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Abbreviations

CAM	complementary and alternative medicine
CCHRS	Code of Conduct for Health Research in Sri Lanka
CENTRAL	Cochrane-controlled trials register
CKD	chronic kidney disease
CMC	chemical-manufacturing-control
CONSORT	consolidated standards of reporting trials
DoH	Department of Health
DSMB	Data Safety Monitoring Board
EBM	evidence-based medicine
EFGCP	European Forum for Good Clinical Practice
ERC	Ethics Review Committee
EU	European Union
FERCSL	Forum for Ethics Review Committees in Sri Lanka
ICH	International Conference on Harmonization
WHO ICPC	WHO International Classification of Primary Care
ICTRP	International Clinical Trials Registry Platform
NIPO	National Intellectual Property Office
RCR	randomized controlled research
RCTs	randomized control trials
SIDCER	Strategic Initiative for Developing Capacity in Ethical Review
TM	traditional medicine
T&CM	traditional and complementary medicine

Message of the Regional Director

Many Member States of the WHO South-East Asia Region have a long history of traditional medicine. In almost all countries of the Region, traditional medicine is part of health-care delivery services, potentially contributing towards the achievement of universal health coverage and the WHO Thirteenth General Programme of Work.

Traditional medicine knowledge is valuable only if it works. Research in TRM and its proper practice can play a vital role in its acceptance. The core function of WHO is to support Member States in strengthening national research capacity towards evidence-based medicine. The WHO Regional Office for South-East Asia has made strengthening national research capacity in traditional medicine a top priority of the regional traditional medicine programme, in line with the WHO Global Traditional Medicine Strategy 2014–2023, as well as the Delhi Declaration on Traditional Medicine, adopted at the International Conference on Traditional Medicine in February 2013.

Sri Lanka is one of several Member States of our Region with a long history of use of traditional medicine, providing a compelling case study. Through this review on current research activities in traditional medicine in Sri Lanka, all readers – including traditional medicine researchers – will gain an understanding of the overall situation of research in Sri Lanka, including an insight into the total number of research activities in the defined time period, the different types of research conducted, the various health conditions studied, and the key challenges and issues to be overcome for improving the quality of traditional medicine research. Long-term development of traditional medicine will help harmonize and appropriately integrate it into health-care delivery services currently dominated by allopathic medicine.

In the evolution of allopathic and traditional medicine, the quest for evidence, quality and safety continues. This publication is a contribution to that effort.

Dr Poonam Khetrapal Singh
Regional Director
WHO South-East Asia Region

Preface

It gives me great pleasure to know that a country case study on research in traditional medicine has been done in the WHO South-East Asia (SEA) Region. It is the first such study of its kind.

Use of traditional medicine has expanded and gained popularity globally not only in low- and middle-income countries but also in high-income countries where conventional medicine is predominant in the national health-care system. Given such a global expansion in the use of traditional medicine, the safety, efficacy and quality of traditional medicines have become important concerns for both health authorities and the public.

Thus, one of the goals of the WHO Traditional Medicine Strategy 2014–2023 and of action points of the Delhi Declaration on Traditional Medicine adopted in 2013, is to promote safe and effective use of traditional medicine through research and regulation. The WHO Regional Office for South-East Asia has identified capacity-building in traditional medicine research as one of the regional priority areas.

Given the increasing demand for evidence-based traditional medicine and its global popularity, some Member States of the WHO SEA Region have paid attention to research in traditional medicine and have supported substantial research activities. Many of the research reports have been published in the national and international journals. Despite the fact that several research studies have been done in various countries, these have not yet been analysed systematically in terms of topics, areas of research, issues and challenges, and the gaps that require to be researched. Therefore, it has resulted in insufficient reflection of the research findings on policy guidance and directions towards development of traditional medicine, and appropriate integration of traditional medicine in the public health-care delivery system. In order to facilitate Member States of the WHO SEA Region to undertake such analytical activities and processes, the Regional Office initiated country studies on traditional medicine research status and the existing principles and practices for conducting research, such as code of conduct, ethical framework, monitoring and evaluation, regulatory system, reporting and dissemination, legal framework for protecting intellectual property rights, administrative procedures and process.

Sri Lanka is one of the Member States with a rich heritage and long history of use of traditional medicine. The Government has strongly supported the development of the traditional system of medicine for a long time and the country had an independent Ministry of Indigenous Medicine till 2014.

This project analyses the current research status in traditional medicine for the period of 2014–2019 in terms of research activities, types of clinical research, main health conditions studied, main gaps, issues and challenges relating to clinical research in traditional medicine.

However, it was inevitable that the project would have its limitations due to a constrained budget, time and capacity for analysis. Nevertheless, we hope that the findings of this study would add value to our research endeavours in traditional medicine and facilitate policy-makers in framing appropriate and effective policies, and making evidence-based decisions. It would help also researchers in identifying research topics and improving their quality of research in traditional medicine.

We welcome any observations and comments on the country study report.

Dr Kim Sungchol
Regional Adviser for Traditional Medicine
Department of Health Systems Development
WHO South-East Asia Region

Executive summary

Preamble

In 2014, the World Health Organization endorsed the WHO Traditional Medicine (TRM) Strategy 2014–2023 *(1)* with the goals of harnessing the potential contribution of TRM to ensuring health, wellness and people-centred health; promoting safe and effective use of TRM; and achieving universal health coverage (UHC) by regulating TRM products, practices and practitioners.

In 2014, the WHO Regional Office for South-East Asia (WHO-SEARO) adopted a regional resolution on traditional medicine, wherein all Member States agreed to adopt and implement the *WHO TRM Strategy 2014–2023* and the Delhi Declaration on TRM *(2)*. To assist and support Member States in implementing these strategies, WHO-SEARO organized a regional workshop on TRM and identified the regional TRM action points in 2015 *(3)*. The workshop aimed to strengthen research capacity in traditional medicine through training and documentation of research activities. As per this action point, the WHO-SEARO TRM programme is conducting a number of activities, including regional workshops on clinical research methodologies.

Given the increasing demand for evidence-based traditional medicine, many Member States in the SEA Region have invested time and resources in TM research. Research output is evident in domestic and international journals and publications. Sri Lanka was the only country in the world with an independent Ministry of Indigenous Medicine before 2015 (later it was integrated with the Ministry of Health, Nutrition and Indigenous Medicine). The Sri Lankan government has provided substantial support for research and development (R&D) in traditional medicine. However, the outcomes of the research effort are not widely known and have not been disseminated to the public in many cases. Therefore, this country review was planned to better understand the scope of research in traditional medicine in terms of key achievements, gaps, challenges and roadmap for R&D in traditional medicine. The research activity may further nourish and support future activities in other Member States.

Key message

A lack of rigorous clinical trials was found to be the major drawback in TM research being undertaken in Sri Lanka. While the quality of the clinical trials was not the focus of this review, most studies were published only in conference proceedings and few in peer-reviewed journals, and even fewer in journals with high citation indexes. Many of the randomized controlled trials (RCTs) did not adequately report on key study components such as sample selection methods, selection of outcome measures, statistical analysis and data collection methods. Most studies were at a high risk of bias. The use of relevant Ayurvedic or TM outcome measures was also absent in some clinical trials.

Case studies and case series dominate the research being carried out in Sri Lanka. The quality of these lacked uniformity and can be improved by adhering to a case study-reporting format such as that suggested in this review. The implementation of proper guidelines and training for TM research in Sri Lanka would help in developing the potential of TM and contribute to better use of valuable resources.

The framework for conducting TM research in Sri Lanka is fairly well-established. There is a quality ethics review process for all TM health research, with a dedicated TM Ethics Review Committee (ERC) – the ERC/Institute of Indigenous Medicine (ERCIIM). Most institutional ethics committees are recognized by the WHO Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) network. However, ethics review committees for indigenous medicine need to be strengthened by recognized affiliations such as SIDCER.

Many TM research institutes have established ethics review committees, but more are needed. To improve research quality, TM health researchers should be trained in and encouraged to follow good clinical practice (GCP) training, and clinical trials should be registered with the Sri Lankan Clinical Trial Registry (SLCTR) or the clinical trial registires that are accepted by WHO. A major obstacle is that clinical trial protocols reviewed by TM-based institutional ethics review committees are still not accepted by SLCTR (for example, Ethics Review Committee, Institute of Indigenous Medicine (ERCIIM)). A separate clinical trial registry for TM systems for Sri Lanka may be a solution to this.

Undertaking this review highlighted difficulties in being able to comprehensively locate all TM research that has been undertaken in Sri Lanka. Much of the review required hand searching or investigating specialized e-repositories (grey literature search). The establishment of a digitalized library (in a manner that protects intellectual property) would greatly recognize the value and assist in the use of TM research findings.

Most of the TM health research reviewed was carried out by university-based institutes. There is a need to build the capacity of TM research institutes such as Bandaranayake Memorial Ayurvedic Research Institute (BMARI) to promote high-quality, national-level research.

The World Health Organization may act as a trusted technical mediator to improve the technical capacity of TM research in Sri Lanka. WHO may help in developing research capacity by providing research training programmes with the support of local and international experts. Furthermore, WHO can support documenting the local knowledge of TM, improving health information systems and developing policies and strategies to provide greater care to people.

Recommendations

Recommendations for developing TM research in Sri Lanka that have emerged from this review include:

(1) supporting multidisciplinary research projects with official collaborations across institutions to build impact;

(2) encouraging private-public partnership (perhaps with MoUs) to facilitate national-level research on key diseases and key TM interventions;

(3) improving the current standards of research project review boards, research committees and ethics review committees at major research institutes, e.g. BMARI;

(4) considering the research capacity and requirements when planning a national TM research strategy;

(5) developing international collaborations through researcher training and through WHO collaborative centres;

(6) encouraging all TM researchers to adhere to accepted quality standards when conducting research, e.g. GCP;

(7) collaborating across all universities/institutes to promote best practices in developing TM research culture;

(8) facilitating dissemination of research findings and TM research impact through publications in indexed journals;

(9) improving publications and reporting, encouraging the use of internationally recognized standards for observational studies, including case studies and case series *(4)*; and

(10) establishing a traditional medicine- and traditional knowledge-specific registration and innovation patent system. This will be aided by the implementation of the proposed Act, called The protection of traditional knowledge in Sri Lanka, drafted in 2009, with further amendments by stakeholders involved in TM in Sri Lanka.

1

Overview

1.1 Background

Traditional medicine (TM) continues to be used by almost 50% of the population in countries such as the United States of America (42%) and Australia (48%), with higher use reported in many developing countries *(5)*. In India, Ayurvedic medicine is used by an estimated 59% *(6)* of the population. In Japan, around 70% of physicians prescribe Kampo medicines in daily practice *(7)*. Unani medicine is still used by a vast majority of people in West Asia and South Asia.

An estimated 80% of the population in developing countries depend on traditional systems of medicine as a source of primary health care *(8)*. In Sri Lanka, an estimated 75% of the population use traditional medicine. In rural areas, traditional systems of medicine cater to 60–70% of the population's primary health care needs *(9,10)*. There are around 20 353 registered Ayurvedic physicians and an additional 8000 traditional practitioners in the country.

Over the past decade, herbal medicine and related products have become a topic of increasing global importance, having repercussions for both world health and international trade. Recognition of medical and economic benefits of plant-based medicines is growing in both developing and industrialized countries, although it varies greatly from country to country *(11)*.

Although difficult to calculate with accuracy, the total global market for herbal medicine was estimated to be US$ 83 billion in 2019 and is expected to reach US$ 411.2 billion by 2026 and US$ 550 billion by 2030 with a compound annual growth rate (CAGR) of 18.9% through 2030 *(12,13)*. Currently, governments, international agencies and corporations are increasingly investing in traditional herbal medicine research. Along with herbal medicine, other herbal products such as cosmetics, fragrances, tea, health foods and nutraceuticals are equally popular and constitute a large proportion of the global herbal business (*14)*.

Sri Lanka is blessed with at least four extant systems that use herbal products in a variety of ways in clinical practice: Ayurveda, rich and uniquely native *Desheeya Chikitsa*, Siddha and Unani. Ayurveda and the indigenous system of medicine, *Desheeya Chikitsa,* have been practised in Sri Lanka for more than 3000 years.

According to the Sri Lanka Ayurveda Act (No. 31 of 1961), "Ayurveda" includes all the traditional medical systems, namely Siddha, Unani and *Desheeya Chikitsa*, the latter being the earliest system of medicine existing in Sri Lanka before the advent of Ayurveda *(15)*. Ayurveda forms a part of the National Health Services, provided by the Government of Sri Lanka, and includes a separate ministry for indigenous medicine. The government's health planning blueprint recognizes the importance of Ayurveda and its workforce, particularly in preventative medicine *(16)*.

In Sri Lanka, there were 19 754 Ayurvedic physicians registered under the Sri Lanka Ayurveda Medical Council in 2010. Among those registered, general practitioners of Ayurveda accounted for 84.9% of registrations, Siddha 12.7% and Unani 2.7%. Specialist physicians were primarily Ayurvedic practitioners (96.5%). Apart from these registered physicians with the Ayurveda Medical Council, there are more than 8000 traditional medical practitioners, who are descendants of reputed families with secret formulae to cure diseases, engaged in public health care.

Research in Sri Lanka on TM is supported by a strong basic science sector. However, this is not matched by quality clinical trials. The trends, quality and outcomes of clinical studies are not widely known and are not routinely shared with the public.

This review was undertaken to:

(1) provide an understanding of the context of TM research in Sri Lanka;

(2) explore the breadth of the literature, map and summarize the evidence, and inform future research on TM in Sri Lanka through a scoping study; and

(3) outline challenges in research and development on traditional medicine in Sri Lanka.

2

Conducting Traditional Medicine Research in Sri Lanka – Governance and Ethics

This chapter outlines the research context for traditional medicine research in Sri Lanka. The main organizations and key guidelines involved in research governance of traditional medicine in Sri Lanka are:

(1) Ethical Framework for Traditional Medicine Research

(2) Code of Conduct for Health Research in Sri Lanka (CCHRS)

(3) Sri Lanka Clinical Trials Registry (SLCTR)

(4) Ethics committees in Sri Lanka for TM research

(5) International and national clinical research guidelines & reports

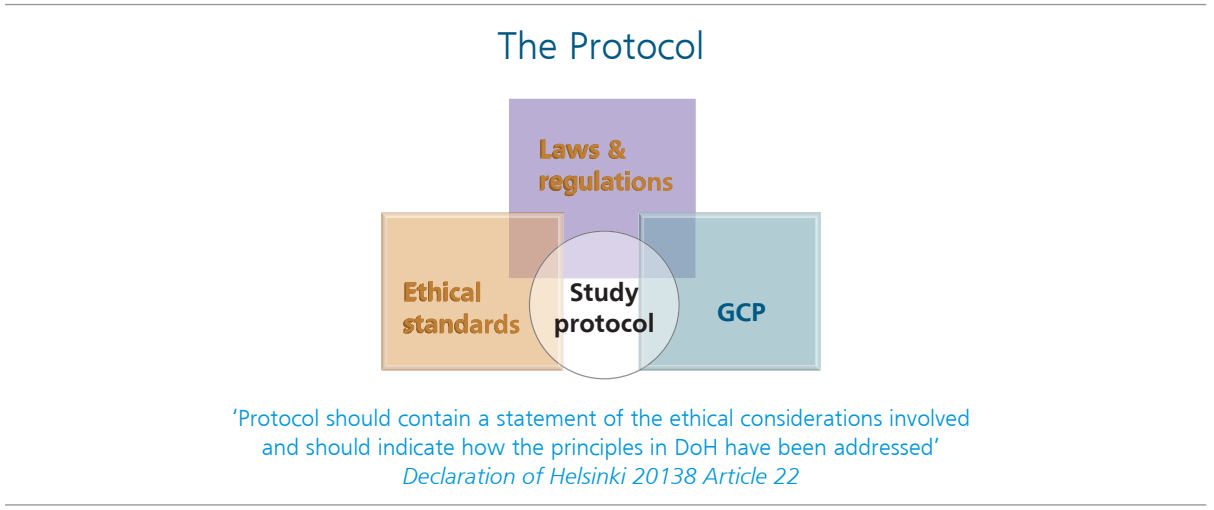
(6) Main institutions in Sri Lanka involved in TM research and development, policy-making and grants.

2.1 Ethical framework of research on herbal medicine

In Sri Lanka, research on traditional systems of medicines is subject to the same ethical requirements as all research related to human subjects in the allopathic system of medicine. Traditional medicine research should follow the Code of Conduct for Health Research in Sri Lanka (CCHRS, see Section 2.2), receive ethics approval from an appropriate ethics review committee (see Section 2.4) and, where appropriate, be registered with SLCTR (see Section 2.3). The research should also abide by laws and regulations in the country and good clinical practice (GCP) (Fig. 1).

An ethical framework, previously outlined by Emanuel et al. and revised for international research, offers a useful starting point for thinking about the ethics concerning traditional systems of medicine research (17). This framework includes eight ethical requirements for clinical research (Table 1). These ethical requirements are universal and comprehensive, but should be adapted to the particular social context in which the research is implemented (18). The Sri Lankan ethical framework is also based on these principles.

Fig. 1. *Protocol development[based on the course material of the diploma course in research and development of products to meet public health needs (2013), Nagasaki University, Japan]*



'Protocol should contain a statement of the ethical considerations involved and should indicate how the principles in DoH have been addressed'
Declaration of Helsinki 20138 Article 22

Table 1. *A comprehensive framework for research ethics*

Collaborative partnership	Research leadership must include bilateral representation based on mutual respect between equal partners with community advice. It includes a responsibility to invest in scientific training and capacity-building for ongoing research in a host country where such resources are not developed
Social value	Knowledge gained from the research should have the potential to lead to new generalizable knowledge or improvements in health. Partners should specify in advance to whom benefits will accrue and in what way.
Scientific validity	Research should be designed to produce beneficial and generalizable knowledge. This includes designing research so that it can be feasibly implemented in the settings where it will be conducted.
Fair subject selection	Subjects should be selected on the basis of scientific importance, not based on convenience, vulnerability or bias.
Favourable risk–benefit ratio	The potential benefits of individual participation should outweigh the risks of participation. Benefits to the community or population being studied should also be optimized. Compelling societal benefit can justify risks to individuals in certain circumstances.
Independent review	To maintain the integrity of the research, bodies not tied to the investigators must agree that the risks and potential benefits of the research are justified.
Informed consent	Investigators must obtain valid permission for study participation from subjects in a manner that is sensitive to the cultural context in which the study is conducted.
Respect for subjects	Researchers should have a plan for how the research results will be disseminated, ensuring that participants know their right to withdraw and monitoring the research for relevant adverse events.

(Source: Tilburt JC, Kaptchuk TJ (2008) Herbal medicine research and global health: An ethical analysis. Bull World Health Organ 66: 594–599)

2.2 Code of Conduct for Health Research in Sri Lanka

The Code of Conduct for Health Research in Sri Lanka applies to all medicine research undertaken in the country (19). CCHRS was developed in 2018 by the education, training and research unit within the National Health Research Council in Sri Lanka under the Ministry of Health. Technical assistance to develop this code was provided by Monash University, Melbourne, Australia.

Prior to the development of CCHRS, responsible conduct of research was guided by a multitude of existing non-binding guidelines, regulations and declared policies of individual research institutions. CCHRS is a comprehensive national document that fulfils a long-standing gap in the health- and health-related research community of Sri Lanka.

The CCHRS provides a set of duties and responsibilities for institutions and researchers to follow in order to promote integrity of health- and health-related research.

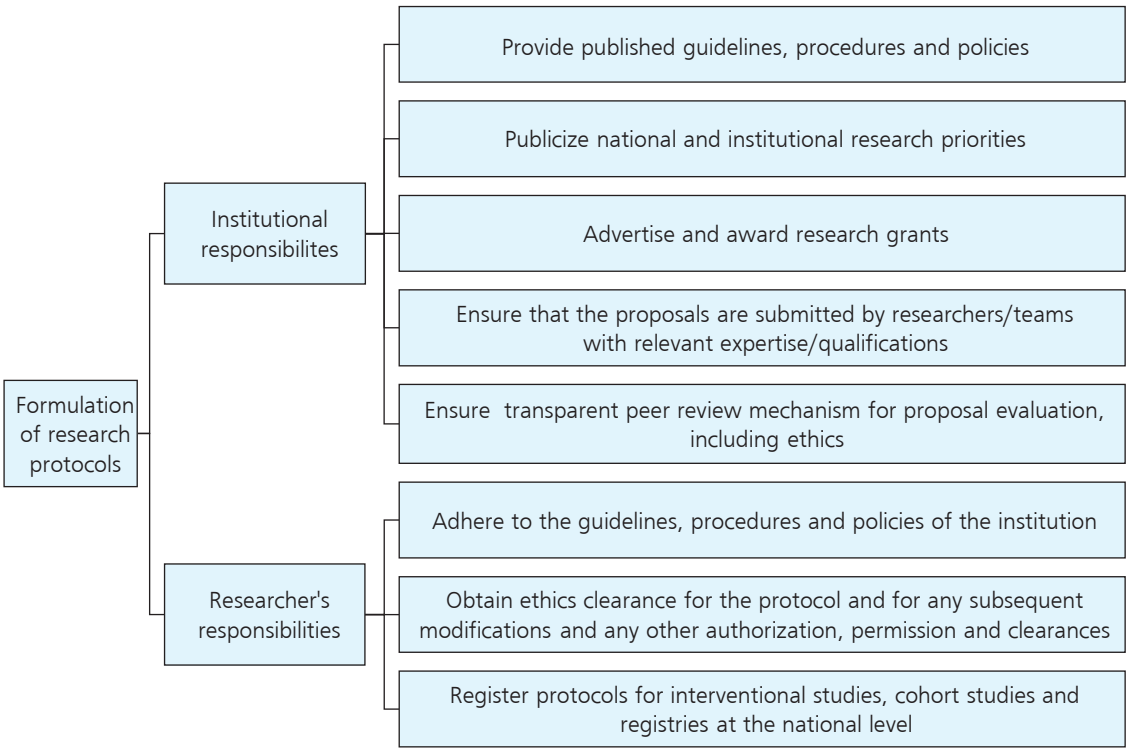
All health research institutes and researchers adhere to this code in Sri Lanka. We have provided a brief overview of the requirements of CCHRS and how it applies to TM research in Sri Lanka.

2.2.1 Development of a research protocol

The CCHRS defines research protocol as a summary document of a research plan that outlines the topic, research question, aims and objectives, study design and methods, plan for data analysis, sources of funds and timeline. A research protocol also details the steps taken to address ethics issues in the conduct of the research.

Key institutional and researcher's responsibilities related to formulation of research protocols (Fig. 1) are detailed in CCHRS. To date, in TM research in Sri Lanka, there is no direct process to register protocols for interventional studies, cohort studies and registries at the national level. Protocols may be registered with the International Prospective Register of Systematic Reviews (PROSPERO).

Fig. 2. *Traditional medicine research protocol formulation in Sri Lanka (CCHRS)*



2.2.2 Conduct of research

Research should be conducted honestly, accurately, objectively and efficiently to ensure its integrity. This will result in high-quality, safe, ethical, generalizable and reproducible research that leads to meaningful improvements in health and well-being. Poor-quality research entails an unfortunate waste of time, effort and valuable resources.

