEXCIL

AYUSHEXCIL, established in January 2022 and officially launched by Prime Minister Narendra Modi in April 2022, a DGFT notified Council serves as a vital organization dedicated to the advancement and export of India's traditional Ayush systems of medicine. With a clearly defined vision of promoting the growth and global recognition of the Ayush industry, AYUSHEXCIL has undertaken a multitude of initiatives and established itself as a key player in this Ayush Export.

Structure and Functioning

Structured with three dedicated subcommittees – Regulatory & Technical, Other Ayush Verticals, and Service Sector – AYUSHEXCIL adopts a strategic approach to addressing all aspects of the Ayush industry. Each subcommittee focuses on specific areas, ensuring comprehensive coverage and effective execution of plans.

Guiding Principles

Driven by a core mission encompassing various objectives, AYUSHEXCIL is committed to:

- Protecting and fostering scientific research in the realm of Ayush healthcare, while facilitating the exchange of knowledge and expertise on an international scale.
- Bridging the gap between government and private entities involved in the Ayush sector, promoting collaboration and ensuring a unified approach.
- Supporting industry and institutions engaged in Ayush product and service development, training, research, and sales.
- Conducting regular market research to identify overseas opportunities and spearheading industry-driven trade missions to foreign countries.
- Raising awareness about the benefits of Ayush systems, expanding their global reach, and understanding international demand.
- Building relationships with foreign regulatory bodies, coordinating country delegations, and inviting global regulators to India.
- Expanding the network of importers and boosting the international market potential of domestic Ayush products.
- Encouraging stakeholder interaction through events, meetings, and exhibitions to foster the international market development of Ayush products and services.

Scan to read the booklet

Contact Us

Ayush Export Promotion Council

Federation House, Tansen Marg, Todermal Road Area, Mandi House, New Delhi, Delhi 110001