CCHRS recommends that institutions and researchers responsible ensure high-quality research that is conducted with integrity. Researchers should have the necessary qualifications and competence to conduct research. The scientific integrity and credibility of a study depend substantially on the study design and methodology. The research protocol should meet the application requirements of an ethics review committee (20). **TM researchers should ensure that they address all comments provided during the ethics review process.**

When conducting traditional medicine-based health research, it is suggested that at least one of the researchers should be an Ayurvedic, Unani or Siddha medical doctor registered under the Sri Lanka Ayurveda Medical Council. In the event that the health research is a collaboration with the allopathic medicine system, the research team should include a medical doctor registered with the Sri Lanka Medical Council. According to the ERC guidelines, when conducting clinical research, investigators should be proficient in good research practices, including good clinical practice and good laboratory practice (GLP), where relevant, as well as trained in statistical analysis, data interpretation and research ethics.

Data should be collected and recorded meticulously. Primary materials should be stored appropriately and retained for inspection for a specific period of time. In general, the minimum recommended period for retention of research data spans five years from the date of publication, but varies, based on the type of research, such as:

- clinical trials – minimum 15 years;
- cohort studies – retained permanently;
- gene therapy – clinical records retained permanently; and
- where research has community or heritage value – retained permanently.

If a research project includes more than one type of research, a longer period of retention is applied.

2.2.3 Monitoring and evaluation of research

Research project evaluation is mainly carried out by higher degree committees at the university level and boards of research at national-level institutes in an unbiased manner, with a blind peer review process. Furthermore, health research projects are evaluated and monitored by institutional ethics review committees through independent review process. Ethics review committees evaluate both the ethics and scientific backgrounds of each project.

Monitoring of research is undertaken by an individual ERC that has granted ethics clearance. The ERC monitors approved research studies to ensure compliance. The ERC may request, at any time, information on any relevant aspects of the study and discuss any issue of relevance with the researchers. The principal investigator is required to provide progress reports, at least annually, and a final report following the conclusion of the study. In the case of clinical trials, quarterly reports are required, which are reviewed by the ERC in the first instance. Extension of approval for a further period is subject to the progress reports submitted by the principal investigator as called for in the letter of approval.

In determining the frequency and type of monitoring required for approved studies, the ERC considers the degree of risk to participants in the research. The ERC may adopt whatever measures it considers appropriate for monitoring. The ERC requires, as a condition of approval for each proposal, that investigators immediately report anything which might warrant review of the ethical approval of the protocol.

The ERC requires, as a condition of approval for each proposal, that investigators inform the ERC, providing reasons, if the research study has been discontinued before the expected date of completion. Should the ERC become aware, on soild grounds, of circumstances that have arisen which prevent a research study from being conducted in accordance with the approved protocol, it may withdraw approval. In such circumstances, the ERC informs the principal investigator and the institution about such withdrawal of approval in writing, and recommends to the institution that the research study be discontinued or suspended or that other necessary steps be taken (21).

2.2.4 Dissemination of research findings

Health-care resources are finite. It is imperative that the delivery of high-quality health care is ensured through the successful implementation of cost-effective health technologies. However, there is growing recognition that the full potential for research evidence to improve practice in health-care settings, either in relation to clinical practice or to managerial practice and decision-making, has not yet been realized (22).

Addressing deficiencies in the dissemination and transfer of research-based knowledge to routine clinical practice is high on the policy agenda both in the United Kingdom (23) and internationally. Accordingly, CCHRS encourages timely dissemination of research findings as an important part of the research process. It facilitates translating research findings into practice, guiding future research and passing on the benefits of research to health-care services and to society. This code applies to dissemination of research findings through publications in journals as well as mass media, the Internet and other communication platforms.

2.2.5 Administrative procedures, process and approval for research

After ethics approval by an ERC, investigators are required to obtain approval from the site or the institution where the research project is to be conducted. Investigators are required to negotiate individual arrangements with the heads of service departments in those institutions, where the use of their resources is involved. Institutions involved in research projects should ensure that an agreement is reached among the researchers. The agreement should be in writing. It must cover confidentiality, copyright issues, intellectual property rights, storage and sharing of generated data, sharing commercial returns, responsibility for ethics and safety clearances and reporting to appropriate agencies. Furthermore, it is necessary to specify the ownership of data of collaborative research in the event of a premature end or on completion of the research.

2.2.6 Research misconduct and managing allegations

CCHRS considers the following behaviours or actions to be classified as research misconduct:

- intentional use of research findings to fulfil goals or purposes other than what is stipulated in the protocol;
- misconduct in relation to the collection of data;
- fabrication, falsification, conscious misinterpretation or misrepresentation of data, deception in proposing and carrying out and reporting the results of research;
- plagiarism, misleading ascription of authorship, including listing of authors without their permission, inappropriate omission of authors and including as authors those who have not contributed to the research, and lack of appropriate acknowledgment of the work of others;
- failure to declare or manage any conflict of interest;
- unauthorized deviation from the research protocol approved by an ethics review committee;
- willful support, assistance, concealment or facilitation of research misconduct by others;

- failure to provide adequate guidance or mentorship for researchers or trainees under supervision; and
- inappropriate utilization of funds by researchers, including not conforming to the policies of the funding agency.

Institutions are responsible for managing allegations of research that has not been conducted responsibly. It is required that misconduct or breaches be identified, investigated and managed.

2.2.7 Managing conflict of interest

Avoid and minimize conflict: Although it is not possible to avoid all sources of conflict, it is in the best interests of the scientific community and individual scientists to recognize conflicts of interest and to take steps to nullify or mitigate those conflicts.

Disclose interests: If conflicts cannot be avoided, then those conflicts should be disclosed. At least, the institution and any other parties with a significant interest should be made aware of the extent and nature of the conflict.

Manage conflicts: Disclosure is often not enough. For every step of the research process, attempts should be made to isolate the conflicted individuals from all decision-making functions.

Keep learning: Both the potential for conflicts of interest and the strategies for dealing with those conflicts are evolving. Considering the potential for misperceptions of a researcher's motives, it is best to assume that good intentions are not enough. Seek information so as to comply with the spirit and letter of current regulations (24).

2.2.8 Legal framework and regulation mechanism

The Sri Lankan policy on indigenous medical systems has been drafted but not yet finalized. There is no clinical research Act established for traditional systems of medicine in Sri Lanka. Subsequently, all indigenous medical system research is regulated by individual research authorities within universities and research institutes such as BMARI.

2.2.9 Financial regulations

All research institutes adhere to institutional financial policies and regulations and are responsible for internal audit systems of their own institutes and also responsible for national auditing. Researchers should strictly adhere to financial regulations stipulated by the funding agencies and institutional financial grants should be handled through the institutional accountant.

2.3 Sri Lanka Clinical Trial Registry

SLCTR *(25)* provides a facility for registration of trials involving human participants, conducted in Sri Lanka or overseas. SLCTR is a primary registry linked to the WHO Registry Network of the International Clinical Trials Registry Platform (WHO-ICTRP) *(26)*. SLCTR was established by the Sri Lanka Medical Association (SLMA). It may also help promote collaborative research between Sri Lankan and foreign researchers. Some traditional medicine clinical trials are registered with SLCTR, following approval by an accredited ethics review committee. ERC accreditation is provided by the Subcommittee

on Clinical Trials (SCOCT) of the National Medicinal Regulatory Authority of the Ministry of Health, Sri Lanka (27).

2.4 Ethics review committees in Sri Lanka

Ethics approval should be obtained for all TM research conducted through an ERC registered with the National Health Research Ethics Committee or Forum for Ethics Review Committees in Sri Lanka *(28)*. Depending on the study protocol, ethics clearance for TM can be obtained from the following ERCs in Sri Lanka:

- ERC/Institute of Indigenous Medicine
- ERC/Gampaha Wickramarachchi Ayurveda Institute
- ERC/Faculty of Medicine – Colombo
- ERC/Faculty of Medical Sciences – Sri Jayawardenepura
- ERC/Faculty of Medicine – Jaffna
- ERC/Faculty of Medicine – Kotelawala Defence University
- ERC/Faculty of Medicine – Kelaniya
- ERC/Faculty of Medicine – Peradeniya
- ERC/Faculty of Medicine and Allied Sciences – Rajarata
- ERC/Faculty of Applied Sciences – Rajarata
- ERC/Faculty of Graduate Studies, University of Colombo
- ERC/Faculty of Medicine – Ruhuna
- ERC/Faculty of Dental Sciences – Peradeniya
- ERC/Faculty of Medicine – Eastern University.

Most of the ERCs are recognized by the WHO Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) network *(29)*.

2.4.1 Ethics Review Committee of the Institute of Indigenous Medicine (ERC/Institute of Indigenous Medicine)

ERC/Institute of Indigenous Medicine (ERCIIM) is one of the oldest and main ERCs engaged with the ethical clearance process for the traditional systems of medicine in Sri Lanka since 2011 *(20)*. The postgraduate section of the Institute of Indigenous Medicine, University of Colombo, established ERCIIM in 2011 to approve the research projects in indigenous/Ayurveda/traditional systems of medicine to ensure the validity and quality of research.

Various professionals in Ayurveda, indigenous and scientific sectors have to meet the same level of rigor as all researchers. Obtaining ethics clearance and approval from the ERC regulates existing TM research and encourages candidates, who intend to engage in research activities in the field of traditional systems of medicine in Sri Lanka, to meet high standards. ERCIIM submission process and

guidelines have been formulated to ensure that biomedical research proposals, involving human participants, tissue, data and animals used in research in Ayurveda/traditional/indigenous systems of medicine in Sri Lanka, meet international standards.

The objectives of the ERCIIM are to:

- protect the mental and physical welfare, rights, dignity and safety of human participants and animals used in research;
- facilitate ethical research by effective and efficient review and monitoring processes;
- review research in accordance with national and/or local regulations as well as with the World Health Organization's good clinical practices guidelines; and
- promote evidence-based biomedical research for upgrading the Ayurveda/traditional/indigenous and integrated systems of medicine to ensure safety and rights of research participants, researchers and the general public.

ERCIIM maintains a quality review process and is affiliated with the Forum for Ethics Review Committees in Sri Lanka. It adheres to international and national ethics guidelines. In 2019, ERCIIM was accredited by the Ministry of Health, Nutrition and Indigenous Medicine in Sri Lanka. ERCIIM maintains its own trial registry.

2.5 International and national clinical research guidelines and reports

The following international and national guidelines are adhered to when conducting clinical research.

Table 2. *Key international guidelines and reports*

1964	Declaration of Helsinki (last updated in 2013)
1978	The Belmont report (USA) *(30)*
1995	Clinical safety data Management: Definitions & standards for expedited reporting: ICH harmonized tripartite guideline *(31)*
1996	ICH harmonized tripartite guideline for good clinical practices *(32)*
2002	International ethical guidelines for biomedical research involving human subjects (Council for International Organizations of Medical Sciences – CIOMS)
2005	ICH harmonized tripartite guidelines (updated)
2011	Standards and operational guidance for ethics review of health-related research with human participants (WHO) *(33)*
2013	EFGCP guidelines on medical research for and with older people in Europe

Local

- Ethics review committee guidelines – FERCSL – 2007 *(34)*
- Guidelines for ethics review of research proposals involving animals in Sri Lanka – FERCSL – 2009 *(35)*

2.6 Main institutions in Sri Lanka involved in TM research and development, policy-making and grants

2.6.1 Bandaranaike Memorial Ayurvedic Research Institute

The Bandaranaike Memorial Ayurvedic Research Institute (BMARI), which was established in October 1962, functions under the jurisdiction of the Ministry of Health, Nutrition and Indigenous Medicine. BMARI is the National Centre of Excellence in Medical Research related to Ayurveda, Siddha, Unani and other medicinal systems identified by the institute. BMARI has implemented a project with the main focus on four noncommunicable diseases prevalent in Sri Lanka (cardiovascular diseases, chronic kidney diseases with known and unknown etiology, cancer and diabetes) and one communicable disease (dengue). However, it is also expected to pay attention to other important fields, if and when the BMARI research committee finds it necessary to invedstigate any particular area of concern. Special attention will also be paid to endorse health research regulatory processes, collaborative links with stakeholders and health research ethics.

2.6.2 Coordinating Secretariat for Science, Technology and Innovation

The Coordinating Secretariat for Science, Technology and Innovation (COSTI) was established on 1 February2013 as mandated by a Cabinet decision of 9 September 2011 with the specific aim of coordination and monitoring of science, technology and innovation activities in the country. It is expected to work towards promoting value addition and commercialization in line with the National Science Technology and Innovation (STI) Strategy of Sri Lanka, approved by the Cabinet in August 2010.

2.6.3 Industrial Technological Institute

The Industrial Technological Institute (ITI) is a wholly-owned institute of the Government of Sri Lanka that functions under the jurisdiction of the Ministry of Science, Technology and Research. It is a statutory board incorporated on 1 April 1998, under the Science and Technology Development Act No. 11 of 1994 and, as per its mandate, the objective of ITI is to elevate the level of technology in Sri Lanka to that required for rapid industrialization. ITI supports the industry by undertaking contracts on testing, investigation and research for improving product quality, technical processes and methods used in industry, and for discovering new processes and methods to be used in the industry.

2.6.4 National Science and Technology Commission

The National Science and Technology Commission (NASTEC) is the apex policy-formulating and advisory body to the Government of Sri Lanka on science and technology matters. Created by an Act of Parliament, NASTEC started operating in August 1998. NASTEC is most effective in prioritizing areas of national importance with regard to science and technology and advising the government on the rational allocation of funds for research and development. Many countries such as India and China have made enormous strides in national development through timely and appropriate interventions of research and development. Realizing the important role that R&D activities can play in the development of its economy, Sri Lanka formulated a medium-term Research and Development Framework. NASTEC, working under the instructions of the Ministry of Science, Technology and Research, has been accorded the leadership role in this endeavour.

Main objectives of the framework are:

(1) enhancing the quality of life of the people of the country;

(2) enhancing the economic development of the country; and

(3) laying the foundation for Sri Lanka to become a scientifically and technologically advanced nation while preserving its environment.

The formulation process commenced with the identification of focus areas that need immediate R&D interventions and appropriate interventions that may be executed with regard to the identified focus areas. The 10 focus areas identified are:

(1) Water

(2) Food, agriculture and nutrition

(3) Health

(4) Shelter

(5) Environment

(6) Energy

(7) Mineral resources

(8) Apparel industry

(9) ICT and knowledge services

(10) Basic sciences, emerging technologies and indigenous knowledge.

Although Sri Lanka has earned a place well above the other countries in South Asia with regard to important health indicators, noncommunicable diseases (NCD) such as diabetes, cancer, ischaemic heart disease and chronic kidney diseases are on the rise. The need to address the high burden of NCD as well as control and management of vector-borne diseases and re-emerging tropical diseases such as dengue is discussed at length. Special attention has been paid to exploiting the potential of readily available indigenous knowledge and herbal resources to develop drugs through proper research and development.

2.6.5 National Health Research Council

The National Health Research Council functions as an advisory body to the Education, Training and Research (ET&R) unit of the MoH to promote health research in Sri Lanka. NHRC consists of 15 members, including representatives from six medical faculties of Sri Lanka, Sri Lanka Medical Association and Post Graduate Institute of Medicine and officials from the Ministry of Health. Awarding of NHRC research grants is one of the major activities performed by the council. Research proposals submitted for funding are scrutinized for suitability by the NHRC and grants are made available for the approved proposals through the consolidated fund of the Ministry of Health.

2.6.6 National Intellectual Property Office

The National Intellectual Property Office of Sri Lanka (NIPO), established under the Intellectual Property Act No. 36 of 2003, is mandated with the administration of the intellectual property system in Sri Lanka. Main functions of the NIPO include administration of intellectual property, collection and dissemination of intellectual property information and promotion of the use of intellectual property system in the development process by the intellectual property owners, enterprises and industries.

2.6.7 National Research Council

The National Research Council (NRC) was established under the Ministry of Science, Technology and Research to plan and coordinate the research efforts of researchers and facilitate their research in public-sector, scientific research and development organizations in Sri Lanka so that the country can benefit from a vibrant research community. NRC has a wide range of activities that brings together academics and professionals from across the country and ensures public and private sector participation in achieving scientific advance through collaborative research. NRC is the apex body for government research funding in Sri Lanka.

2.6.8 National Science Foundation

National Science Foundation (NSF), a state-funded institution under the Ministry of Science, Technology and Research, was established in 1998 by Act No. 11 of 1994 as the successor to the Natural Resources Energy & Science Authority of Sri Lanka (NARESA). The National Science Foundation is mandated to serve and strengthen the science and technology sectors in Sri Lanka and its activities conform to the National Science & Technology Policy. Accordingly, NSF facilitates research, development and innovation to create a knowledge economy. It also facilitates capacity-building, infrastructure development, technology transfer, knowledge creation and sharing in all fields of science and technology to improve the quality of life of people.

2.6.9 Postgraduate Institute of Indigenous Medicine

The Postgraduate Institute of Indigenous Medicine (PGIIM) Ordinance No. 5 of 2017 was established by an order passed by the Ministry of Higher Education under Section 24A (1) of the Universities Act, No. 16 of 1978, and published in the Gazette Extraordinary No. 2031/38 of 2017. PGIIM is attached to the University of Colombo, Sri Lanka. PGIIM provides training and research in the Ayurveda, Siddha and Unani systems of medicine.

3

A Scoping Review of Traditional medicine research in Sri Lanka (2015–2019)

3.1 Background

Traditional medicine has the potential to play a key role in the global management of chronic diseases and preventative medicine. Lack of high-quality evidence for traditional medicine interventions is a barrier to wider utilization. However, the movement towards evidence-based medicine is not always considered congruent with the way TM systems are practised. Typically, TM diagnosis and treatment are individualized to address a patient's unique presentation of symptoms. Nonetheless, a body of scientific evidence supporting TM is emerging in countries such as Sri Lanka.

The purpose of this scoping review was to explore the breadth of TM research in Sri Lanka, map and summarize the evidence, and inform future research. A scoping review takes a broader focus than a systematic review and may include not only randomized controlled trials, but also quasi-randomized, observational studies and case reports (case studies and case series) *(36)*.

3.2 Review methodology

The objective of this scoping review was to:

(1) understand the diseases or conditions that are being investigated in TM research in Sri Lanka;

(2) provide insight into the types of interventions; and

(3) gain an overview of study types and reporting.

3.2.1 Data sources

A comprehensive search for studies conducted between January 2015 and November 2019 was undertaken. WHO commissioned this report and recommended to review the research activities carried out over the last 5 years. The following sources were searched:

(a) PubMed, Cochrane-controlled Trials Register (CENTRAL) (https://www.cochranelibrary.com/), Sri Lanka Clinical Trial Registry (https://slctr.lk/), WHO International Clinical Trials Registry Platform (ICTRP) (http://apps.who.int/trialsearch/), the Cumulative Index to Nursing and Allied Health Literature and Web of Science were searched.

(b) Grey literature search included hand-searching the e-repositories of the universities and institutions in Sri Lanka for dissertations, theses, conference abstracts and proceedings, and key Sri Lankan journals. The institutions searched included University of Colombo, Institute of Indigenous Medicine, Gampha Wickramarachchi Ayurveda Institute, University of Peradeniya, University of Jaffna, University of Sri Jayewardenepura, Eastern University, University of Kelaniya, Sir John Kotelawala Defence University and Open University, Bandaranayke Memorial Ayurveda Research Institute and Institute of Indigenous Medicine, University of Colombo.

(c) Clinical trial registries were searched. These included the Sri Lankan Clinical Trials Registry (SLCTR) and the International Standard Randomized Controlled Trial Number (ISRCTN) (https://www.isrctn.com/).

An example of search strategy from PubMEDsearch is provided in Table 3. Grey literature was searched by the research team. Search results were managed in Excel.

Table 3. *Example search strategy – PubMed (including Medline)*

Search:	
#1	(("complementary therapies"[MeSH Major Topic] AND (humans[Filter])) OR (("medicine, ayurvedic"[MeSH Major Topic]) OR ((("herbal medicine"[MeSH Major Topic]) OR (traditional medicine[Title/Abstract])) OR (((((Ayurved*[Title/Abstract]) OR (siddha[Title/Abstract])) OR (unani[Title/Abstract])) OR (chikitsa[Title/Abstract])) OR (desheeyachikitsa[Title/Abstract]))))
#2	((("sri lanka"[Affiliation]) OR (ceylon[Affiliation])) OR (colombo[Affiliation])) OR (BMARI[Affiliation])
#3	#1 AND #2 Filters: Humans

3.2.2 Inclusion criteria

Studies were included if they:

(1) involved a traditional medicine intervention (Ayurveda, Unani, Siddha, *Desheeya Chikitsa* or other traditional medicine system); and

(2) were conducted in Sri Lanka (including multicentre studies conducted in collaboration with other countries).

Types of studies included were systematic reviews, randomized controlled trials, quasi-randomized, case control, case series and observational studies.

We included studies if these were available as full papers published in scientific journals (available as e-copies); full paper articles published in Sri Lankan journals but not available online (retrieved as hard copies from the relevant libraries); conference abstracts (with adequate details for inclusion); and PhD, MPhil, MD and MSc academic work, in thesis or dissertation formats, available at higher education institutes in Sri Lanka (retrieved as e-repositories or from relevant university libraries). Studies were restricted to those published in English, Sinhalese and Tamil. We included studies that appeared on the registry during the scoping review window but were published after November 2019.

We excluded laboratory-based studies on the molecular, chemical or pharmacological properties, in-vitro studies and animal studies.

3.2.3 Screening

Titles and abstracts of electronic databases were identified by KP and SG. Identified articles in grey literature were screened by KP. Full text articles were screened by KP and SG. In the case of abstracts, if enough information was included for a decision to be made using the eligibility criteria, abstracts were evaluated for inclusion.

3.2.4 Limitations

This scoping review was limited by the currency of Sri Lankan e-repositories. E-repositories had not been updated continuously during the review period, and hence, some papers may not have been recorded. In some instances, theses and dissertations were not available electronically or could not be located in hard copies and could not be included in the review. Case reports were retrieved by in-person visits to key institutions. Due to the COVID-19 restrictions in 2020, we were unable to return to extract any additional data required.

Many clinical research studies are not indexed to the country where they were conducted. As such, we were limited to searching according to author affiliation.

3.2.5 Data extraction

Two reviewers independently screened results and selected studies. Any disagreements were resolved by consensus. A data extraction spreadsheet was used by KP and SG. Extraction was undertaken independently, results discussed and updated in an iterative process. We extracted key characteristics of studies, including study design, disease/condition, intervention, control, sample size, outcome measures and publication source. An assessment of methodological limitations or risk of bias of the evidence included within a scoping review was not undertaken as it was not relevant to the objectives of the scoping review.

3.2.6 Data presentation

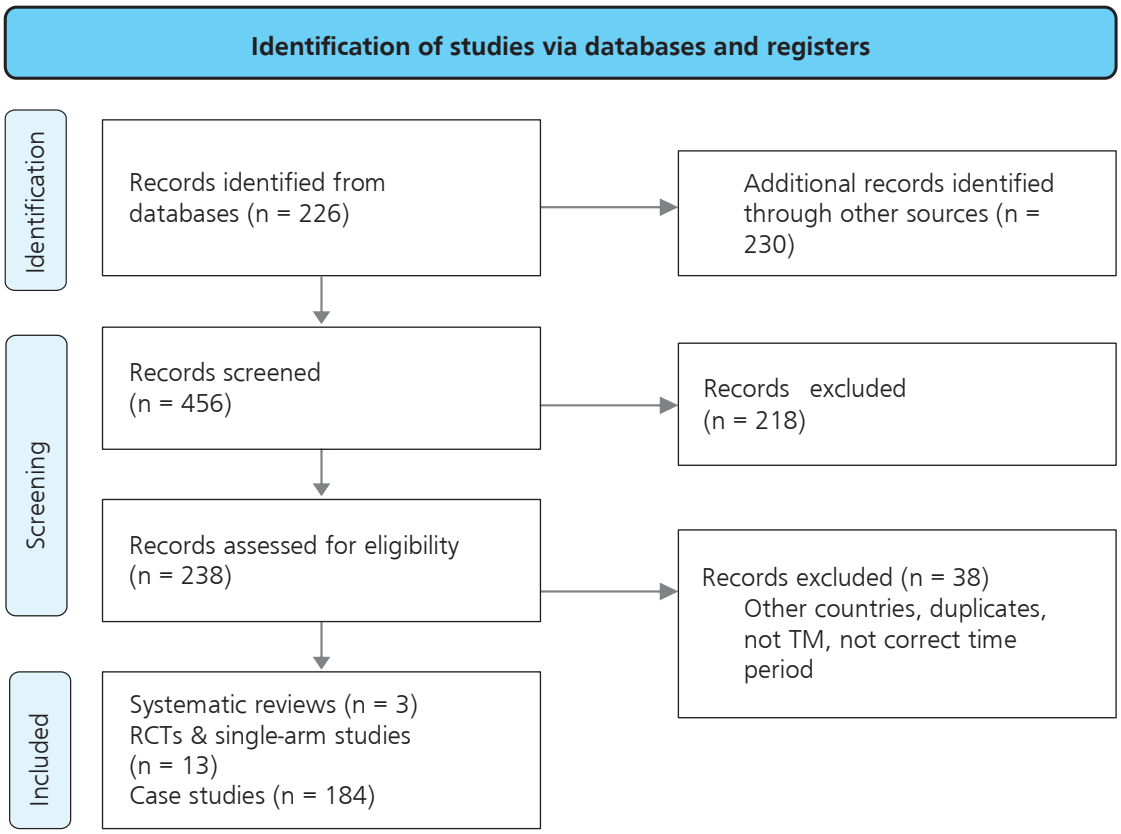
A descriptive approach was adopted to summarize the study characteristics. Figures were used to show the spread across Ayurveda, Siddha and Unani interventions, categories of diseases, intervention methods, control methods and outcomes, including Ayurveda-related indicators or not, research purposes and study designs.

Journals were considered against the SCRImago Q ranking, which defines the rank of that journal in the specific subject field (SJR: SCImago Journal & Country Rank, http://www.scimagojr.com). For example, a Q1 journal is in the top 25% of its field and Q2 is in the top 50% of its subject field. In other words, these are journals that are most cited in their subject categories and can be considered a metric of impact of the research.

3.3 Results

A total of 456 papers were identified for clinical research and case reports. The searching of grey literature provided the bulk of case reports.

Fig. 3. *PRISMA flow diagram for scoping review*



3.3.1 Systematic reviews

Three systematic reviews were identified, two of herbal interventions and one of yoga *(37–39)*.

Jayawardena et al. examined the effects of yoga compared with exercise in the management of type 2 diabetes. The review included eight RCTs and was published in a Q2 journal. None of the studies included were conducted in Sri Lanka. Both interventions were effective.

Rajapakse et al. reviewed *Carica papaya* extract for dengue fever and it was published in a Q1 journal. Nine RCTs were included, none of which had been conducted in Sri Lanka. Study quality prevented a clear conclusion and the clinical value of *Carica papaya* extract improvement in platelet count or early discharge was unclear in the absence of more robust indicators of favourable clinical outcome.

Ranasinghe et al. reviewed the medicinal benefits of *Cinnamomum zeylanicum* and included 70 studies. The review was published in a Q1 journal. None of the studies included had been conducted in Sri Lanka.

3.3.3 Randomized controlled trials and single-arm studies

We included 13 randomized controlled trials, a single-arm safety study and a single-arm pre-test-post-test study. Interventions and conditions included four studies in metabolic conditions (diabetes), two studies in digestive disorders (gingivitis and peptic ulcers) and three studies in women's health (dysfunctional uterine bleeding and polycystic ovarian syndrome). All of the published clinical trials had achieved ethics review approval prior to the commencement of the trials. We included any study that had preliminary results published and a single study protocol *(40)*.

Study interventions included complex, fixed Ayurvedic formulas, commercial products, pastes and single herbs. For the 13 RCTs, study controls were active interventions (n = 7), placebo (n = 2) or no interventions (n = 4). There were no individualized or semi-standardized studies.

All of the clinical trials clearly mentioned the study setting and used inclusion and exclusion criteria. Some of the published trials mentioned the method used for sample size calculation. All of the trials included the baseline assessment. Primary outcomes and secondary outcomes were clearly mentioned in most of the trials. Few published trials included data handling and record-keeping methods in their protocols. Most of the trials were conducted by postgraduate researchers and trials were funded by government-based organizations. Funds were granted by the University Grants Commission (UGC), and NSF, Sri Lanka. Other trials were funded by private organizations or conducted in individual interests.

Ten published clinical trials adhered to accepted methods in randomization in RCTs. Randomization methods included randomization sequence generated using an online randomization website (www.randomisation.com); block randomization method; and in two studies, individually sealed opaque envelopes were used *(41,42)*.

Five studies were published in peer-reviewed journals (Table 5). Four of these studies were in journals with a SCRImago Q ranking. Most studies were published in conference proceedings or journals with low impact.

Table 4. *Study conditions and interventions*

Author	Condition	ICD-11	Intervention #1/intervention #2/control	Primary outcome measures
(Anuruddhika Subhashinie Senadheera, Ekanayake, & Wanigatunge, 2015)	Diabetes	Metabolic	3. Commercially produced *Scopariadulcis* porridge (SDC) 3x/weeks 4. None	FPG; HbA1c
(Dahanayake et al., 2020a)*	Allergic rhinitis	Respiratory	1. *Tamalakyadi* decoction 120 ml 2x/day 2. Freeze dried *Tamalakyadi* decoction, dissolved in water 120 ml 2x/day 3. Loratadine 10 mg 1x/day	Total Nasal Symptom Score (TNSS)
(Ediriweera, Perera, Perera, Peshala, & Edirisinghe, 2015)	Acne	Skin	1. *Manjistadiya* paste: (*Rubiacordifolia, Coriandrum sativum, Santulum albam, Kokoona zeylanica, Curcuma aromatic, Coscinium fenestratum*) 2. Placebo paste	Eruptions, pain, tenderness
(Ekanayaka, Rupasinha, Sooriyarachchi, & Goonaratna, 2017)	Hyperlipidemia	Metabolic	1. *Swasthathriphala* (*Terminalia chebula* 318 mg, *Terminalia bellerica* 105 mg and *Phyllanthus emblica* 211 mg) plus *atorvastatin* 2. Placebo plus *atorvastatin*	Serum lipids
(Hafeel, Mobeen, Rizwana, & Yasir, 2017)	Peptic ulcer	Digestive System	1. Powder (*Aloe barbadensis Linn., Astragalus sarcolla Dymock., Boswellia serrata Roxb., Glycyrrhiza glabra Linn. and Commiphora myrrha Engl*), 4 g 3x daily	Number andsize of ulcers in UGIT Endoscopy findings
(Howshigan, Perera, Samita, & Rajapakse, 2016)	Gingivitis	Digestive System	1. *Sudantha*, Ayurvedic toothpaste 2. Placebo toothpaste	Quigley Hein plaque index (PS), bleeding on probing (BOP) and probing pocket depth (PPD)
(Karunanayaka, Hettihewa, Silva, & Karunanayaka, 2018)	Hand hygeine	N/A	1. Various alcohol and non-alcohol hand scrubs	Antimicrobial efficacy measured by counting the number of microbial colonies using a colony counter (24 hours after applying the formula/ control)

Author	Condition	ICD-11	Intervention #1/intervention #2/control	Primary outcome measures
(Kumarapeli, Karunagoda, & Perera, 2018)	Polycystic ovarian syndrome	Endocrine	1. *Satapushpa-Shatavari* Powder (SSP), 5 g orally + 10 ml cow ghee 2. *Satapushpa-Shatavari Grita* (SSG), 60 ml as enema 3. Both enema and powder	Reduction in ultrasound volume, hirsutism and menstruation improved
(Pallie, Perera, Goonasekara, Kumarasinghe, & Arawwawala, 2020)	Diabetes	Endocrine	1. 120 mL of *Tragiainvolucrata L.* decoction 2x/day 2. 500 mg of metformin	FPG, HbA1c
(H. Perera, Karunagoda, Perera, Samarasingha, & Arawwawala, 2017)	Dysfunctional uterine bleeding	Genitourinary	1. *Bumyamalaki* (*Phyllanthus niruri.)* 2. *Pushyanuga Churna*	Hb%, BT, CT platelet, endometrial thickness
(Rajavarthani S et al, 2018)	Rheumatoid arthritis	Musculoskeletal system	1. *Rasnasapthakaya* decoction plus dried ginger powder (dissolved), 120 ml 2x/daily 2. *Rumalaya* tablet 500 mg 2x/daily	PRIMARY: Full blood count, ESR, rheumatoid factor (RF)
(VPS Seneviratne, Hapuarachchi, Perera, & de Zoysa, 2017)	Selected cognitive functions	Nervous system	1. *Centellaasiatica* caplets (500 mg) 1x/day 2. *Gotukola* caplets same dose with cow's milk	Change in MMSE and Montreal–Cognitive Assessment (MoCA) scores
Varnakulendren N (2018)	Anaemia	Blood	1. *Ayabirungarajakarpam* (ABK) capsule 500 mg with lime juice twice per day for 48 days	
(Weerakoon, Perera, Gunasekera, & Suresh, 2016)	fever	Safety	2. *Sudarshana* (Phase I study)	Healthy volunteers did not report any adverse effects or any other complications during treatment and follow-up
Weerakoon WASS, Dulani Gunasekara	fever	Infectious or parasitic	1. *Sudashana* suspension 312.5 mg/kg/24 hrs 2. *Sudarshana* powder (Phase II study)	

Notes: *protocol only

Table 5. *Study characteristics*

Author	Journal/Conference	Journal	Sample	Study design	Blinding	Length of study
(Anuruddhika Subhashinie Senadheera et al., 2015)	BMC CAM	Q1 (CAM)	35	RCT crossover	None	3 months
(Dahanayake et al., 2020b)	Protocol published/conference proceedings*	Q1	70/70/70	RCT open label	None	14 d
(Ediriweera et al., 2015)	*Journal of Ayurveda Holistic Medicine*	Not listed	60	RCT	None	30 d
(Ekanayaka et al., 2017)	*Ceylon Med J*	Q3 (Medicine, misc.)	198	RCT	Double	3 mths
(Hafeel et al., 2017)	*International Journal of Current Advanced Research*	Not listed	22	Pre-test-post-test	None	30 d
(Howshigan et al., 2016)	*Ceylon Med J*	Q3 (Medicine, misc.)	66	RCT	Single	6 mths
(Karunanayaka et al., 2018)	International Symposium on Ayurveda and indigenous medicine (ISAIM 2018)	Conf.	330	RCT	Single	1 d
(Kumarapeli et al., 2018)	*International Journal of Pharmaceutical Sciences and Research*	Not listed	60	Open label RCT	Single	
(Pallie et al., 2020)	Clinical Trials in Degenerative Diseases	Not listed	36/36	RCT comparative effectiveness	None	14 d
(H. Perera et al., 2017)	The Secretariat of ICAUST–2015 and AYU EXPO	Conf.	60	RCT	Single	16 wks
(Rajavarthani S et al, 2018)	Conference proceedings	Conf.	30	RCT	None	14 d
(VPS Seneviratne et al., 2017)	Proceedings of the Tradmed International Symposium	Conf.	30/30	Open label, RCT	None	12 wks
Varnakulendren N (2018)	Thesis only	N/A	116	Pre-test-post-test	None	90 d
(Weerakoon et al., 2016)	Proceedings of the Second International Conference on Natural Products Genomics	Conf.	35	safety	None	
Weerakoon WASS, Dulani Gunasekara	Thesis only	Not listed	42	RCT	None	3 d

Note: *This study was located as an abstract from conference proceedings in 2019. However, the complete study protocol was published in 2020 and has been included as a more complete reference here.

3.3.4 Studies listed on WHO registries and ERC

There were 19 trials listed on the Sri Lankan Clinical Trials Register (SLCTR) and/or the ISRCTN between January 2015 and November 2019, regardless of status, related to herbal medicines. ISRCTN is a clinical trial registry recognized by WHO and International Committee of Medical Journal Editors (ICMJE) that accepts planned, ongoing or completed studies of any design. All SLCTR studies are automatically registered on ISRCTN. Progress reports were inconsistently available on the database to provide clarity on which studies may have been abandoned. Of those studies that were located on the clinical trial registries, seven RCTs have not clearly mentioned masking in their protocols. Six trials described using single blinding, six double blinding methods and some were open label trials (Table 7).

Most (73%) of the research studies registered on WHO-accepted trial registries used a randomization design and appeared to meet accepted trial standards (Tables 6 and 7). Among these, three trial protocols were published in accepted peer review journals before starting the trial. One published trial protocol used a "double classification" method where subjects primarily met Western diagnostic criteria and then were further classified according to the Ayurveda system. Two protocols were published in a journal and followed the requirements of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement *(42)*. Within those studies on the clinical trial registries, clear efforts were evidently made to follow the CONSORT (Consolidated Standards of Reporting Trials) guidelines (http://www.consort-statement.org/).

Table 6. *Sri Lankan herbal drug trials registered on WHO-accepted trial registries*

Ethics committee	Research title	Condition	Registration	Status
University of Jayewardenepura	A phase I study of the safety, possible toxicity of a novel Ayurvedic preparation, *Sudarshana* suspension	Safety	SLCTR/2015/005	Complete
University of Jayewardenepura	A phase I study of the possible toxicity of the Ayurvedic preparation, *Rasnasapthakaya*	Safety	SLCTR/2015/006	Complete
University of Jaffna	Hypoglycaemic and antioxidant activity of the Siddha medical preparation, *Mathumehachooranam*, in patients with diabetes mellitus	Diabetes	SLCTR/2015/008	Recruiting
University of Ruhuna	The efficacy of *Costusspeciosus* leaves on the postprandial glucose surge in healthy subjects; a clinical trial	Diabetes	SLCTR/2015/011	Withdrawn
University of Kelaniya	A randomized control trial of virgin coconut oil in the treatment of Alzheimer's dementia (VCO–AD study)	Dementia	SLCTR/2015/018	Partially complete (F/Up)

Ethics committee	Research title	Condition	Registration	Status
University of Ruhuna	Phase II clinical trial – the effects of extract of *Costusspeciosus* (*thebu*) on hepatic insulin resistance and biochemical profile of patients with non-alcoholic fatty liver disease	NAFL	SLCTR/2015/019	Recruiting
University of Jayewardenepura	Therapeutic evaluation of the antipyretic activity of the Ayurvedic preparation, *Sudarshana* suspension, in febrile children	Fever	SLCTR/2015/026	Complete
University of Jayewardenepura	A phase II/III study of the anti-inflammatory activity of *Rasnasapthakaya* decoction in patients with rheumatoid arthritis	Rheumatoid arthritis	SLCTR/2015/028	Complete
University of Jaffna	Supplement effect of *Cherukurinja* (*Gymnemalactiferum*) on glycemic control and on selected biochemical and physiological parameters among patients with type 2 diabetes mellitus	Diabetes	SLCTR/2016/007	Recruiting
University of Colombo	Effectiveness of *Cinnamomum zeylanicum* (Ceylon cinnamon) in lowering blood glucose in type 2 diabetes mellitus: arandomized double-blind placebo controlled clinical trial	Diabetes	SLCTR/2017/010	Recruiting (protocol)
University of Jaffna	Efficacy of *Silymarin* (milk thistle fruit extract) compared to a placebo in improving liver fibrosis in patients with non-alcoholic fatty liver disease, a pilot study	NAFL	SLCTR/2017/016	Recruiting
Rajarata University of Sri Lanka	Effect of papaya (*Carica papaya*) leaf extract on plasma leakage and platelet count in dengue fever: a randomized controlled trial	Dengue	SLCTR/2017/034	Recruiting
University of Colombo	A randomized controlled trial to compare the efficacy of topical Ayurvedic oil preparation against placebo in symptomatic knee osteoarthritis	Knee osteoarthritis	SLCTR/2017/039	Recruiting

Ethics committee	Research title	Condition	Registration	Status
University of Ruhuna	Effect of a standardized herbal capsule of *Cocciniagrandis* (L.) *Voigt* on selected metabolic parameters in patients with type 2 diabetes mellitus: a randomized controlled trial	Diabetes	SLCTR/2018/012	Complete
IIM, University of Colombo	Compare the effects of two Ayurveda drug regimens on the treatment of uterine fibroids	Obstetrics and gynaecology	ISRCTN16108738	Complete (protocol)
IIM, University of Colombo	Comparing the effects of two Ayurveda drugs on the treatment of allergic rhinitis	Allergic rhinitis	ISRCTN18149439	Recruiting (protocol)
Rajarata University of Sri Lanka	Pharmacotherapeutic and physicochemical evaluation of *Ayabirungarajakarpam* – a poly herbometallic drug for *Paandu* –anaemia	Anaemia	SLCTR/2018/035	Complete
Ethics Review Committee, Medical Research Institute, Ministry of Health	Formulation and evaluation of the antimicrobial efficacy of novel alcohol-based and non-alcohol-based natural hand scrubs with medicinal plant extracts	Antimicrobial	SLCTR/2019/016	Complete
University of Ruhuna	Dietary behaviour of patients with urolithiasis and anti-urolithic effects of selected local fruits	Kidney	SLCTR/2019/031	Recruiting

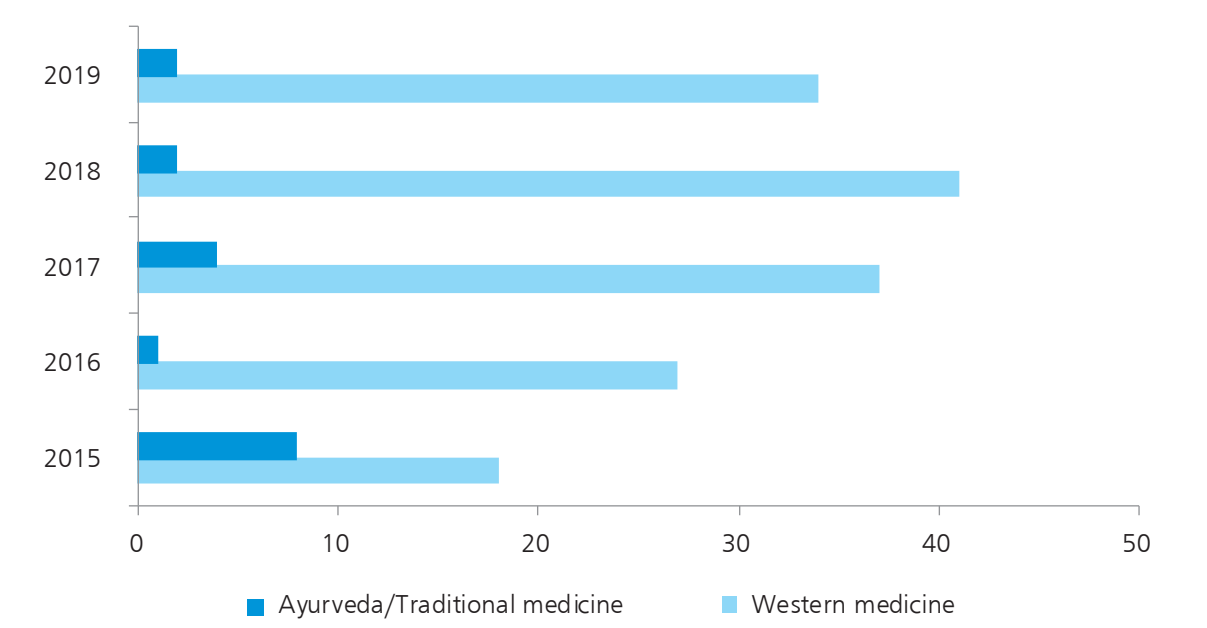
Table 7. *Study design methods used in trials registered on WHO-accepted trial registries*

	Method used	No. of trials (%)	The Sri Lanka Clinical Trials Registry (SLCTR) – Reference
Study type	Interventional	(19) 100	SLCTR/2015/005 SLCTR/2015/006; SLCTR/2015/008 SLCTR/2015/011; SLCTR/2015/018; SLCTR/2015/019; SLCTR/2015/026; SLCTR/2015/028; SLCTR/2016/007 SLCTR/2017/010; SLCTR/2017/016; SLCTR/2017/034 SLCTR/2017/039; SLCTR/2018/012; ISRCTN16108738; ISRCTN18149439; SLCTR/2018/035; SLCTR/2019/016; SLCTR/2019/031
Study design allocation	RCT	(14) 73.7	SLCTR/2015/011 SLCTR/2015/018 SLCTR/2015/019 SLCTR/2015/028 SLCTR/2016/007 SLCTR/2017/010 SLCTR/2017/016 SLCTR/2017/034 SLCTR/2017/039 SLCTR/2018/012 ISRCTN16108738 ISRCTN18149439 SLCTR/2019/016 SLCTR/2019/031
	Non-RCT	(5) 26.3	SLCTR/2015/026; SLCTR/2015/005; SLCTR/2015/006 SLCTR/2015/008; SLCTR/2018/035
Masking	Double blinded	(6) 31.6	SLCTR/2015/018 SLCTR/2015/019 SLCTR/2016/007 SLCTR/2017/010 SLCTR/2017/039 SLCTR/2018/012
	Single blind	(6) 31.6	SLCTR/2015/008 SLCTR/2015/011 SLCTR/2015/026 ISRCTN16108738 ISRCTN18149439 SLCTR/2019/016
	None	(7) 36.8	SLCTR/2015/005 SLCTR/2015/006 SLCTR/2015/028 SLCTR/2017/016 SLCTR/2017/034 SLCTR/2018/035 SLCTR/2019/031
Control	Placebo	(8) 42.1	SLCTR/2015/018 SLCTR/2015/019 SLCTR/2017/010 SLCTR/2017/016 SLCTR/2017/039 SLCTR/2018/012
	No control	(3) 15.8	SLCTR/2015/005 SLCTR/2015/006 SLCTR/2018/035
	Standard therapy	(6) 31.6	SLCTR/2015/008 SLCTR/2015/028 SLCTR/2017/034 ISRCTN16108738 ISRCTN18149439 SLCTR/2019/031
	Active	(2) 10.5	SLCTR/2019/016 SLCTR/2016/007
Assignment	Single	(3) 15.8	SLCTR/2015/006 SLCTR/2015/008 SLCTR/2018/035
	Parallel	(11) 57.9	SLCTR/2015/011 SLCTR/2015/018 SLCTR/2015/026 SLCTR/2015/028 SLCTR/2015/028 SLCTR/2016/007 SLCTR/2017/034 SLCTR/2018/012 ISRCTN16108738 ISRCTN18149439 SLCTR/2019/031

	Method used	No. of trials (%)	The Sri Lanka Clinical Trials Registry (SLCTR) – Reference
Purpose	Treatment	(13) 68.4	SLCTR/2015/008 SLCTR/2015/018 SLCTR/2015/019 SLCTR/2015/026 SLCTR/2015/028 SLCTR/2017/010 SLCTR/2017/016 SLCTR/2017/034 SLCTR/2017/039 SLCTR/2018/012 ISRCTN16108738 ISRCTN18149439 SLCTR/2018/035
	Other	(2) 10.5	SLCTR/2015/005 SLCTR/2019/016
	Basic science	(2) 10.5	SLCTR/2015/011 SLCTR/2016/007
	Health services	(1) 5.3	SLCTR/2019/016
	Prevention	(1) 5.3	SLCTR/2019/031

During the five-year period of this review, 157 (90%) clinical trials on the Sri Lanka Clinical Trials Registry were for Western medicine (Fig. 4). Research relating to indigenous medicine/Ayurveda comprised the remaining 10%.

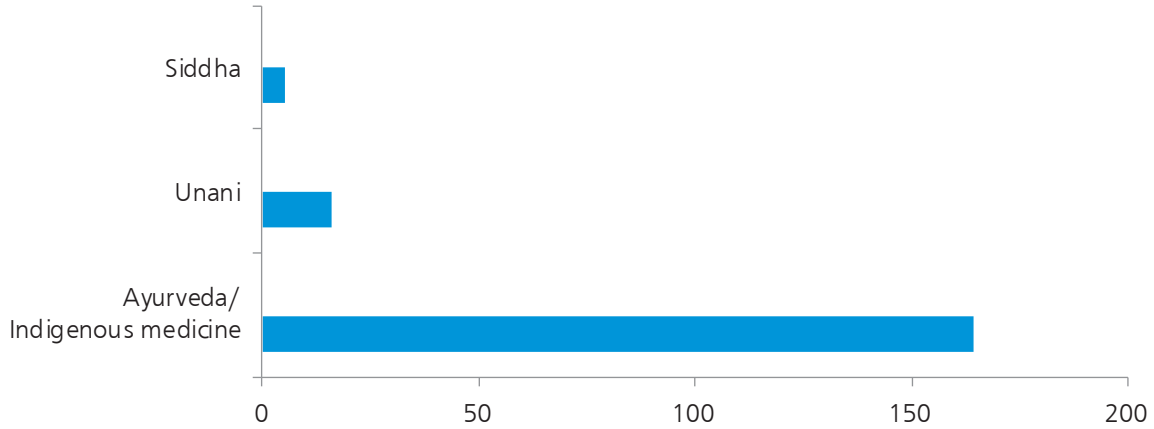
Fig. 4. *Overview of clinical trials registered on the Sri Lankan Clinical Trial Registry in each sector (20 January 2015 to 10 November 2019)*



3.3.5 Case reports: Case series and case studies

There were 184 case control, case studies and case series undertaken to examine the use of TM in a wide variety of diseases and conditions during 2015–2019 (Table 8). The bulk of these were published as posters or conference proceedings and few in peer-reviewed, indexed journals. Of the 186 studies, few articles were published in international peer-reviewed journals. Nearly 88.7% case studies and case series (Fig. 5) were conducted on Ayurvedic medicine with only 8.6% on Unani and 2.7% on Siddha medicine.

Fig. 5. *Comparison of case studies/case series by different TM systems in Sri Lanka during 2015–2019*



The majority of case reports included traditional *panchkarma* therapies such as the use of herbal oils, body treatments (including oil massage), steam therapy, herbal paste therapy, nasal therapy, vomiting therapies, enema therapy and purgation therapies. For example, case reports included:

- *Kshara* is an Ayurvedic procedure, derived from a combination of various herbs, that is applied to the pile mass with the help of a special slit proctoscope.
- *Parisheka Sveda* is where a medicated liquid is to be poured over the desired part or the whole body.
- *Janu Vasti* is where the *janu* (knee) is subjected to a therapy called *vasti* (warm, medicated oil placed over the knee joint). *Vasti* denotes "a compartment that holds" (in this case, a pool of medicated oil).

The main conditions or diseases investigated in the case reports included skin, fractures and diabetes. Obesity and cardiovascular risk factors have also been the subject of a growing number of case studies (Fig. 6).

Table 8. *Characteristics of case studies and case series in Sri Lanka (2015–2019)*

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
An Ayurvedic approach in the management of Meniere's disease – A case study	(Abegunasekara, 2016)	Herb	Meniere's	Cardiovascular	Ayurveda
A clinical evaluation of the efficacy of "*shadbindutaila*" *nasya* in the management of "*grivasandigatavata*" (cervical spondylosis)	(Alwis & Silva, 2017)	*Nasya*	Cervical spondylosis	Musculoskeletal	Ayurveda
Use of Ayurveda and Sri Lankan traditional medicine for healing shaft of humerus fracture following nonunion	(A. Attanayake, De Silva, Jayaweera, & Perera, 2018)	Topical application	Fracture	Musculoskeletal	Ayurveda/ Indigenous medicine
Evaluation of the therapeutic effect of *triphalakatakanpata* decoction and assessing the quality of life among diabetes mellitus patients	(A. P. Attanayake, 2015)	Decoction	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda
Assessment of fracture healing following Ayurveda treatment in malunion distal radius comminuted fracture of wrist without removing the internal fixator: A case study	(A. P. Attanayake, 2016)	Topical application	Fracture	Musculoskeletal	Ayurveda
Healing effect of Sri Lankan traditional and Ayurveda medicine in comminuted fracture over shaft of tibia following nonunion: A case report	(A. P. Attanayake, Silver, & Jayaweera, 2017)	Topical application	Fracture	Musculoskeletal	Ayurveda
Evaluation of the clinical efficacy of *Heen Bowitiya* leaves [*Osbeckiaoctandra*] *phanta* in the management of diabetes mellitus	(Balasooriya, 2016)	Herb	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda
A case study on the management of haemorrhoidal prolapse	(Batvitha, 2018)	Herb	Haemorrhoids	Cardiovascular	Ayurveda
Application of *Kshara* in the management of fistula in ano: A case study	(Bavitha, 2018)	*Kshara* application	Fistula	Skin	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
A case study on assessment of Ayurveda treatment modality in adenocarcinoma in colon	(BMARI, 2017)	Herb	Cancer	Digestive	Ayurveda
An assessment of effectiveness of traditional and procedures for CKD by traditional practitioner of *Suwa Udana Weda Piyasa*	(BMARI, 2017)	Herb	Chronic kidney disease		Ayurveda/ Indigenous medicine
A study on effectiveness of traditional practices for CKD by traditional practitioner of Mahavilachchiya clinic	(BMARI, 2017)	Herb	Chronic kidney disease	Urological	Indigenous medicine
A case study on the efficacy of an Ayurveda drug regimen on clinical symptoms and selected biochemical parameters on chronic kidney disease patients	(BMARI, 2017)	Herb	Chronic kidney disease	Urological	Ayurveda
Clinical assessment of post dengue complications before and after Ayurveda treatments – case series	(BMARI, 2017)	Herb	Dengue fever	General unspecified	Ayurveda
Evaluation of therapeutic effect of *thriphalakatakana pata* decoction on diabetes melitus	(BMARI, 2017)	Decoction	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda
A case report on assessment of the fracture healing effect for green stick fracture without lateral angulation	(BMARI, 2017)	Topical application	Fracture	Musculoskeletal	Ayurveda
Evaluate the efficacy of an Ayurveda treatment regimen on *uttanavatarakta* – case study	(BMARI, 2017)	Herb	Gout	Endocrine/ Metabolic and nutritional	Ayurveda
Evaluation of therapeutic effect of a traditional herbal formula (DT6 powder) on hyperglycemia	(BMARI, 2017)	Herbal powder	Hyperglycemia	Endocrine/ metabolic and nutritional	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Case series on management of hyperlipidemia with polyherbal formulations	(BMARI, 2017)	Herb	Hyperlipidemia	Endocrine/ metabolic and nutritional	Ayurveda
Clinical study of "*meda Dhushta Lakshana*" before and after *vamana karma*	(BMARI, 2017)	Emetic	Lipid disorder	Endocrine/ metabolic and nutritional	Ayurveda
Effect of *El-Vireka*, *Mudgadi Kashaya* and *Triphala Udvartana* in *athisthaulya* (obesity) – A case study	(Chandrasiri & Ediriweera, 2019)	Decoction	Obesity	Endocrine/ metabolic and nutritional	Ayurveda
Evaluation of efficacy of *Sihin Midi* (*Premnaintegrifolia L.*) decoction in *athistaulya* (obesity) patients	(De Silva, Hapuarachchi, Harapathdeniya, & Perera, 2017)	Decoction	Obesity	Endocrine/ metabolic and nutritional	Ayurveda
Therapeutic efficacy of the decoction of *Premnaintegrifolia Linn* in the management of obesity (*athisthaulya*): A case study	(De Silva, 2018)	Decoction	Obesity	Endocrine/ metabolic and nutritional	Ayurveda
A clinical study comparing the efficacy of the decoctions of *Gaskaralheba* (*Achyranthesaspera*) and *Hathavariya* (*Asparagus racemosus*) in the treatment of *sraviarshas* (bleeding piles)	(Dissanayaka, 2017)	Decoction	Haemorrhoids	Cardiovascular	Ayurveda
Comparative clinical study on the efficacy of treatment for *sraviarshas* (bleeding piles) using the decoctions of *Rathkaralheba* (*Cyathullaprostrata*) and *Gaskaralheba* (*Acyranthesaspera*)	(Dissanayake, 2015)	Decoction	Haemorrhoids	Cardiovascular	Ayurveda
Effect of *Post e Anar* and *Safoof e Zaj* in *Hikkathul Farzj*: A preliminary study	(Farzana & Sultana, 2016)	1. Powder and pomegranate (*Punicagranatum L.*) decoction	*HikkathuFarzj* (Pruritis vulvae)	Female genital	Unani

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
A case study on *Varmghudadadarqiyyah* (thyroid swelling)	(Fazeenah, 2018)	Herb	Goitre	Endocrine/ metabolic and nutritional	Unani
Evaluation of Unani treatment modality in myocardial infarction – case study	(Fazmiya & Sewwandi, 2017)	Herb	Myocardial infarction	Cardiovascular	Ayurveda
A prospective of modified Unani therapeutics for gallstone (*Hasat-e-Mirarah*) – case series	(Fazmiya, 2015)	Herb	Cholelithiasis	Digestive	Unani
A clinical study on the efficacy of *Sapta Winsati Guggulu* in the management of *sushkaarsa*	(Fernando, 2016)	Herbal pills	Haemorrhoids	Digestive	Ayurveda
Management of hyperlipidemia (*medhovruddhi*) with the use of Ayurvedic and traditional medicine: A case study	(Gamage, Welivitigoda, & Kisholorjan, 2017)	Herb	Lipid disorder	Endocrine/ metabolic and nutritional	Ayurveda
Management of *Avabhahuka* (frozen shoulder) through Sri Lankan Ayurveda treatment protocol: A case study	(Gunarathna & Kulathunga, 2019)	Herb	Frozen shoulder	Musculoskeletal	Ayurveda/ Indigenous medicine
Leech application for management of inflamed haemorrhoids: A case study	(Gunarathna, 2018)	Leech therapy	Haemorrhoids	Cardiovascular	Ayurveda
Clinical evaluation of *Sheeta Kashaya* of *Hibiscus furcatus* with and without *vamana karma* with *Linderniapusilla* in the cases of *prameha- madhumeha* (type 2 diabetes mellitus)	(Gunatilaka, Ediriweera, Weerasinghe, & Karunarathne, 2015)	*Himakasaya* (cold herbal decoction) + emetics	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda
Effectiveness of *Syzygiumcumini* (naval) root decoction of on diabeties mellitus (*mathumeaham*)	(Hasana, 2016)	Decoction	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda
Unani approach to paralysis (*falij*) – A clinical contrive	(Jabeen, 2017)	Herb	Hemiplegia	Neurological	Unani

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
A case study on effectiveness of dry cupping in frozen shoulder	(Jamaldeen & Rismiya, 2017)	Cupping	Frozen shoulder	Musculoskeletal	Unani/Cupping
Clinical efficacy and antibacterial activity of *Panchawalkala Avagaha* in the management of haemorrhoids	(Jayakody and Pushpakumara, 2017)	Sitzbath	Haemorrhoids	Cardiovascular	Ayurveda
A comparative study on the effect of *Bhadradi Niruha Vasti* and *Lekhanadi Churna* orally in the management of *atisthaulya* W.S.R.to obesity	(Jayalath, 2016)	Enema + oral herbal powder	Obesity	Endocrine/ metabolic and nutritional	Ayurveda
Effectiveness of *Dasanga Guggulu* in obesity	(Jayasinghe, 2016)	Herbal pills	Obesity	Endocrine/ metabolic and nutritional	Ayurveda
Clinical assessment of efficacy and safety profile of *Dasanga Guggulu* compared with *tripalachurna* in management of obesity	(Jayasinghe, Kulatunga and Ratnapala, 2017)	Herbal pills	Obesity	Endocrine/ metabolic and nutritional	Ayurveda
Integrated approach for managing adenocarcinoma of common bile duct – a case report	(Jayasundara, Kaluthotage et al. 2016)	Herbal decoction + herbal mineral drugs	Bile duct cancer	Digestive	Ayurveda/ Indigenous medicine
An experimental study on the effectiveness of traditional local application for knee joint contusion	(Jayawardhane, 2015)	Herb	Contusion	Musculoskeletal	Ayurveda
Assessment of the outcome of Ayurvedic treatments for vertebral fracture with motor dysfunction	(Jayaweera et al., 2018)	Herb	Fracture	Musculoskeletal	Ayurveda
Therapeutic effects of indigenous herbs and its impact on HIV/AIDS subjects	(Kamashi and Suguma, 2017)	Herb	HIV/AIDS	Blood, blood-forming organs and immune mechanism	Ayurveda/ Indigenous medicine

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Clinical study on the efficacy of the *Nikādi Taila* in the management of *Sñryāvarta*	(Karunarathna, 2015)	Topical application	Migraine	Neurological	Ayurveda
Study on effect and efficacy of leech therapy and *Vellangiriya* decoction in the management of migraine (*shirobhitapa*)	(Keerthirathne, 2016)	Leech therapy + decoction	Migraine	Neurological	Ayurveda
A case study on effect of Ayurvedic treatment in the management of gallbadder calculi	(Keerthirathne, 2018)	Herb	Gallstones	Digestive	Ayurveda
Clinical study on the efficacy of the specially prepared *Brihati* syrup in the management of dry cough (*vāta-pittajakāsa*)	(Kumara, 2015)	Herbal syrup	Cough	Respiratory	Ayurveda
A clinical case study to evaluate the efficacy of *Neelyadi* oil local application for partial fistulotomy followed by *Ksharasuthra* therapy in the management of *Bagandara* with special reference to fistula in ano	(Kumara, 2015)	Topical application	Fistula	Skin	Ayurveda
Introduction of new line of treatment regime on non-alcoholic fatty liver disease (NAFLD) (*yakruthdalyaudara*) – A case study	(Kumara, de Silva and Sakunthala, 2017)	Herb	Fatty liver	Digestive	Ayurveda
The assessment of the curing effect of *Thalaipeankollithailam* (herbal oil) on those affected by *thalaipean* (head louse)	(Kumutharanjan, 2018)	Topical application	Head lice	Skin	Siddha
Effectiveness of *mahavarthikava* pill on *escherichia coli*	(Liyanage, 2015)	Herbal pills	E. coli	Digestive	Ayurveda
Padanshika karma in the management of sudden withdrawal of *okasathmyaahiphena* addiction: A case study	(Liyanage, 2018a)	Herb	Drug abuse	Psychological	
Ayurvedic management of bipolar affective disorder: A case report	(Liyanage, Hettige et al. 2017)	Herb	Bipolar	Psychological	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Study the quality of life following *Kshara sutra* treatment for fistula in ano	(Madushani, 2016)	*Kshara* application	Fistula	Skin	Ayurveda
Intervention of weight reduction designed for obesity remedied on chronic and severe arthritis on both knees: case study	(Manuha, 2015)	Weight control	Obesity	Endocrine/ metabolic and nutritional	Ayurveda
Evaluation of therapeutic effect of *Madhumeharivati* on hyperglycaemia	(Mendis, 2016)	Herbal pills	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda
Hypoglycaemic effect of *Thebu* among hyperglycaemic patients	(Muthalib, 2016)	Herb	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda/ Indigenous medicine
Management of *Vicharchika* through Ayurveda: A case study	(Nilani, 2018)	Herb	Eczema	Eczema	Ayurveda
Pilot study of efficacy of single *Sevarathai* leaves for *Vellainoi–Leucorrhoea*	(Niruba, 2016)	Herb	Leucorrhoea	Female genital	Ayurveda
Effect of *Euphorbia hirta* on the management of constipation (*malakkaddu*)	(Paheerathan, 2015)	Herb	Constipation	Digestive	Ayurveda
Ayurvedic management of *myositis ossificans* of vastus lateralis muscle (*urusthamba*): A case study	(Paudel, Kumar and Gopikrishna, 2017)	Herb	Myositis	Musculoskeletal	Ayurveda
Evaluate the efficacy of a drug formula (*KL Choorna*) on proteinuria in chronic kidney disease (CKD) patients	(Perara, 2017)	Herbal powder	Kidney disease	Urological	Ayurveda
Clinical study of successful development in health tourism via *Shirodhara* treatment for anxiety, depression and insomnia	(Perera, 2016)	*Shirodhara*	Depression	Psychological	Ayurveda
Indigenous approach in the management of renal calculi (*muthrashmari*): A case report	(Perera, 2018)	Herb	nephrolithiasis	Urological	Indigenous medicine

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Clinical study of the effectiveness of prepared formula for the acne vulgaris	(Piyathilaka, Kumara et al. 2016)	Paste (*Coriandrum sativum, Acoruscalamus, Symplocus. Cochinchinensis, Saussurealappa*)	Acne	Skin	Ayurveda
Evaluation of the effect of *Hinguadilepa* in the management of *Khadara* (corns)	(Pramodani, 2015)	Topical application	Corn	Skin	Ayurveda
Clinical evaluation of *Tripaladi Udvartana* followed by *sarvangasweda* in the management of obesity (*sthaulya*)	(Pramodani, 2016)	*Udvarthana*	Obesity	Endocrine/ metabolic and nutritional	Ayurveda
A study on effect of *Nasya Karma* and *Thiladilepa* in treatment of *YuvanaPidaka* (acne vulgaris) – a case report	(Premasiri and Ediriweera 2018)	*Goyukola* (*Centellaasiatica*) *Nasya* + *Thiladilepa* paste (*Sesamum indicum* mixed with lime juice)	Acne	Skin	Ayurveda
A comparative study on the effect and efficacy of *mashabaladi* decoction oral and *mashabaladi* decoction *nasya* for *grivasandhigatavata* (cervical spondylosis)	(Priyadarshani and Samarakoon, 2017)	Decoction	Cervical spondylosis	Musculoskeletal	Ayurveda
A comparative clinical study on the effect of *Bhunimbhadi Ashtadashanga* decoction and *Dhanyaka Shunti* decoction on *vatajahridroga* (ischaemic heart disease)	(Priyadarshani, 2016)	Decoction	Heart disease	Cardiovascular	Ayurveda
Clinical evaluation of the efficacy of *Prathisaraneeya Kshara* in the management of haemorrhoids	(Rajapakse, 2018)	*Kshara* application	Haemorrhoids	Cardiovascular	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
The efficacy of the *Erandasaptakapantain* the management of *Kashtartava*	(Ranathunga, 2016)	Herbal tea	Menstruation scanty	Female genital	Ayurveda
A comparative clinical study on the effect of *Tripaladi* decoction & *Patoladi* decoction on *amlapitta*	(Ranaweera, 2016)	Decoction	GERD	Digestive	Ayurveda
A comparative clinical study on the effect of *Phalathrikadi* and *Hemadrumasyadi* decoctions on *Apathya Nimittaja Prameha* (type II DM)	(Ratnayake, 2016)	Decoction	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda
Efficacy of *Aegle marmaloes* half ripe fruit juice in dysentery – a case study	(Rayeeza, 2016)	Herb	Dysentry	Digestive	Ayurveda
Ayurveda treatment regime in the management of Guillon-Barré syndrome: A case study	(Rismiya, 2018)	Herb	Guillain-Barré syndrome	Neurological	Ayurveda
Preliminary case study on type 2 diabetes mellitus	(Rizwana and Hafeel, 2017)	Herb	Diabetes	Endocrine/ metabolic and Nutritional	Ayurveda
Management of *Murivu Nerivu* by traditional physician	(Sabesan, Ajila et al. 2015)	Herb	*Murivunerivu* (fracture and dislocation)		Ayurveda
A comparative study of the effect of *Ksharsutra Bandhan* (ligation) with rubber band ligation in the management of *arsha* (haemorrhoids)	(Sahave, 2015)	Kshara application	Haemorrhoids	Cardiovascular	Ayurveda
A case study on *Zof-e-Intishar* (erectile dysfunction) with a Unani external application	(Saja, 2015)	Topical application	Impotence	Male genital	Unani
A comparative clinical study on the efficacy of *Sinhasyadi* and *Chinnodbhawadi* decoctions on *Amlapitta* (GERD)	(Samarasinghe KAAL,2016)	Decoction	GERD	Digestive	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
A case study on lipoma with *Irsal-e-Alaq* (leech therapy)	(Samiya, 2015)	Leech therapy	Lipoma	Skin	Unani
Effect of traditional medicated past and *Othiyam Paddai Thailam* on fracture – a case study	(Saranya and Gowri, 2017)	Topical application	Fracture	Musculoskeletal	Siddha
A comparative effectiveness of *Apamargathikshnakshara* application and sclerotherapy in the management of *arsha* (first-and second-degree piles): PILOT study	(Shah, 2018)	*Kshara* application	Haemorrhoids	Cardiovascular	Ayurveda
Efficacy of Unani management modalities in congenital hypothyroidism – a case study	(Shifra, 2017)	Herb	Hypothyroidism	Endocrine/ metabolic and nutritional	Ayurveda
Topical application of paste on cutaneous corns in sole – case study	(Shiyamala and Varnakulendran, 2017)	Topical application	Corn	Skin	Ayurveda
Efficacy of combine drug therapy on carpal tunnel syndrome	(Shiyamala , 2015)	Herb	Carpal tunnel syndrome	Neurological	Ayurveda
Clinical study of the Unani compound medical preparation for antilipidaemic activity in hyperlipidaemic patients	(Sirajudeen, 2016)	Herb	Dislipidemia	Endocrine/ metabolic and nutritional	Unani
A comparative study of the efficacy of *Arka* (*Calotropisgigantia*) and *Apamarga* (*Achyrathusaspera*) *prathisaraneeyakshara* in the management of *pittajaarsha*	(Solohokara, 2018)	*Kshara* application	Haemorrhoids	Cardiovascular	Ayurveda
Evaluation of the therapeutic effect of "*Varakadi*decoction" on *madhumeha* (diabetes mellitus) – A case study	(Sri Kanthi, 2016)	Decoction	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda/ Indigenous medicine
A study on non-medicinal management of cervical spondylosis	(Srivastava Prasad and Atul, 2017)	Topical application	Cervical spondylosis	Musculoskeletal	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
The effect of meditation in insomnia due to stress: A case study	(Sujeethasi, 2018)	Meditation	Insomnia	Sleep disturbance	Spiritual/Ayurveda
The assessment of curing effect of *Neeliyathithailam* on those affected by dandruff	(Thilageswary and Vasanthy, 2016)	Topical application	Dandruff	Skin	Ayurveda
The effectiveness of *Neelyadi*oil local application in recovery of partial fistuletomy followed by *ksharasutra* therapy – a case study	(Thilak, Swapna and Kumara, 2017	Topical application	Fistula	Skin	Ayurveda
The "*Othiyampaddaipaththu*" in Boxer's fracture management at rural Ayurvedic hospital Pandateruppu, Jaffna	(Thileeban, 2015)	Topical application	Fracture	Musculoskeletal	Siddha
Assessment of traditional treatment modality in the management of adenocarcinoma of prostate: A case report based on cytokine expression	(Umayangani 2018)	Herb	Cancer(prostate)	Male genital	Ayurveda/ Indigenous medicine
Assessment of effectiveness of treatment modality in the management of *avabahuka* (frozen shoulder)/case study	(Umayangani, 2015)	Herb	Frozen shoulder	Musculoskeletal	Ayurveda
S. and assessment of the Ayurvedic/traditional treatment regimen in adenocarcinoma of prostate – case series review	(Umayangani, Jayathilake et al. 2017)	Herb	Cancer (prostate)	Male genital	Ayurveda
Role of traditional practitioners on treating vertebral lesion caused by trauma – a case study	(Uthayakumar, 2016)	Herb	Fracture	Musculoskeletal	Ayurveda
"*AdathodaiKudineer*" – potentially polyherbal Siddha formulation for management of bronchial asthma	(Uttayam, 2014)	Herb	Asthma	Respiratory	Siddha

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Effectiveness of *Kovaikizhanguchooranam* for the management of *mathumegam*	(Varuna, 2016)	Herbal powder	Diabetes	Endocrine/ metabolic and nutritional	Siddha
The effect of *Roganikhash*, sunlight soap and *Chunam* paste for "*Kadara*" as an external application – A case study	(Weerasekara, 2015)	Topical application	Corn	Skin	Ayurveda/ Indigenous medicine
Evaluation of the therapeutic effect of Ayurvedic herbo-mineral formulation *Chandraprabhavati* on *meha* – A case study	(Weerasekara, 2016)	Herbal pills	Diabetes	Endocrine/ metabolic and nutritional	Ayurveda
Clinical experiences in management of hyperlipidaemia and ischaemic heart disease (IHD) by means of polyherbal formulations (PF): Case series	(Welivitegoda et al., 2017)	Herb	IHD	Cardiovascular	Ayurveda
Study the efficacy of line of treatment for chronic wound with cellulitis by means of indigenous medicine: A case report	(Welivtegoda, 2018a)	Herb	Cellulitis	Skin	Ayurveda/ Indigenous medicine
Effective Ayurveda treatment regime on *Dushta Vrana* – A case study	(Wickramasinghe and Sakunthala	Herb	Ulcer	Skin	Ayurveda
Efficacy of indigenous treatment regime on *Mandam* in Sri Lanka – case series	(Wickramasinghe, Alupothakumbura, and Sakunthala, 2017)	Herb	Indigestion	Digestive	Ayurveda/ Indigenous medicine
Hepatitis B patient management through Unani medicine – a case study	(Zaidi, 2016)	Herb	Hepatitis	Hepatitis	Unani
Katupila (*Securinegaleucopyrus*) as a potential option for diabetic wound management	(Ajmeer, Dudhamal, Gupta, & Mahanta, 2014)	Topical application	Diabetes		Ayurveda
Pyoderman gangrenosum treated with *Marham-e-raal* – a case series	(Ahmad, Alam, & Dandroo, 2017)	Herb	Skin disease	Skin	Unani

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Case study on actinomycosis (*Kakanantikakushta*)	(BMARI, 2017a)	Herb	Bacterial infection	Musculoskeletal	Ayurveda
Clinical effect of *Sepalika* (*Nycanthesarbortristis*) *Niruha Vasti*, *Sepalika Sudulunu Kashaya* and *Lakshadilepa* on *Grudhrasi* (sciatica) – A case study	(E. Edirisinghe, Ediriweera, & Weerasinghe, 2018)	Enema + decoction	Sciatica	Musculoskeletal	Ayurveda
Effect of *Sapa Vireka Choorna* on *Vibandha* (*mala adassiya*/chronic constipation) – series of case studies	(E Edirisinghe, Ediriweera, & Dhamasiri, 2019)	Herbal powder	Constipation	Digestive	Ayurveda
Effect of Sri Lankan traditional medicine *Jathiphalaadi Lepa* and *Heen Demata Yusha Nasya* on *manibandhashoola* [carpal tunnel syndrome] – a case report	(Lankani & Ediraweera, 2018)	Nasya + topical application	Carpal tunnel	Neurological	Ayurveda/ Indigenous medicine
A clinical study on efficacy of *Siyakkai* (*Acacia concinna*) hair wash on *Darunaka* (*Pityriasis capitis*)	(Ediraweera, 2021)	Herbal hairwash	Tinea	Skin	Ayurveda
Effect of *Vamana Karma*, *Triphala Kashaya* and *Dehigetadi Lepa* in treatment of *kitibha* (psoriasis) – a case study	(Jayasekara & Ediraweera, 2019)	Decoction + topical application	Psoriasis	Skin	Ayurveda
Principles of traditional medicine in the management of cancer – a case report	(Jayasundara, Gunthilaka, & Perera, 2014)	Decoction + herb-mineral drugs	Cancer	Cancer	Indigenous medicine
Therapeutic effects of Sri Lankan Ayurveda treatment regimens for uterine fibroids – a case series	(E Priyadarshani, Karunagoda, & Perera, 2016)	Herb	Uterine fibroids	Pregnancy, childbearing, family planning	Ayurveda
A clinical survey on effect on maternal stress during pregnancy for autistic disorders	(Leena, 2018)		Autism	Pregnancy, childbearing, family planning	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Assessing the therapeutic effect of Kakulu rice flour (KRF) paste for carpal tunnel syndrome	(Mendis, Wijesinghe, & Attanayake, 2017)	Herbal paste	Carpal tunnel	Neurological	Ayurveda
Sri Lankan traditional *Virechana Karma* with *Ehela Peni* (*Cassia fistula*) and application of *Kaluwala Alepa* (*Alpinia malaccensis*) in treatment of *sidhmakushta* (pityriasis versicolor) – a case study	(Navodi, Ediriweera, & Kumara, 2017)	Purgation (*Vireka*) + topical application	Pityriasis versicolor	Skin	Ayurveda/ Indigenous medicine
Effects of *Dhanyamlaparisheka* in the management of *Amavata* with special reference to rheumatoid arthritis – a case study	(R. Ranasinghe, Ediriweera, & Officer, 2015)	Dhanyamla decoction + *Parasheka*	Rheumatoid arthritis	Musculoskeletal	Ayurveda
Effect on *Agni* in management of cancer: a case study of Ayurvedic perspective	(V Seneviratne, Perera, & SD, 2014)	Herb	Cancer	Cancer	Ayurveda
Efficacy of Unani management modalities in congenital hypothyroidism – a case study	(Shifra, 2017)	Unani herb	Hypothyroidism	Endocrine	Unani
Effect of *Rakthamokshana* (blood-letting therapy) and Sri Lankan traditional medicine on *sirajagranthi* (varicose veins) – a case study	(M. Wickramasinghe & Ediriweera, 2018)	Bloodletting	Varicose veins	Cardiovascular	Ayurveda
Efficacy of *jawarish-e-kamoonsaada* in the management of common gastrointestinal complaints: A clinical study	(Silmiya, 2015)	Herb	Digestive disorder	Digestive	Unani
Therapeutic effect of Ayurveda treatment regimens for subfertility – case series	(BMARI, 2017g)	Herb	Fertility	Pregnancy, childbearing, family planning	Ayurveda
A clinical evaluation of *triphalachurna* in the management of *medoroga* (hyperlipidaemia and obesity)	(S. Jayasinghe, 2015)	Herbal powder	Obesity	Endocrine/ metabolic and nutritional	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
A case study on the management of obsessive-compulsive disorder with special reference to *Butonmada*	(R. Liyanage, 2018)	Herb	OCD	Psychological	Ayurveda
Effect of Sri Lankan traditional medicine and Ayurveda on *sandhigatavata* (osteoarthritis of knee joint)	(P. K. Perera, Perera, & Kumarasinghe, 2014)	Herb	Osteoarthritis	Musculoskeletal	Ayurveda
Traditional Sri Lankan medicine intervention in the management of knee osteoarthritis (*janusandigatavata*): Case series	(P Perera & Kumarasinghe, 2018)	Herb	Osteoarthritis	Musculoskeletal	Ayurveda/ Indigenous medicine
A clinical study on the management of *Sandhigatavata*: A case study	(Jayasena, 2018)	Herb	Osteoarthritis	Musculoskeletal	Ayurveda
Clinical evaluation of a selective treatment regime on *sandhigata-vata*	(J. Jayasinghe, Kulatunga, & Madushani, 2018)	Herb	Osteoarthritis	Musculoskeletal	Ayurveda
Efficacy of acupuncture on osteoarthritis of knee joint: A case report	(Gamage, 2018)	Acupuncture	Osteoarthritis	Musculoskeletal	Ayurveda
Therapeutic efficacy of *Janu Vasti* and the traditional local application in the management of *sandhigatavata* (osteoarthritis)	(Jayawardhane, 2016)	Topical application + *Janu Vasti*	Osteoarthritis	Musculoskeletal	Ayurveda
Therapeutic effects of Sri Lankan traditional medicine and ayurveda treatment regimes on *Sandhigatha Vata* (osteoarthritis) – a case series	(A. Perera, 2015)	Herb	Osteoarthritis	Musculoskeletal	Indigenous medicine
Case studies with selected treatment regimen in the management of *sandhigatavata* (osteoarthritis)	(Sewwandi, 2015)	Herb	Osteoarthritis	Musculoskeletal	Ayurveda
Clinical evaluation of *Shirodhara* and *Matra Vasti* with *Baladi Yoga* on fatigue after stroke (*pakshaghata*)	(D. Silva, 2015)	Enema + *Shirodhara*	Paralysis	Neurological	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Improvement of certain haematological values in a patient with polycythemia (rubra) vera following Ayurveda treatment: A case report	(Perera, 2015a)	Herb	Polycythemia vera	Blood, blood-forming organs and immune mechanism	Ayurveda
Role of *Shatavari Ksheera Basti* in the management of *GharbhaKshaya* (IUGR), a case study	(Sajeewani, 2015)	Enema	Pregnancy disorder	Pregnancy, childbearing, family	Ayurveda
Management of benign prostatic hyperplasia – an Ayurvedic approach	(Dwivedi, 2016)	Herb	Prostate hyperplasia	Male genital	Ayurveda
A preliminary study on prevalence of proteinuria and abnormal serum creatinine levels among the patients attended for Ayurveda treatments	(BMARI, 2017f)	Herb	Proteinuria	Urological	Ayurveda
Impact of clinically effective Ayurveda treatment on liver and kidney functions of psoriasis patients	(BMARI, 2017e)	Herb	Psoriasis	Skin	Ayurveda
A clinical study of *Virechana Karma* with *Dimorphocalyxglabellus* decoction of *vasaguduchyadiya* and *aniththadilepa* in the management of psoriasis	(BMARI, 2017d)	Decoction	Psoriasis	Skin	Ayurveda
Clinical study of *Nimbadilepa* with *pinda* oil in the management of thickness condition of *sidhma Kushta* (psoriasis)	(BMARI, 2017c)	Topical application	Psoriasis	Skin	Ayurveda
An observational study on the therapeutic effect of polyherbal formula in the management of (*Daa us Sadaf*) psoriasis vulgaris	(A. Fazeenah, 2016)	Herb	Psoriasis	Skin	Unani

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Case report on management of *kushta* (psoriasis) with *Virechana Karma* (induced purgation) and *Rasayana* (rejuvenation) therapy	(Mahesh, Parappagoudra, & Navodayraju, 2017)	Purgation (*vireka*) + rejuvenation (*rasayana* therapy)	Psoriasis	Skin	Ayurveda
A study on the efficacy of traditional *shirolepa* in the management of scalp psoriasis	(Pramodani, 2015)	Topical application	Psoriasis	Skin	Ayurveda
A comparative clinical evaluation of *Vasaguduchyadi* decoction and *AniththadiLepa*with and without *Virechana Karma* with Weliwenna in the management of *kitibha* (psoriasis)	(Dewanarayana, 2015)	Decoction + topical application	Psoriasis	Skin	Ayurveda
Effect of *unmadagajakesarirasa* on *Astavidha Manobhavas* of *kaphajaunmada*	(Ariyaratne, 2016)	Herbal pills	Psychological disorder	Psychological	Ayurveda
Effect of *unmadagajakesarirasa* on *kaphajaunmadama*	(Ariyaratne, 2015)	Herbal pills	Psychological disorder	Psychological	Ayurveda
Effectiveness of *Navarakizhi* on *Sith Peralum Umathuwa*	(C. Liyanage, 2015)	Topical application	Psychological disorder	Psychological	Ayurveda/ Indigenous medicine
Case study on *zoaf-e-kulya* (renal failure)	(Raesuddeen, 2015b)		Renal failure	Urological	Unani
Therapeutic potentials of *Dhanyamla* (a fermented cereal) against *Amavata*	(P. Ranasinghe, 2018)	Herb	Rheumatoid arthritis	Musculoskeletal	Ayurveda
Comparative evaluation of *Dhanyamla Vasti* and *Kayaseka* in the management of *Amavata* Wsr to rheumatoid arthritis	(P. Ranasinghe, 2015)	Enema + decoction	Rheumatoid arthritis	Musculoskeletal	Ayurveda
Clinical study on *Bala Koranda Taila* (BKT) *matravasti* and *Eranda Saptaka Kashaya* (ESK) in the management of *gridrasi*	(Nishshanka, 2016b)	Topical application	Sciatica	Musculoskeletal	Ayurveda

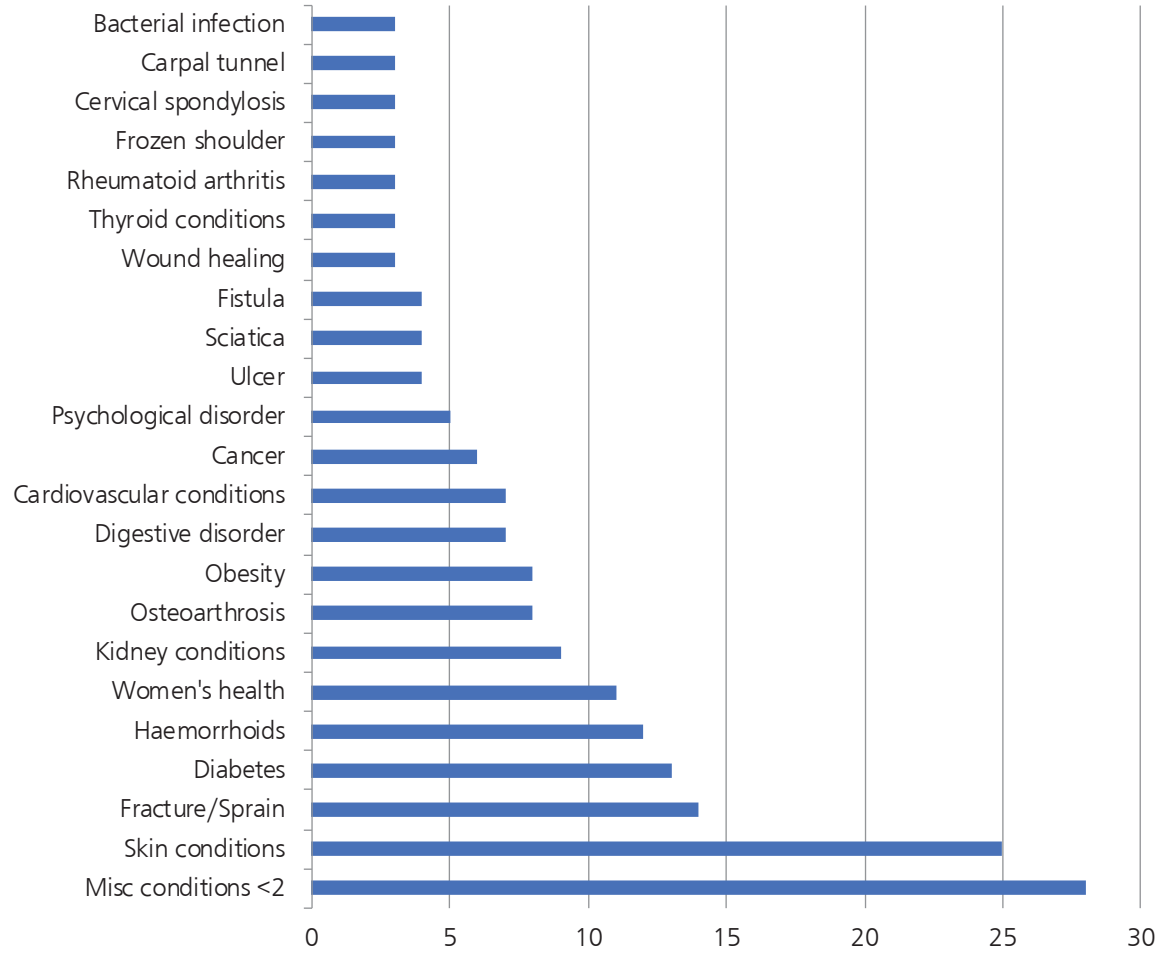
Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
A comparative clinical study on the effect of *Chitrakadi* oil *matravasti* and *Sinhasyadi* decoction orally in the management of *gridhrasi* (sciatica)	(Vidanapathirana, 2016)	Decoction + topical application	Sciatica	Musculoskeletal	Ayurveda
Clinical study on *Erandasaptakakashaya* in the management of *gridrasi*	(Nishshanka, 2016a)	Decoction	Sciatica	Musculoskeletal	Ayurveda
A case study on *Da ul Faqaa* (*Pemphigus vulgaris*)	(Salma, 2015)		Skin disease	Skin	Unani
Selective Ayurveda treatment modality for Lichen Planus (*vishajakushta*) – a case study	(Perera, Dissanayake, & Jayakody, 2017)	Herb	Skin disease	Skin	Ayurveda
Effect of *Roghan e khas* on overgranulation tissue formation in post-episiotomy wound – a case study	(Musmira, 2015)	Topical application	Skin disease	Skin	Ayurveda
Successful Ayurvedic treatment modality for *Prurigo nodularis* (type of *vishajakushta*) – a case study	(Perera, 2015b)	Herb	Skin disease	Skin	Ayurveda
Development of a substitute oil for *Vipadikahara Grita Taila* and its evaluation against *Vipadika* skin disease (a case study)	(Hewageegana, 2015)	Topical application	Skin disease	Skin	Ayurveda
A successful pregnancy outcome after repeated spontaneous abortion due to myoma (*Sala'elaifiya*) – acase report	(Farzana, 2015)	Herb	Spontaneous abortion	Pregnancy, childbearing, family	Unani
A comparative clinical study to evaluate the effectiveness of *nyagrodhadilepa* and *manjisthadilepa* on ankle sprain: A case study	(Meher & Gopikrishna, 2017)	Topical application	Sprain	Musculoskeletal	Ayurveda
The *Varma* therapy management for *sulukku* (sprain)	(Nithyapriya, 2015)	Herb	Sprain	Musculoskeletal	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Case series on effect of Ayurvedic treatment regimens for *vandyathva* (subfertility)	(J. Jayasinghe, 2015)	Herb	Subfertility	Pregnancy, childbearing, family planning	Ayurveda
A clinical evaluation of the effect of *Shothahara* compound on *Shotha*	(Kumari, 2015b)	Topical application	Swelling	General and unspecified	Ayurveda
Case study on synovitis	(Raesuddeen, 2015a)	Herb	Synovitis	Musculoskeletal	Ayurveda
Clinical study on *beejadushtijanyapandu* (thalassemia major) in children and its management with *Musta-thriphaladiavaleha* and *Gandhakadi yoga*	(Kalawana, 2018)	Herbal paste + yoga	Thalassemia	Blood, blood-forming organs and immune mechanism	Ayurveda
A preliminary study on local effect of traditional herbal remedy used in traumatic nail injuries	(Karunarathna, 2016)	Topical application	Traumatic nail	General and unspecified	Ayurveda/ Indigenous medicine
Clinical evaluation of *sivappukukilthaila* paste with *panchathuvarpikasayam* in the management of wound	(Rajeev, 2016)	Topical application	Ulcer	Skin	Ayurveda
Effect of leech therapy on diabetic foot ulcer – a case study	(Gunarathna, 2016)	Leech therapy	Ulcer	Skin	Ayurveda
Case study on *Kshara* application in diabetes foot ulcer	(Samaranayake & Pushpakumra, 2017)	*Kshara* application	Ulcer	Skin	Ayurveda
Management of urolithiasis with reference to Ayurvedic concepts: A case study	(Pathirana, 2018)	Herb	Urolithiasis	Urological	Ayurveda
Therapeutic effects of Sri Lankan Ayurveda treatment regimes for uterine fibroids – a case series	(E Priyadarshani, 2015)	Herb	Uterine fibroid	Female genital	Ayurveda
Pessary treatment for uterine prolapse and health-related quality of life: A case study	(Rumaiza, 2016)	Pessary	Uterine prolapse	Female genital	Ayurveda

Study title	Author/Year	Intervention 1	Condition	ICPC*title	TM type
Wound-healing effect of traditional herbal formulation (*Pachchennai* oil) on varicose ulcer	(BMARI, 2017h)	Topical application	Varicose ulcer	Cardiovascular	Siddha
An Ayurvedic approach of computer vision syndrome and management with *Tripala Ghrit Akshitharpana*: A case study	(Kumaradharmasena, 2018)	*AkshiTharpana*	Vision	Eye	Ayurveda
Ayurvedic management of macular odema (*AkshiTimira*): A case study	(Surangi, 2018)	*AkshiTharpana*	Vision	Eye	Ayurveda
A case study on management of chronic wound with polyherbal formulation	(BMARI, 2017b)	Herb	Wound healing	Skin	Ayurveda
Effect of Ayurvedic therapies in the management of infected wounds	(Sing, 2017)	Herb	Wound healing	Skin	Ayurveda

*Notes: *ICPC–WHO International Classification of Primary Care*

Fig. 6. *Overview of focus diseases conducted as case reports*



3.3.6 Community-based health research and surveys

Thirty-nine studies examining the community-based aspects of traditional medicine were identified. Some of these studies have attempted to collect data on knowledge, attitude and practice regarding Ayurveda treatments or specific diseases in relevant areas (Table 9).

Table 9. *Community-based research*

Author*	Research title	Focus
(BMARI, 2017a)	Hospital-based study on knowledge, attitude and practice on dengue (includes findings on traditional medicine)	Dengue
(BMARI, 2017a)	A survey on post-dengue complications (includes findings on traditional medicine)	Dengue
(BMARI, 2017a)	Assessing the quality of life of diabetic patients following Ayurvedic treatments	Diabetes
(BMARI, 2017a)	Distribution of Ayurveda medical centres for diabetes mellitus within central provinces	Diabetes
(BMARI, 2017a)	Nutritional status of pre-school children in selected estates in Sri Lanka (includes findings on traditional medicine)	Nutrition
(BMARI, 2017a)	Demographic characteristics of people who visit BMARI in 2013 according to ICD (International Classification of Disease)	Population study on TM
(Fatima, 2015)	Evaluation of traditional food "*Kitchadi*" on weight gain among the pre-school children of four gravatte division in Galle	Community study of TM
(Fonseka, 2015)	Role of diabetic retinopathy screening (includes findings on traditional medicine)	Diabetes
(Jayalal, 2015)	Study on the need of stress management in Ayurveda health-care system in Sri Lanka	Stress
(Jayasinghe, Kulatunga, & Ratnapala, 2017)	Identification of association between risk factors and serum cholesterol	CVD risk factors
(Kalyani, 2017)	A study of dispensing Ayurvedic drugs on consumer satisfaction: Special reference to Puttalam district in Sri Lanka	Herbal medicine regulation
(Kavtiha, 2015)	A study on lifestyle of elders in J/283 Gramaniladari division (idaikkadu), Sri Lanka (includes findings on traditional medicine)	Lifestyle
(Kumari, 2015a)	An assessment of the perception of stress in type 2 diabetic patients in accordance with perceived stress scale (PSS 10) (includes findings on traditional medicine)	Diabetes
(Lakmali, 2015a)	A study of clinical risk management in Ayurveda-teaching hospitals in Sri Lanka	Safety (Ayurveda)
(Lakmali, 2015b)	A study of the factors influencing for the patterns of consumer behaviour in the medical sector (includes findings on traditional medicine)	Drug safety
(R. P. Liyanage, Hettige, & Karunarathne, 2017)	Behavioural patterns of Ayurveda/traditional practitioners in diagnosis, treatment and referral of suspected leprosy patients to Western medical system	Leprosy

Author*	Research title	Focus
(Loganathan, 2015)	A study of distribution of "diagnosed hypertension" in Mathagal J/151 Grama Niladhari division from April to June 2012 (includes findings on traditional medicine)	CVD risk factors
(Munasinghe, 2015)	ICS0 effect of obesity on quality of certain semen parameters of Sri Lankan male (includes findings on traditional medicine)	Fertility
(Nayanathara, 2015)	Prevalence of risk factors for noncommunicable diseases in the selected population of urban areas in Thalawathuhenpita – North Grama Niladari divisions in Kelaniya district secretariat division of Gampaha district of Western Province, Sri Lanka and to develop a training programme with reference to Ayurveda medical system	Education – Ayurvedic
(Niranjan, 2015)	A study of management practices for preventing noncommunicable diseases in elderly population in Trincomalee urban council area (includes findings on traditional medicine)	Ageing
(Nizamdeen, 2015)	Prevalence of diabetes and impaired fasting glucose (IFG) in adult population in the Kadawath-sathara, Galle district (includes findings on traditional medicine)	Diabetes
(Pathiraja, 2017)	The application of international human rights standards as a mechanism to protect the rights of the people living with HIV/AIDS: A Sri Lankan perspective	HIV/AIDS
(PK Perera, Silva, & Chandra, 2017)	Health-seeking behaviour among patients with knee osteoarthritis in Sri Lanka	Osteoarthritis
(W. Perera, Perera, Ambagahawita, Wijesundara, & Bandaranayaka, 2018)	People's knowledge, attitude and practices towards dengue infection and prevention in a semi-urban area, Sri Lanka	Dengue
(Prashan, Kalpani, Pathirage, & Chathura, 2021)	Knowledge and attitudes on first aid among GCE advanced level students in government schools of Gampaha education zone, Sri Lanka	Medical knowledge
(Priyadarshi, 2015)	Application of *Rasayana* for paediatric population	Lifestyle
(Ralapanawa, Jayawickreme, Ekanayake, & Kumarasiri, 2016)	A study on the knowledge and attitudes on advanced life support among medical students and medical officers in a tertiary care hospital in Sri Lanka	Medical knowledge
(Rathnakara, 2015)	Prevalence of respiratory disorders of children, attending the Ayurveda Teaching Hospital, Colombo	Respiratory
(Samarakoon, 2015)	A study on effective distribution of Ayurveda drugs in Eastern Province of Sri Lanka	Rationale use of drug
(Sandamali, 2015)	Prevention of suicide (with especial reference to "*sumithrayo*" in Panduwasnuwara Western d.s. in Kurunegala District)	Suicide

Author*	Research title	Focus
(Silva & Thathparan, 2017)	Analytical survey of patients attending to *swithra* (vitiligo) clinic	Skin disease
(Sivalathajini, 2015)	Nutritional status survey among children in Sahayapuram, Jaffna, Sri Lanka (includes findings on traditional medicine)	Nutrition
(Stanieri et al., 2018)	A visual grid to digitally record an Ayurvedic *prakriti* assessment; a first step toward integrated electronic health records	Ayurvedic diagnosis
(Thillany & Sathiyaseelan, 2015)	Study on the dominance of *Arogyam* and intellectual activities in Guna changes among the elders in Shanthinilayam, Kaithady	Ageing
(Waratenne, 2015)	A study of Sri Lankan cuisines with special reference to *Ashtha Aaharavidhi Visheshayatana*	Ayurvedic nutrition
(A. Wickramasinghe, 2015)	Comprehensive survey of patients attending to the orthopaedic clinic in Ayurveda Teaching Hospital, Borella	Musculoskeletal
(Wijesinghe, Pilapitiya, Hettiarchchi, Wijerathne, & Siribaddana, 2017)	Regulation of herbal medicine use based on speculation? A case from Sri Lanka	Herbal medicine regulation
(Wimalasooriya, 2016)	Effect of an indigenous food supplement "*Suwaposhini*" on nutritional status of pre-school children in Galle district – a prospective community trial	Community study of TM
(Zabir, 2015)	Knowledge, attitude and preventive measures of breast cancer among Maligawatta area women (includes findings on traditional medicine)	Cancer

Note: *Some of these studies were published as conference papers or posters during the review period and have since been published as research articles.

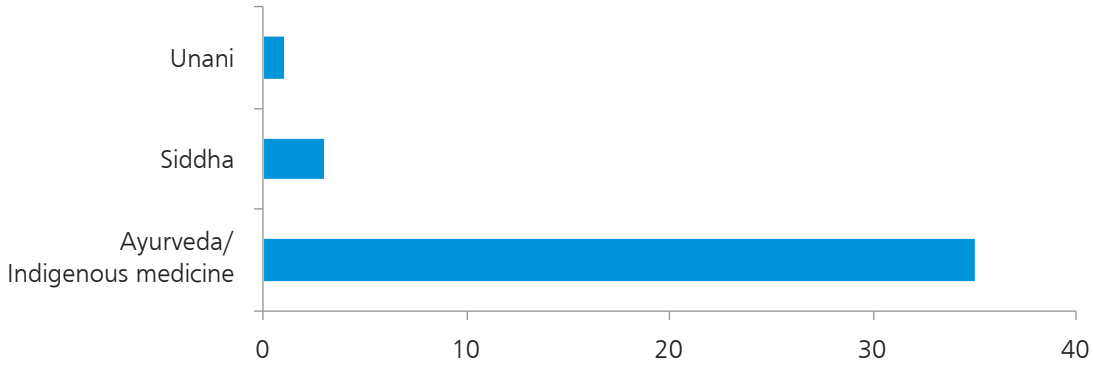
Compared to case reports, 39 studies were undertaken during the review period in Sri Lanka, examining community behaviour, attitudes and practices around TM (Fig. 8). Some of these studies adhered to knowledge, attitudes and practices (KAP) and survey models.

There were four (9.7%) studies, including two KAP studies and two survey-based studies, conducted on dengue fever. One (2%) KAP study was conducted on breast cancer among women. Five (12%) studies were conducted on diabetes, including one study on the quality of life (QOL) of patients and TM practices, two on prevalence studies of dengue fever, one on a diabetic retinopathy screening programme and one on stress and diabetes-based screening. Seven (17%) studies were nutritional status assessment surveys. One (2%) study was focused on prevalence of respiratory disorders among children. One study (2%) was conducted on the application of international human rights standards as a mechanism to protect the rights of the people living with HIV/AIDS from a Sri Lankan perspective. Two (5%) prevalence studies were conducted on musculoskeletal disorders, including osteoarthritis. Furthermore, two (5%) noncommunicable diseases-based survey studies were conducted during this period.

One study collaborated with some of the Australian universities and published concept protocol to develop electronic health record (EHR) system through advanced *prakriti*-based phone app *(187)*. The main contention advanced in this article is that Ayurvedic medicine can transition organically to be based on EHR, if the demand for electronic records is created by patients and clinicians. A model for this involves the use of an application accessible on smartphones. The app uses a visual triangle that enables a *prakriti* assessment to be readily entered and stored in a smartphone and shared with a patient. This first step has the potential to create a demand for the *prakriti* record to be expanded to include other health data and expanded again to enable records to be shared by many health-care providers. The model outlined presents an approach that facilitates the deployment of health record banks in a manner that may be affordable and sustainable.

In our review of community-based studies, we found that several studies had utilized the KAP survey model. The model includes constructing survey protocol, preparing a survey, course of the KAP survey in the field, data analysis and presentation of the survey report, conclusion, references and abbreviations. In our analysis of these studies, we noted that the method of training of surveyor was not included in most of the studies.

Fig. 7. *Comparison of community-based health research and surveys conducted on different traditional medicine systems in Sri Lanka during 2015–2019**



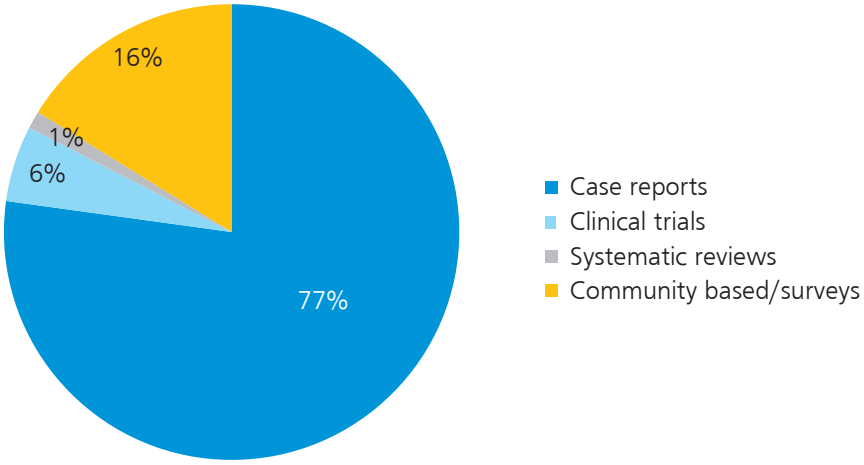
Note: *Some studies included more than one type of TM.

Most of the community-based research on TM conducted in Sri Lanka focused on Ayurveda, compared to the Siddha and Unani systems of medicine (Fig. 7).

3.3.7 Summary of types of traditional medicine system research

When comparing the types of research undertaken in traditional medicine, most of the research involves case studies and case series. There is a need to encourage researchers to publish their work in journals, which in turn makes their findings accessible to the community and other researchers. Nonetheless, these studies demonstrate a broad range of areas where TM in Sri Lanka has potential.

Fig. 9. *Types of Ayurveda/TM research conducted during 2015–2019*



Of the 202 case reports, clinical trials and systematic reviews that have been completed and included in this review, 42 (21%) were conducted in the BMARI priority areas (Table 10). Diabetes garnered maximum focus.

Table 10. *Types of research conducted in the BMARI priority areas during 2015–2019*

	Cardiovascular disease	Diabetes	Kidney	Cancer	Dengue	Total
Case reports (n = 184)	7	13	9	6	1	36 (20%)
Clinical trials (n = 13)	1	2			1	4 (31%)
Systematic reviews (n = 3)		1			1	2 (67%)
Total	8 (19%)	16 (38%)	9 (21%)	6 (14%)	3 (7%)	42

3.4 Discussions

The TM research undertaken in Sri Lanka over the five-year period of this scoping review shows a developing research programme. While the largest number of studies involved case reports, some quality clinical trials had been undertaken and published in peer-reviewed journals. There is still considerable scope for improving these randomized controlled trials and seeking publication in journals that will have a higher impact. Some clinical trials did not appear to have progressed to publication beyond conference proceedings. These challenges are similar to those faced by reviews of studies registered on the Indian clinical trials registry *(188)* and reviews of studies published in Indian Ayurvedic journals *(189)*.

Ethics approval and subsequent registration with either SLCTR or ICRTN were the norms for most clinical trials. However, there were still some trials that were not registered on SLCTR and were only conducted with the approval received from institutional ethics review committees. There were two trials registered on the ICRTN registry for the first time (https://doi.org/10.1186/ISRCTN18149439,

https://doi.org/10.1186/ISRCTN16108738). This is a key achievement to improve trial visibility. Several studies also had published clinical trial protocols. Clinical trial research can be improved considerably by encouraging the publication of research protocols such as that published by Dahanayake et al (2020).

Traditional medicine clinical research in Sri Lanka is strongly supported by the education system and dedicated Ayurvedic hospitals

The establishment of BMARI provides a strong focus for TM research. The research focus of BMARI on cardiovascular diseases, chronic kidney diseases, cancer and diabetes along with one communicable disease (dengue) is only somewhat apparent in the research output identified in this scoping review. Of the systematic reviews, clinical trials and case studies, only 21% were in the targeted research areas of BMARI. The predominance of musculoskeletal and skin condition case studies may reflect the high usage of traditional medicine for these conditions. There may be a need to draw more attention to the priority areas of BMARI, such as diabetes. A survey of diabetic patients visiting a Sri Lankan hospital found that 76% used some form of herbal medicine to reduce blood glucose *(190)*.

The registered clinical trials found were mainly Ayurvedic interventions, only some of the studies mentioned Ayurvedic outcomes. TM/Ayurveda treatment aims to achieve a balanced state of the *dosha*s by treating the individual manifestation of a disease. Different manifestations require different treatments. Where a clinical trial is testing a fixed herbal formula, it may be anticipated that the formula may be more effective for certain *dosha* imbalances. Outcome measures for Ayurvedic effectiveness need to be considered in addition to conventional outcomes *(191)*.

Clinical trials are considered the main source of evidence-based medicine (EBM) and forms the backbone of clinical practice in any system of medicine. Evidence-based medicine categorizes different types of clinical evidence and ranks them according to the strength of their freedom from the various biases that beset medical research *(192,193)*. Levels of evidence are provided to studies and they are ranked based on the methodological quality of their design, validity and applicability to patient care. These decisions provide the strength of recommendation *(194)* (see Table 11).

Table 11. *Levels of evidence*

Level of evidence (LoE)	Description
Level I	Evidence from a systematic review or meta-analysis of all relevant RCTs (randomized controlled trials) or evidence-based clinical practice guidelines based on systematic reviews of RCTs or three or more RCTs of good quality that have similar results
Level II	Evidence obtained from at least one well-designed RCT (e.g. large multisite RCT)
Level III	Evidence obtained from well-designed controlled trials without randomization (i.e. quasi-experimental)
Level IV	Evidence from well-designed case-control or cohort studies
Level V	Evidence from systematic reviews of descriptive and qualitative studies (meta-synthesis)
Level VI	Evidence from a single descriptive or qualitative study
Level VII	Evidence from the opinion of authorities and/or reports of expert committees

The highest level of evidence is a meta-analysis where systematic reviews of several randomized controlled trials are analysed. Almost all Western countries apply EBM to the treatment of patients and this is supported by government guidelines and the pharmaceutical industry. EBM integrates individual clinical expertise and patient preferences with the best available external clinical evidence from systematic research *(193)*. EBM evolved to respond to an increasing amount of research and to balance the use ofclinical expertise alone.

EBMof Ayurveda/TM is difficult to practice without high-quality clinical trials and publications. Developing EBM in Ayurveda/TM empowers researchers and clinicians' decision-making ability. Yet developing an EBM for Ayurveda, similar to other traditional forms of medicine, faces considerable challenges.

This is perhaps one of the reasons why our review found a predominance of case reports rather than clinical trials. Case reports enable reporting of the treatment approach, *Chikitsa sutra*, applied to each disease, with variations for each individual. Traditional medicine systems classify drugs according to the *Rasapanchaka* (Ayurvedic pharmacology).

The drug action is ascribed to certain attributes present in a drug, namely *rasa* (taste), *guna* (property), *virya* (potency), *vipaka* (post-digestive taste) and *prabhava* (effect) while in modern pharmacology, the drug action is attributed to the chemical structure of a molecule. The *Rasapanchak* modality can deliver treatment as it takes into consideration the *prakriti* of the person as well as the pharmacodynamics and pharmacokinetic properties of a drug, unlike in modern treatment which elicits varied response from person to person having the same drug for the same disease. The practice of a whole traditional medicine system and/or individualization is complex and poses challenges to research methods, particularly the dominant RCT design *(195)*.

Whereas a randomized controlled trial is considered the most appropriate research method, employing individualized or semi-standardized formulas or treatments could be considered. These methods have been developed for Chinese herbal medicine. In an individualized RCT, each participant is provided with an individualized prescription that may change over time and this is clearly documented in the study. Semi-standardized involves using a base treatment or formula that all participants receive but adjusting to the individual presentation *(196)*.

The dynamic therapeutic approach of Ayurveda and TM may render conventional research methods inappropriate. In such circumstances, the choice of study design should be discussed on a case-by-case basis with experts in fundamentals of CAM systems. Methodologies such as single-case design, black-box design and open-label design, and ethnographic and observational studies may be more appropriate for clinical research in instances where conventional RCTs could not be used in TM/Ayurveda *(197)*.

The taste and smell of Ayurveda drugs make it difficult to produce placebos

This may be the reason why very few placebo control trials appeared. According to Ayurveda, taste (*rasa*) will have a particular effect on the body, which will contribute to healing. Hence, the same taste (*rasa*) in the placebo could also bring a similar effect to a certain extent. Hence, use of placebos

and blinding are debatable with research that is planned in accordance with the fundamentals of TM/Ayurveda approach. But 42% placebo control trials were conducted and 31% of the trials were double-blinded and 31% single-blinded in trials registered with WHO accepted trial registries in Sri Lanka.

Traditional medicine indications were noted in the clinical trials and case reports, usually alongside a Western medicine term for the disease or condition. In general, for clinical trials, participants are selected according to standard diagnostic criteria for RCT and *panchakarma* therapies were few. However, some of these participants may not have been suitable for a standardized intervention, according to the principles of TM/Ayurveda, since TM/Ayurvedic treatment widely differs according to *prakurthi*, *ama-nirama* and the *doshaja* state.

Case reports in our review included traditional panchakarma therapies whereas most clinical trials tended to revolve around oral herbal interventions only

The case reports provide insight into the phenotypic features (*prakriti*) used in Ayurvedic medicine; these are not dissimilar to the genotypes that are increasingly being used in personalized medicine. The *prakriti* is used to determine the individualized or personalized treatment regime in Ayurveda. Similarly, the recent pharmacogenomics approach also targets patients according to their genotypes and RCTs have struggled to keep pace with this *(198)*.

Some published clinical trials included those on the adverse effect management system and data safety monitoring board (DSMB). Observational studies such as case reports in TM represent considerable effort and are an important source of data for future investigation. To maximize the potential of this research and ensure that researchers' time and effort are well-invested, the use of internationally recognized standards for observational studies such as those developed by the EQUATOR network, The CARE Guidelines: Consensus-based Clinical Case Reporting Guideline Development, are recommended *(199)*. This will facilitate the publication of case series and reports.

The clinical trials and case reports show promising clinical outcomes. However, without an analysis of the quality of the trials and studies, no conclusions can be drawn. The Ayurvedic clinical trials for osteoarthritis and uterine fibroids warrant rigorous larger-scale studies. Ayurveda may provide a favourable treatment option for these conditions in contrast to invasive surgeries or hormone therapy. Other clinical trials have led to the development of consumer products such as herbal toothpaste and herbal cough syrup, and more recently, a treatment for fever.

Other studies have demonstrated potential and may be suitable for development as commercial products, such as the anti-acne and memory booster/brain tonic products. Researchers may have focused on these diseases as conventional medicine has limited treatment options to manage conditions and/or Ayurveda therapy provides better efficacy and is more cost-effective when compared to conventional medicine. These research outcomes should be further analysed with extensive researches and meta-analyses.

4

Research gaps and challenges – The way forward for TM research in Sri Lanka

4.1 Introduction

This section will focus on the challenges to developing the traditional medicine industry and research in Sri Lanka, covering:

(1) Safety and standardization of herbal products

(2) Supporting research:

  (i) clinical trials

  (ii) case reports

  (iii) community

  (iv) supportive TM research policies.

(3) Developing the TM market:

  (i) public-private enterprise partnerships.

(4) Protecting traditional medicine knowledge in Sri Lanka:

  (i) Intellectual Property Rights Act

  (ii) Draft Legal Framework for the Protection of Traditional Knowledge.

(5) Summary of the current status and challenges of TM research.

4.2 Safety and standardization of herbal products

4.2.1 Standardization of herbal products

Consistent quality of herbs, containing well-defined constituents, is required to provide reliable therapeutic effects. *Standardization* requires adjusting a herbal drug preparation to meet the defined content of a constituent or group of substances with known therapeutic activity *(200)*. The standardization process faces numerous challenges related to marker identification, active principle(s), lack of defined regulations, non-availability of universally acceptable technical standards for testing and implementation of quality control/safety standards (toxicological testing) *(201)*.

The acceptance of a principal herbal compound as a future drug candidate requires correct identification, authentication and concentration of active principle and defined quantities of active components in polyherbal formulations. Regulation and standardization to ascertain the consistent chemical profile and biological activity of a future drug candidate include *(200)*:

(1) quality assurance by determining adulterants, pesticides residue, aflatoxin content, bacterial/fungal growth and heavy metals contamination, etc.;

(2) prevention of adverse reactions by evaluating pharmacodynamics, pharmacokinetics, dosage, stability, shelf-life and toxicity (acute/chronic) etc.; and

(3) reproducibility by repetitive testing using different batches to control batch-to-batch variation and development of standard assay markers.

The Sri Lankan herbal drug industry should aim to exceed parameters above the basic WHO-GMP standards. Good manufacturing practices (GMP) lead to a more comprehensive approach to quality and risk management of the entire manufacturing process. The levels of implementation and enforcement of GMP critically determine the quality of products and, overall, successful development of the TM industry. For example, regulation of herbal products in the People's Republic of China was developed on the basis of WHO-GMP and EU-GMP and mirrored the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) *(202)*.

PIC/Sis an international, non-binding arrangement that aims to achieve constructive co-operation in the field of GMP. The mission PIC/S is to lead international development, implementation and maintenance in GMP standards and quality systems of inspectorates in the field of medicinal products (*http://www.picscheme.org*). This is to be achieved by developing and promoting harmonized GMP standards and guidance documents; training competent authorities in particular inspectorates; assessing (and reassessing) inspectorates; and facilitating the cooperation and networking for competent authorities and international organizations.

According to the Ayurvedic Act *(203)*, registered Ayurveda practitioners may manufacture or prepare extemporaneously any traditional herbal medication for clinical use. Registered Ayurvedic hospitals or manufacturing firms are also permitted, provided the formulation is in accordance with the pharmacopoeia specifications and new formulations. The process of registration and market authorization of traditional medicineis carried out by the Ayurveda Formulary Committee of the Department of Ayurveda (*http://www.ayurveda.gov.lk/*) and committee members are appointed by the Health Minister of the Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka. However, the registration process is mainly conducted as desk reviews.

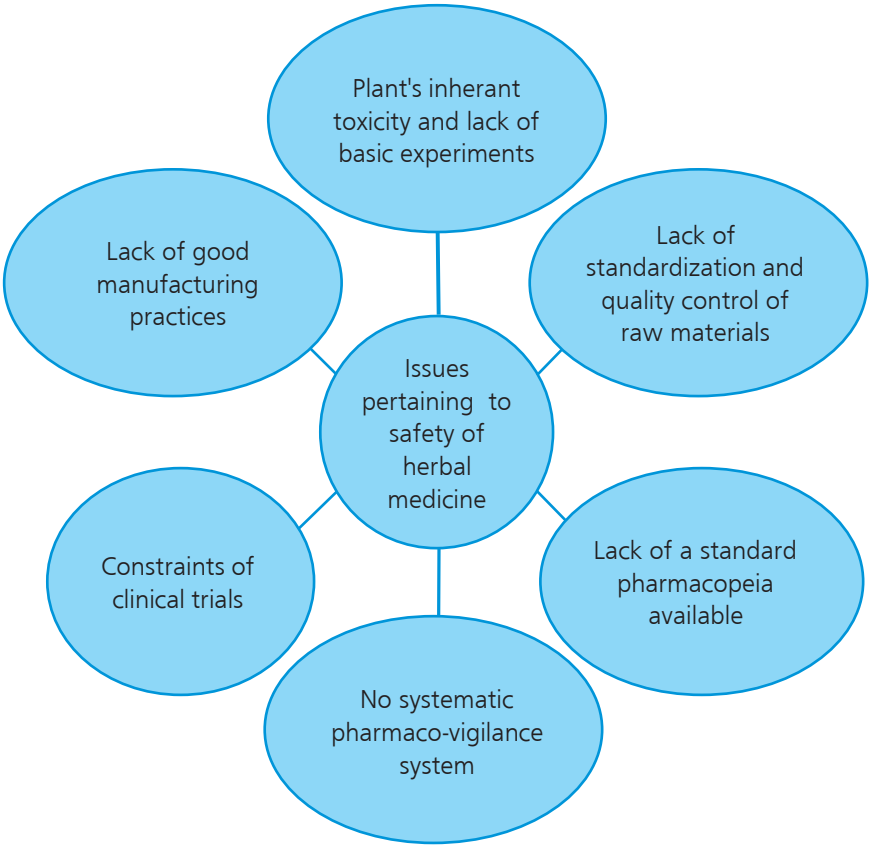
Currently, there is no system for pharmacovigilance in traditional medicines in Sri Lanka. The future of all the formulary processes may be best placed under a pharmacopeia commission with a research and development unit, similar to what exists in India. This may help to address certain legal provisions in the country which limit access to some commonly used ingredients of Ayurvedic drugs, such as cannabis and opium.

BMARI is taking steps to establish a GMP-compliant drug manufacturing unit with modern machinery. This step is an essential part of TM research and development. However, this depends on financial support from the Sri Lankan government.

4.2.2 Safety of herbal medicine

An overview of the issues around the assessment of the safety of herbal products is the first priority in herbal drug development and faces several challenges (Fig. 12). The toxic effects of a herbal preparation may be attributed to the inherent toxicity of plant constituents and ingredients, manufacturing malpractice and contamination *(200)*, botanical drug interactions, etc. Evaluation of the toxic effects of plant constituents of herbal formulations requires detailed phytochemical and pharmacological studies. It is, however, safe to assume that, based on human experiences in various cultures, the use of toxic plant ingredients has already been largely eliminated and recent reports of toxicity could largely be due to misidentification and overdosing of certain constituents *(204)*.

Fig. 10. *Issues pertaining to safety of herbal medicine*



Potential contaminants of herbal medicines include microorganisms, microbial toxins, pesticides, fumigation agents, radioactivity and presence of toxic compounds of toxic metals *(204)*. Some of these contaminants have been identified by the Committee for Proprietary Medicinal Products (CPMP) of the European Community (EC) for use in controlling the purity of herbal medications in the European Union (EU) *(205)*. The CPMP guidelines highlight the need for effective control of starting materials and finished products and emphasize the importance of good manufacturing practice. Safety standards should thoroughly address and include product specifications when considering product registration in

regulatory authorities. Mosihuzzaman and Choudhary (2008) note that a key challenge is to objectively assess conflicting toxicological, epidemiological and other data and verification of herbal materials used. This requires a standard audit process to identify potential contaminants in herbal products.

In this review, we have not focused on preclinical research data, but using standard process of preclinical studies prior to undertaking clinical research is of utmost importance.

4.3 Supporting TM research: Clinical trials, case reports, community-based studies and policies

4.3.1 Clinical trials

When undertaking a clinical trial of a conventional drug, there are four issues that need to be addressed:

(1) chemical-manufacturing-control (CMC) issues

(2) non-clinical issues

(3) clinical issues

(4) ethical issues *(206)*.

Studies of herbal products face additional complexities, compared to conventional medicine research. These include the multi-ingredient composition of an intervention and the fact that typically substantial prior human use precedes its formal investigation. These features have important ramifications for CMC, non-clinical, clinical and ethical issues.

International organizations and national authorities have published statements for supporting clinical trials of herbal products, whereby the justification required for conventional drugs has been adapted to traditional medicines. The International Conference on Harmonization (ICH) outlines the key information recommended for inclusion in a core clinical report of any study where therapeutic, prophylactic or diagnostic agent has been introduced in human subjects.

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the United States of America to discuss scientific and technical aspects of drug registration. ICH's mission is to achieve greater harmonization to ensure that safe, effective and high-quality medicines are developed and registered in the most resource-efficient manner. But it is still difficult to apply these guidelines to TM research. TM clinical trials may need a different approach or process to meet the ICH recommendations, particularly considering the fact that many of the products have been in use for long periods.

In Sri Lanka, very few clinical trials have been conducted in herbal medicine development. Several clinical trials of herbal medicine in Sri Lanka did not undergo an institutional ethics review process but were registered on SLCTR. Clinical trials of herbal interventions should be conducted by graduate, qualified traditional (Ayurveda, Unani or Siddha) practitioners and allopathic practitioners.

Clinical trials require institutional ethical clearance, for example, through the Ethics Review Committee of the Institute of Indigenous Medicine of the University of Colombo before commencement and should adhere to the latest version of the Declaration of Helsinki with regard to good clinical

practice (GCP). Investigators should achieve GCP training and certification before conducting a trial. Usually, these trials are conducted in educational institutes as a part of their postgraduate research or by manufacturing companies to find out the therapeutic efficacy and safety of herbal mixtures.

Sometimes trials were conducted as comparative studies with Western medicine as positive control groups. For example, a formulation containing *Salaciareticulate* (*Kothalahimbutu*) has been tested in a clinical trial and found to be useful in type 2 diabetes as an adjunct to glibenclamide and metformin in standard dosage *(207)*. Some of these clinically tested new formulas have not yet been included in the government-accepted Sri Lankan Ayurveda Pharmacopeia *(208)*.

To improve the safety and consistency of novel phytochemical preparations, regulatory authorities should maintain an updated version of pharmacopeia with product monographs. However, in Sri Lanka, this is not being followed due to the lack of a pharmacopeia commission.

There is limited capacity for clinical research in traditional medicine in Sri Lanka due to limitations in human resources to undertake such studies and restricted institutional capacity. Some private companies are conducting clinical trials in Sri Lanka in collaboration with universities to research efficacy and support the medicinal claims of their products. The results of these clinical trials are published in indexed journals and this has enabled these companies to increase the market share of their products locally and overseas.

Most clinical trials have been published in journals with limited impact

For example, the *Journal of Ayurveda Holistic Medicine* is not ranked in SCImago and is not indexed on PubMED. Three journals, publishing specifically on Ayurveda, listed in PubMed, are *Journal of Ayurveda and Integrative Medicine* (Q2 complementary and alternative medicine), *International Journal of Research in Ayurveda and Pharmacy (*Q3 complementary and alternative medicine) and *International Journal of Ayurveda Research* (not assigned a quartile yet). To improve clinical trial publication potential, following a template such as the example provided in Appendix 2 may be helpful.

4.3.2 Case reports in traditional medicine

Ayurveda/TM therapy is generally tailored to meet the unique presentation or patterns of symptoms and individual characteristics. This is not dissimilar to "omics"-based pharmacology, which aims to individualize or personalize by examining specific indications for therapies by identifying biomarkers in population.

Case studies in TM are important due to completeness of the application of classical approach of Ayurveda/TM concepts such as *prakriti, agni, dhatu, srotas, rasayana, shatkriyakala, agnibala, ojabala, manobala*, etc. Among clinical research conducted during 2015–2019, 77% were case-based studies. And most of these case studies considered the basic TM concepts mentioned above in diagnosis and treatment. About 11% of the case studies directly exhibit the treatment regimens or formulations used exclusively in Sri Lankan indigenous medicine and Ayurveda during the review period. However, most of the regimens have incorporated indigenous formulas unique to Sri Lanka.

Most of these case studies deal with "*Kadum-bindum"*, a speciality in Sri Lankan indigenous medicine that deals with fractures (orthopaedics). There have been favourable outcomes in almost all

such case studies considered. It was evident in these case studies that the pastes and special oils used in Sri Lankan indigenous medicine has greatly improved fracture healing, in a shorter period of time.

In some of the case studies, attempts have been made to manage complicated systemic illnesses like cancer (*arbudha*), HIV/AIDS and chronic kidney disease with favourable clinical outcomes. The therapies have greatly improved the quality of life of patients, according to these case studies. Many of the patients, who have sought indigenous treatments, have not only successfully addressed their main complaints, but have also considerably reduced other complications and associated diseases, such as dyslipidaemia, diabetes mellitus, hypertension, etc.

Mandama, a childhood disease characterized by nutritional deficiency due to impaired digestion, has been considered in a few case studies. Some of these case studies were based on treatment regimens written in palm leaves on Sri Lankan indigenous medicine on *Mandam-roga*. Case studies relating to diseases of the skin, i.e. psoriasis, acne, etc., show that many patients seek Sri Lankan indigenous treatments when they have skin conditions. Some case studies state that patients seek allopathic treatments initially, which reduce symptoms, but they recur once medication is stopped. Therefore, they turn towards Sri Lankan indigenous medicine as it uses cleansing (blood purifying) methods, which, in some cases, completely resolve the problems. Findings from case studies require validation in large scale randomised controlled trials to translate these traditional medicines into practice.

Some case studies had exemplified the importance of holistic and integrative approach involving body, mind and spirit. But only a few case studies (9%) were published in international peer-reviewed journals

Therefore, there is a need to encourage researchers to publish their work in peer-reviewed journals. This low rate of peer-reviewed journal publication could be because of failure to adhere to scientific research methodologies or to provide accepted case study formats. It is also possible that there may not be any encouragement from the relevant authorities providing facilities for publication process. Another reason is that peer review journals that accept TM-based researches are sparsely available.

To improve case report writing and publication potential, meeting the checklist requirements from the CARE guidelines provided in Appendix 3 may be helpful. A range of resources for writing case reports (case studies and case series) is available on *https://www.care-statement.org/downloads*.

4.3.3 Community-based participatory research in TM

Community-based research can make important contributions to understanding how local environments impact the health status of a population. Community-based participatory research (CBPR) is a widely accepted collaborative approach to research that works to understand and protect public health by involving all partners in the research process *(209)*. CBPR has emerged in the last decades to bridge the gap between science and practice through community engagement and social action to increase health equity *(210)*. Relatively fewer community-based research have been conducted.

Some of the public health care services-based studies had adhered to KAP studies and survey models. There were no cohort and proper case-control studies found during this review period related to TM. There were around 9.7% studies, including KAP studies and survey-based studies, conducted on dengue fever. About 2% KAP studies was conducted on breast cancer among women. About 12% studies were conducted on diabetes, including QOL of patients and TM practices, prevalence studies, diabetic retinopathy screening programme and stress and diabetes-based screening. Around 17% nutritional status assessment survey studies were conducted during this review period while 2% were focused on prevalence of respiratory disorders among children.

Also, 2% research has been conducted on the application of international human rights standards as a mechanism to protect the rights of people living with HIV/AIDS as a Sri Lankan perspective. Around 5% prevalence studies were conducted on musculoskeletal disorders, including osteoarthritis. Furthermore, 5% noncommunicable disease-based survey studies were conducted during this period. But there were no community- and TM-based, major studies found on chronic kidney diseases during this review period even though it is a significant health burden in Sri Lanka.

Major drawbacks of most of these community-based health research and surveys included non-adherence to proper standard intervention design and implementation process

Also, sample selection methods, measures and instrument design were not discussed properly and data collection, data analysis and interpretation were not properly mentioned. Therefore, it is important to provide proper guidelines and training to those who are involved in community-based TM research in Sri Lanka.

We would suggest the following important studies to be conducted as CBPR in Sri Lanka:

- to study community's access to TM care and health problems commonly addressed in TM care setting – this can help set the stage for real policy change on a local level;
- to study the rise in NCD and available measures in TM for prevention; and
- to study the context of improving maternal and child health through TM.

As a solution to the poor quality of reporting of medical research, guidelines for different types of study designs have been developed in conventional medical systems, which secure accurate reporting and transparency for reviewers and readers of the scientific community. It is of utmost importance to implement these guidelines to maintain the quality of reporting TM-based medical research.

4.3.4 Supportive policies and funding for TM research

There are several incentives provided by the government to promote research and development of new innovations. These are in the form of individual incentives like consideration for promotions and special allowances, and fiscal incentives to institutions and priority consideration in research grant schemes. Individual R&D contributions are considered for promotions to the next level at research institutions and universities.

Published research, patents and the ability to attract research grants from outside sources are allocated marks in promotion schemes. Institutions provide limited opportunities for local and foreign

training, scholarships, foreign leave and sabbatical leave to enhance knowledge and assist career advancement. Research scientists are eligible for research allowance as a part of their salary. The National Science and Technology Commission (NASTEC) policy encourages all researchers, including health-related researchers, to collaborate with business partners at the outset of a research project.

The two funding bodies functioning under the Ministry of Science, Technology and Research, National Science Foundation and National Research Council (NRC), also consider alliance with business partners as a criterion in funding research proposals in certain grant schemes.

The Support Scheme for Supervision of Research Degrees (SUSRED) is an award given by the National Science Foundation to supervisors with postgraduate research degrees (MPhils and PhDs) and institutions that support postgraduate research in Sri Lanka, in recognition of the service to the nation. This scheme was implemented in 2011 to motivate, support and recognize scientists in all areas of science and technology.

The Overseas Special Training Programme (OSTP) financially assists scientific and technical personnel (science administrators, science educators, S&T policy-makers and science communicators) as well as full-time research students to receive overseas training for up to 12 months. The International Partnerships for Science and Technology (IPSAT) programme helps Sri Lankan scientists, engineers, science and technology policy-makers and research personnel to undertake collaborative R&D/S&T service assignments with foreign-based scientists for stipulated periods in Sri Lanka.

The President's Awards for Scientific Publications was started in 2001 by the NRC to recognize scientists whose work attained international standards. Under this scheme, Sri Lankan scientists, based in the country, who publish papers in Science Citation Index (SCI)-indexed journals, receive certificates of appreciation. The criteria for making this award were made more stringent recently by restricting the award to those who publish in SCI journals with an impact factor of one or more.

The NASTEC initiated an award system in 2006 to encourage young scientists and recognize their achievements. These awards are presented under two categories, namely scientific research and popularization and promotion of science. The awards are open to members of the Young Scientists Forum (YSF).

The Sri Lankan Budget 2012 announced a range of tax incentives, including reduction of tax on research income, reduction in personal income tax of all those engaged in research and technology, and reduction in income tax for all institutions engaged in research and technology. Such institutions were also exempt from value added tax (VAT). The budget further proposed a triple tax deduction in relation to research and development expenditure undertaken by private enterprises through government institutions, to encourage private institutions to use government research facilities. Under this scheme, a private company is entitled to a tax deduction of three Lankan rupees for every single Lankan rupee invested in R&D in the government sector.

Currently, there are few north-south or south-south partnerships for capacity-building in the area of health innovation established in Sri Lanka. This is mainly due to restricted capacity in the industrial sector for original research and new product development. Most industries focus on replicating technologies and products that are already available. The National Science Foundation, however, has two funding schemes that aim to facilitate such collaborations.

BMARI has established needs-based priorities for health R&D, such as research on cancer, diabetes, CKD, cardiovascular diseases and dengue. These research areas have been prioritized

in keeping with the National Health Research Policy. Although limited R&D work has been carried out in the past, BMARI is planning to improve the capacity to work on medicines development and production. Apart from the government facility to manufacture Ayurvedic medicines, many private-sector industries are involved in R&D for manufacturing medicines.

4.4 Developing the TM market

4.4.1 Public-private enterprise partnerships

Investment in pharmaceutical research and development has increased substantially in the past few years with multidisciplinary research approaches in Sri Lanka on a par with global investment in herbal pharmaceutical research and development (R&D). But, similar to the global scenario, this has not translated into a corresponding increase in output in terms of new drugs approved. This indicates that therapeutic innovation has become more challenging *(211)*. At the same time, health-care costs are steadily spiralling, fuelled by the ageing of the population and a parallel rise in the chronic disease burden *(211,212)*.

According to research findings of Vaudano (Vaudano, 2013), many pharmaceutical companies are realizing that a paradigm shift in the industry's R&D strategy is the only way of reversing the ongoing negative trend *(211)*. Novel strategies, based on an integrated and collaborative approach, are required, building on innovation and leveraging on the strengths and input of all stakeholders in the health system, with the shared goal of delivering effective and sustainable health-care solutions to the society *(213)*.

In 2004, the US Food and Drug Administration (FDA) acknowledged a growing gap between the rate of basic science discovery and the translation of these discoveries into development of medical products. To address this gap, the FDA instituted the Critical Path Initiative (CPI) (*206*), which called for increased efforts to catalyse innovation in product development through the launch of several initiatives. The CPI further emphasized that a joint effort between the research community, industry, and FDA scientists was essential to realize the CPI vision *(214)*. To this end, the FDA convened both external stakeholders and FDA scientists to identify research priorities that could guide the FDA to bring focus to specific unmet public health needs. This effort resulted in the Critical Path Opportunities List (CPOL) published in 2006.

The stakeholders identified six top priority focus areas related to the safety, efficacy, quality and performance of FDA-regulated products *(17)*:

- priority area 1: Better evaluation tools;
- priority area 2: Streamlining clinical trials;
- priority area 3: Harnessing bioinformatics;
- priority area 4: Moving manufacturing into the 21st century;
- priority area 5: Developing products to address urgent public health needs; and
- priority area 6: At risk populations–paediatrics.

In the Sri Lankan context, it may be possible to adapt the CPI developed by the US government. This may increase efforts to catalyse innovation in product development through public-private partnership. Within this CPI, traditional medicine and knowledge can be upgraded to harness opportunities for new clinical drug developments or standardize current herbal products to achieve global acceptability. This lead will reduce health-care expenditure for drug import to the country in the future.

For the industry to partner with TM research institutions in the development of new TM medicines, financial incentives are needed. Investment by the industry is not viable if there is no way to protect or patent or retain market exclusivity or guard research and data. In Australia, a regulatory reform is underway to improve the competitiveness and provide incentive. The new Data Protection Scheme for Assessed Listed Medicines aims to incentivize innovation by protecting the results of investment in the development of TM products (known as complementary medicines in Australia) *(215)*.

The scheme is designed to prevent competitors from seeking market authorization of generic forms of an assessed listed medicine. Competitors will not be able to utilize data that was generated and used by the sponsor of the original TM medicine to obtain market authorization. This provides industry with the means to finance further research and development activities by preventing others from capitalizing on their investment and innovation. Clinical trial information supporting a new intermediate clinical indication will be restricted to a five-year protection period for use only by the owner of the clinical trial data.

4.5 Protecting traditional medicine knowledge in Sri Lanka

4.5.1 Intellectual property rights

Intellectual property rights (IPR) issues are not yet addressed in medicinal products. According to our findings (Perera and Shridhar, 2017), Sri Lanka was unable to build an effective intellectual property rights regime yet, especially for the traditional medical sector. Therefore, the Sri Lankan traditional medicine sector has to face several difficulties, especially in international trade, losing many opportunities to use its own traditional medical knowledge for the benefit of future generations due to the inability to patent traditional knowledge.

Sri Lanka has implemented some rules and regulations in this regard to protect plant varieties and traditional knowledge. Most of these Acts and ordinances deal with natural resources, which collectively indicate a policy in favour of physical protection of natural resources, but are not specific laws relating to medicinal plants and traditional knowledge. Therefore, it is important to develop guidelines and laws and enforce them to ensure benefits of sharing with the community for commercial use of traditional knowledge.

The implementation of the proposed Bill on "The protection of traditional knowledge in Sri Lanka", drafted and placed in the world intellectual property indicators of WIPO (World Intellectual Property Organization) in 2009 with several amendments, would address many of these issues. The National Intellectual Property Office (NIPO) is in charge of implementing IPR-related activities in the country. Still, Sri Lanka does not have any legislation comparable to the Bayh–Dole Act or the Patent and Trademark Law Amendments in the USA. The Intellectual Property Rights Act No: 36 of 2003 has replaced the code of Intellectual Property Act No: 52 of 1979.

This Act has introduced several types of property rights, including copyrights, related rights, expression of folklore, industrial designs, marks, patents, unfair competition, undisclosed information, geographical indication, etc.

According to the Act: *"...plants, animals and other micro-organism other than transgenic micro-organism and an essentially biological process for the production of plants and animals other than non-biological and Microbiological processes shall not be patentable (Section 62.1)."* However, an invention can be patentable if it is new, involves an inventive step and is industrially applicable. Thus, identifying new plant varieties can be regarded as a new innovation and can be patentable.

Furthermore, with regard to traditional knowledge, the Act addresses expression of folklore. Section 24 of the Act offers a sui generis form of protection to the expression of Sri Lanka's folklore. Section 5 of the Act says that "expression of folklore can be identified as a group oriented and tradition based creation of groups or individuals reflecting the expectations of the community as an adequate expression of its cultural and social identity, its standards and values as transmitted orally by imitation or by other means".

4.5.2 Draft Legal Framework for the Protection of Traditional Knowledge (2009)

A Legal Framework for the Protection of Traditional Knowledge in Sri Lanka was prepared in 2009 to provide protection and proper management of traditional knowledge in the country. However, this draft has not yet been approved. According to the draft document:

> *"The Government of Sri Lanka recognizes: the importance and value of traditional knowledge in all the fields of human endeavor including scientific, technological, industrial, economic, cultural, educational, social and spiritual; and the necessity to promote the protection, development, conservation and preservation of traditional knowledge; meet the legitimate needs and expectations of the holders of traditional knowledge; secure the respect and recognition for the traditional knowledge and the holders thereof for their contribution to the knowledge and development; ensure fair and reasonable benefits to the holders of traditional knowledge for the use of traditional knowledge outside the traditional context; regulate use, disclosure, acquisition, preservation and conservation, management, development and application of traditional knowledge; discourage, control, counter and stop misuse of, misappropriation of an unauthorized access to, traditional knowledge; and enable the human race to duly benefit from the traditional knowledge of Sri Lanka." (216)*

"Traditional knowledge" in the Act refers to the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context and includes the knowhow, skills, innovations, practices and learning that form part of traditional knowledge systems. It also refers to knowledge that is embodied in the traditional lifestyle of a community or people or is contained in written or codified knowledge systems passed down to generations. Also, as per the ACT, "traditional knowledge" is not limited to any specific technical field and may include agricultural, environmental, health care and medicinal knowledge, associated with genetic resources or other components.

The "holder of traditional knowledge" is defined as an individual or group of individuals or a community in Sri Lanka who or that is in possession of traditional knowledge distinctively linked to

such an individual, a group of individuals or a community, and that is not in the public domain, but does not include a person or a group of persons incorporated or not incorporated who have acquired such traditional knowledge in violation of the provisions of this Act.

The draft Act calls on the Government of Sri Lanka representing the people of Sri Lanka to preserve, develop and manage traditional knowledge in the public domain for the benefit of the people of Sri Lanka and future generations and to encourage and promote scientific research and innovations, involving and relating to such traditional knowledge. The Director General of Intellectual Property will be responsible for discharging this duty on behalf of the Government of Sri Lanka with the cooperation of the government agencies dealing with related subjects such as indigenous medicine, agriculture, bio-diversity, environment, fauna and flora, wildlife and forest, whenever he/she needs such cooperation and in the manner and circumstances in which he/she needs such cooperation.

Section 6 of the draft document explains that traditional knowledge will be protected using several strategies such as:

- access to traditional knowledge;
- misappropriation of traditional knowledge;
- acquisition of traditional knowledge by theft, bribery, coercion, fraud, trespass, breach of contract or inducement of breach of contract, breach of confidence or confidentiality or inducement of breach of confidence or confidentiality, breach of fiduciary obligations or other relations of trust, deception, misrepresentation, the provision of misleading information when obtaining prior informed consent for access to traditional knowledge;
- unauthorized disclosure or use of traditional knowledge by any person or group of persons, corporate or unincorporated, who legitimately had access to traditional knowledge;
- use of traditional knowledge that violates the terms that were mutually agreed on as a condition of prior informed consent concerning access to that knowledge;
- false claims or assertions of ownership or control over traditional knowledge, including acquiring, claiming or asserting intellectual property rights over traditional knowledge-related subject matter, when those intellectual property rights are not validly held in the light of that traditional knowledge and any conditions relating to its access; and
- willful offensive use of traditional knowledge of particular moral or spiritual value to its holders by third parties outside the customary context, when such use clearly constitutes a mutilation, distortion or derogatory modification of that knowledge or is contrary to public order or morality.

Section 9 (1) of the proposed Act states that there shall be a register for traditional knowledge maintained and kept by the Director General of Intellectual Property. The objectives of the register will be to:

- collect and preserve the traditional knowledge;
- encourage and promote the use of traditional knowledge;

- prevent unlawful access to and patenting of traditional knowledge; and
- ensure the equitable sharing of benefits arising from access to such traditional knowledge.

The Director General of Intellectual Property shall establish and maintain a database containing traditional knowledge in the public domain. Furthermore, Article 15 (2) of the Act states, "The Commissioner for Ayurveda and other concerned government agencies shall identify, collect and transmit such knowledge to the Director General of Intellectual Property to be included in the database." The Director General of Intellectual Property may also create digital libraries and other records of traditional knowledge as may be prescribed by the minister.

In conclusion, conventional IPR discourage the disclosure of traditional knowledge and hamper the documentation of traditional knowledge. Thus, there is a need to develop an alternative, sui generis system, which will meet the needs of holders of traditional knowledge. Such a system will not only ensure the sharing of benefits, but will also create an environment which would encourage the disclosure of traditional knowledge that would otherwise be lost to the world. The development of such a sui generis system is, however, no easy task and requires concerted effort of the local community.

Traditional knowledge, which is in the public domain, needs to be documented in the form of traditional knowledge digital libraries as suggested in the proposed Act of 2009. Documenting traditional knowledge includes recording it, writing it down, taking pictures of it or filming it – anything that preserves it in an accessible form. It is different from the traditional ways of preserving and passing on knowledge within a community and can promote or damage a community's interests, depending on how the documentation is carried out.

It is important to develop guidelines or laws and enforce them to ensure benefit-sharing with the community for commercial use of traditional knowledge. And the traditional knowledge should be recognized in the form and concepts of the traditional medicine system.

Creating a system for the registration of innovations by inventors would be equivalent to giving inventors the right to challenge any use of their innovations without prior permission. For useful innovations, some kind of petty, patent-giving protection for a limited duration might be appropriate, as per the Australian example.

In light of intellectual property issues, it is absolutely important to implement the proposed Act, "The protection of traditional knowledge in Sri Lanka", which was drafted and placed at WIPO in 2009 with further amendments by stakeholders responsible with regard to TM in Sri Lanka.

4.6 Summary of current status and challenges of TM research and development

When considering the framework for TM research in Sri Lanka (Chapter 2), the findings of the scoping review (Chapter 3) and the challenges discussed in this chapter, and the strengths, weaknesses, opportunities and threats (SWOT) to TM research in the country can be summarized as follows:

Fig. 11. *SWOT analysis of TM-based clinical research process in Sri Lanka*

Strengths	Weaknesses	Opportunities	Threats
• Government-accepted TM systems and separate section in the Ministry • Strong support research system, with educational institutions affiliated to universities with teaching hospitals, 49 Ayurveda hospitals and 159 Ayurveda central dispensaries • A separate research institute for TM/Ayurveda (BMARI) • Well-developed ethics review process having local and international affiliations • Trained postgraduate researchers	• Limited funding capacity for clinical research • Low scale of operations and technology in research, including laboratory facilities • No well-equipped research-based hospital/s available for clinical trials • Lack of collaboration with mainstream conventional medicine systems • Low level of private sector involvement in TM research • No clear mechanism to conduct trials if private sector is interested and has initiated • Low rates of publications in SCImago-indexed journals	• Natural, traditional and safe approaches are being welcomed internationally • Increased scope for innovation and change in approach to therapies • Estimated global market size is increasing for TM-based products • Exports of herbal products, backed by clinical trials, are highly accepted across the globe	• Sector might become irrelevant to issues of health care due to lack of innovation/R&D • Brand recognition of alternative medicinal systems, such as Chinese, Latin and South American, African, etc., rising • Intellectual property rights issues • Criticism for herb-mineral drugs safety • Underdeveloped pharmacovigilance system

The challenges specifically for herbal products development include:

(1) There is a lack of quality assurance and control in manufacturing of herbal/TM products, which is a confounding factor in achieving global trade.

(2) The informal sector manufacturing and selling herbal drugs and related products on a small scale is large, and this often makes it impossible to identify quality products.

(3) Many counterfeit product developers are involved in the trade.

(4) Information related to herbal products and their usage is scattered and not available in electronic form, thereby making it difficult to access.

(5) There are few multicentred clinical research projects for herbal formulations.

(6) Communication between policy-makers of orthodox Western medicine and those of Ayurvedic medicine is not adequate (i.e. lack of collaboration between the Ayurveda Formulary Committee and the Cosmetic and Drug Devices Authority).

(7) There is a lack of trained resource persons in herbal product regulation bodies.

(8) Ayurvedic pharmaceutical industry is not motivated to focus on pharmacovigilance of herbal/TM products. Hence, there is a lack of post-market surveys about drug safety.

(9) There is a need to develop standard pharmacopeia for herbal drugs/TM.

(10) There is no legal classification of herbal drugs/TM, according to their therapeutic usage and rules and regulations are not enough to bind patients to prescriptions. Therefore, the consequences of over-the-counter drugs could be serious.

(11) There is no proper recall system for pharmaceutical preparations in Sri Lanka.

These issues and challenges may be relevant to other countries dealing with herbal-related product development and marketing.

According to the WHO Traditional Medicine Strategy 2014–2023 (WHO, 2013), Member States need to adhere to the following strategic actions in the context of sustainable development of herbal medicine sector.

(1) Based on the greatest potential risks and/or benefits attributable to T&CM used in their country: a. monitor the safety of T&CM; b. identify sources of evidence, whether historical, traditional or scientific, which support or invalidate a particular therapy; and c. determine the risk/benefit profile, including cost-effectiveness.

(2) Promote research and development, innovation and knowledge management.

(3) Encourage knowledge generation, translation and dissemination by establishing a comprehensive and inclusive approach to T&CM research and development, including quality and cost-effectiveness.

(4) Develop a national research agenda, which acknowledges and includes various types of research models where appropriate.

(5) Develop and share appropriate methods and criteria for evaluating the safety, efficacy and quality of T&CM products and for assessing the value of T&CM practice (e.g. develop resources for research, devise appropriate research methodologies and encourage investment).

(6) Prevent misappropriation of T&CM by implementing the relevant international instruments in line with the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, adopting or amending national intellectual property legislation and enacting other defensive protection strategies.

(7) Protect and conserve T&CM resources, particularly knowledge and natural resources.

(8) Identify how T&CM information is communicated through practitioners, product advertising, practices and media.

(9) Foster dialogue and partnership between stakeholders. Where relevant to the national need, seek input from international partners with additional information, especially concerning global trends and lessons learned.

(10) Publish standard treatment guidelines for use of T&CM as well as a list of essential herbal medicines, based on research evidences.

Sri Lanka has still not effectively taken the strategic actions mentioned above to upgrade the country's traditional medicine systems. But Sri Lanka is modestly adapting a positive research policy development process, adhering to considerable standard to implement ethical health research strategy, to traditional medicine systems.

According to the review, Sri Lanka has adhered and contributed to the following chief aspects to upgrade TM research in order to improve the health status and the health economy of the nation.

- It has implemented the Code of Conduct for Health Research in Sri Lanka (CCHRS).
- It has adhered to the standard ethics review process in health research, following updated versions of ethics principles and ERCs affiliated to world ethics governing bodies.
- The Sri Lanka Clinical Trials Registry is a primary registry linked to the WHO Registry Network of the International Clinical Trials Registry Platform (WHO-ICTRP). The Sri Lanka Medical Association has taken the initiative to establish SLCTR, which will provide a facility for registration of trials conducted in Sri Lanka or overseas and help promote collaborative research between Sri Lankan and foreign researchers.
- There are a number of government institutions in Sri Lanka actively involved in traditional systems of medicine research and development and policy-making and providing grants.
- There are a few incentives provided by the government to promote research and development targeting new innovations in TM.

References

1. Qi Z. WHO traditional medicine strategy: 2014-2023. Geneva: World Health Organization; 2013. Report No.: 9241506091.
2. World Health Organization. SEA/RC67/11-Traditional medicine: Delhi Declaration (No. SEA/RC67/11). WHO Regional Office for South-East Asia; 2014.
3. World Health Organization. Regional Workshop on Implementation of Health in All Policies. New Delhi, India, 14-17 July 2015 World Health Organization. Regional Office for South-East Asia.; 2017.
4. Equator-network: The CARE Guidelines: Consensus-based Clinical Case Reporting Guideline Development https://www.equator-network.org/reporting-guidelines/care/
5. Bodeker G, Kronenberg F. A Public Health Agenda for Traditional, Complementary, and Alternative Medicine. American Journal of Public Health. 2002;92(10):1582-91.
6. Satow YE, Kumar PD, Burke A, Inciardi JF. Exploring the Prevalence of Ayurveda Use Among Asian Indians. The Journal of Alternative and Complementary Medicine. 2008;14(10):1249-53.
7. Iwase S, Yamaguchi T, Miyaji T, Terawaki K, Inui A, Uezono Y. The clinical use of Kampo medicines (traditional Japanese herbal treatments) for controlling cancer patients' symptoms in Japan: a national cross-sectional survey. BMC Complementary and Alternative Medicine. 2012;12(1):222.
8. Bodeker G, Ong C-K. WHO global atlas of traditional, complementary and alternative medicine: World Health Organization; 2005.
9. Kankanamalage TN, Dharmadasa RM, Abeysinghe DC, Wijesekara RG. A survey on medicinal materials used in traditional systems of medicine in Sri Lanka. Journal of ethnopharmacology. 2014;155(1):679-91.
10. Perera P, editor Current scenario of herbal medicine in Sri Lanka. Conference proceeding, ASSOCHAM, 4th annual Herbal International Summit cum Exhibition on Medicinal & Aromatic Products, Spices and finished products (hi-MAPS), NSIC, Okhla Industrial Estate, New Delhi, India; 2012.
11. Organization WH. Traditional medicine: growing needs and potential. World Health Organization; 2002.
12. Polaris Market Research. Herbal Medicine Market Share, Size, Trends, Industry Analysis Report By Category; By Form; By Source; By Distribution Channel; By Regions, Segments & Forecast, 2020 - 2026. Polaris Market Research; 2021.
13. InsightSlice. Herbal Medicine Market Size, Share, Sales, Analysis, Industry Competition & Player Profiles, 2020 – 20302020.
14. Bannerman RH, Burton J, Wen-Chieh C. Traditional medicine and health care coverage; a reader for health administrators and practitioners. Geneva, Switzerland; 1983.
15. Jones M, Liyanage C. Traditional medicine and primary health care in Sri Lanka: Policy, perceptions, and practice. Asian Review of World Histories. 2018;6(1):157-84.
16. Ministry of Healthcare and Nutrition. Health Master Plan 2007–2016: Healthy and Shining Island in the 21st Century: Ministry of Healthcare and Nutrition; 2007.
17. Emanuel EJ, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. The Journal of infectious diseases. 2004;189(5):930-7.
18. Tilburt JC, Kaptchuk TJ. Herbal medicine research and global health: an ethical analysis. Bulletin of the World Health Organization. 2008;86:594-9.
19. Ministry of Health NaIM, National Health Research Council. Code of Conduct for Health Research in Sri Lanka Ministry of Health, Nutrition and Indigenous Medicine; 2018.
20. Institute of Indigenous Medicine Ethics Review Committee University of Colombo, Sri Lanka [Available from: https://iim.cmb.ac.lk/erciim/?page_id=53.
21. Standard Operational Procedures of ERC Institute of Indigenous Medicine, Faculty of Medicine, University of Colombo

22. Wilson PM, Petticrew M, Calnan MW, Nazareth I. Disseminating research findings: what should researchers do? A systematic scoping review of conceptual frameworks. J Implementation Science. 2010;5(1):1-16.

23. Tooke J C. Report of the High Level Group on Clinical Effectiveness: A report to Sir Liam Donaldson Chief Medical Officer. London: Department of Health; 2017.

24. What is a conflict of interest? University of California, San Diego; [Available from: http://research-ethics.org/topics/conflicts-of-interest/.

25. Sri Lanka Clinical Trials Registry (SLCTR): Sri Lanka Medical Association; [Available from: https://slctr.lk/.

26. International Clinical Trials Registry Platform (ICTRP): World Health Organization; [Available from: https://www.who.int/ictrp/about/en/.

27. National Medicines Regulatory Authority Sri Lanka [Available from: http://nmra.gov.lk/index.php?lang=en.

28. Forum for Ethics Review Committees of Sri Lanka [Available from: http://fercsl.lk/.

29. Strategic Initiative for Developing Capacity in Ethical Review (SIDCER): World Health Organisation; [Available from: https://www.who.int/sidcer/en/.

30. The Belmont report: ethical principles and guidelines for the protection of human subjects of research. United States: National Commission for the Protection of Human Subjects of Biomedical Behavioral Research; 1978.

31. Harmonisation ICo. ICH Harmonised Tripartite Guideline E2A: guideline for clinical safety data management: definitions and standards for expedited reporting -- consolidated guideline. 1995.

32. Harmonisation ICo. Guideline for good clinical practice, ICH harmonised tripartite guideline. 1996.

33. Organization WH. Standards and operational guidance for ethics review of health-related research with human participants: World Health Organization; 2011.

34. Fernando M, Dissanayake V. Ethics Review Committee Guidelines: A Guide for Developing Standard Operating Procedures for Committees that Review Biomedical Research Proposals. Sri Lanka; 2007.

35. Dissanayake V, Guanthilake M, Jayamnna Ne. Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka. 2009.

36. Tricco AC, Lillie E, Zarin W, O'Brien K, Colquhoun H, Kastner M, et al. A scoping review on the conduct and reporting of scoping reviews. BMC Medical Research Methodology. 2016;16(1):15.

37. Jayawardena R, Ranasinghe P, Chathuranga T, Atapattu PM, Misra A. The benefits of yoga practice compared to physical exercise in the management of type 2 Diabetes Mellitus: A systematic review and meta-analysis. Diabetes & metabolic syndrome. 2018;12(5):795-805.

38. Ranasinghe P, Pigera S, Premakumara GA, Galappaththy P, Constantine GR, Katulanda P. Medicinal properties of 'true' cinnamon (Cinnamomum zeylanicum): a systematic review. BMC complementary and alternative medicine. 2013;13:275.

39. Rajapakse S, de Silva NL, Weeratunga P, Rodrigo C, Sigera C, Fernando SD. Carica papaya extract in dengue: a systematic review and meta-analysis. BMC Complementary & Alternative Medicine. 2019;19(1):N.PAG-N.PAG.

40. Dahanayake JM, Perera PK, Galappaththy P, Samaranayake D. Efficacy and safety of two Ayurvedic dosage forms for allergic rhinitis: Study protocol for an open-label randomized controlled trial. Trials. 2020;21(1):37.

41. Ranasinghe P, Galappaththy P, Constantine GR, Jayawardena R, Weeratunga HD, Premakumara S, et al. Cinnamomum zeylanicum (Ceylon cinnamon) as a potential pharmaceutical agent for type-2 diabetes mellitus: study protocol for a randomized controlled trial. Trials. 2017;18(1):446.

42. Dahanayake JM, Perera PK, Galappaththy P, Samaranayake D. Efficacy and safety of two Ayurvedic dosage forms for allergic rhinitis: study protocol for an open-label randomized controlled trial. Trials. 2020;21(1).

43. Anuruddhika Subhashinie Senadheera SP, Ekanayake S, Wanigatunge C. Anti-hyperglycaemic effects of herbal porridge made of leaf Scoparia dulcis extract in diabetics -- a randomized crossover clinical trial. BMC Complementary & Alternative Medicine. 2015;15:1-9.

44. Ediriweera S, Perera K, Perera A, Peshala K, Edirisinghe E. Clinical study on effect of paste of manjistadiya on yuvana pidaka (acne vulgaris). Journal of Ayurveda Holistic Medicine. 2015;3(1).

45. Ekanayaka RAI, Rupasinha A, Sooriyarachchi MR, Goonaratna C. The effect of thriphala, a herbal Ayurveda formulation, on serum lipids, in patients on a maintenance dose of atorvastatin for hyperlipidaemia: a randomized controlled trial. Ceylon Medical Journal. 2017;62(3):128-40.

46. Hafeel M, Mobeen A, Rizwana A, Yasir M. Therapeutic evaluation of unani formulation in peptic ulcer single blind, before and after comparison clinical trial. International Journal of Current and Advanced Research. 2017;9(8).

47. Howshigan J, Perera K, Samita S, Rajapakse PS. The effects of an Ayurvedic medicinal toothpaste on clinical, microbiological and oral hygiene parameters in patients with chronic gingivitis: a double-blind, randomised, placebo-controlled, parallel allocation clinical trial. Ceylon Medical Journal. 2016;60(4):126.

48. Karunanayaka K, Hettihewa S, Silva D, Karunanayaka L, editors. Formulation of novel alcohol based hand scrubs with medicinal plant extracts and evaluation of the antimicrobial efficacy. International Symposium on Ayurveda and indigenous medicine (ISAIM 2018) 2018; University of Colombo.

49. Kumarapeli M, Karunagoda K, Perera PK. A randomized clinical trial to evaluate the efficacy of satapushpa-shatavari powdered drug with satapushpa-shatavari grita for the management of polycystic ovary syndrome (PCOS). International journal of pharmaceutical sciences and research. 2018;9(6):2494–9.

50. Pallie M, Perera PK, Goonasekara CL, Kumarasinghe N, Arawwawala M. Efficacy and safety of freeze-dried form of Tragia involucrata L. decoction in treating diabetes: a randomized controlled clinical trial. Clinical Trials in Degenerative Diseases. 2020;5(3):31.

51. Perera H, Karunagoda K, Perera PK, Samarasingha K, Arawwawala M. A randomized single blind comparative trial to evaluate the efficacy of whole plant of Phyllanthus niruri Linn. crude powder with Pushyanuga Churna in the management of Rakta Pradara due to Dysfunctional Uterine Bleeding (DUB). ŚĀLĀKYA SANDĪPANĪ 2017; Sri Lanka2017.

52. Rajavarthani S et al, editor Ayurveda and Sri Lankan traditional medicine approaches in joint disorders (Sandhigata Roga) and clinical trials. 20th International Ayurveda Symposium; 2018; Birstein, Germany.

53. Seneviratne V, Hapuarachchi S, Perera P, de Zoysa P, editors. Effects of Gotukola (Centella asiatica) capsules with cow's milk in modulation of cognition in young adults – A randomized controlled clinical trial (RCT) [abstract]. Proceedings of the Tradmed International symposium; 2017; Colombo, Sri Lanka: Waters Edge Battaramulla; 2017.

54. Weerakoon W, Perera P, Gunasekera D, Suresh T, editors. A phase I study of the safety and possible toxicity of a novel ayurvedic preparation-Sudarshana Suspension2016: Proceedings of Second International Conference on Natural Products Genomics ….

55. Abegunasekara, editor An Ayurvedic approach in the management of Ménière's disease - A case study. ICAUST 2016; 2016; Sri Lanka.

56. Alwis P, Silva U, editors. A clinical evaluation of the efficacy of "shadbindu taila" nasya in the management of "griva sandigatavata" (cervical spondylosis. ICAUST; 2017; Sri Lanka.

57. Attanayake A, De Silva U, Jayaweera J, Perera DL. Use of Ayurveda and Sri Lankan traditional medicine for healing shaft of humerus fracture following nonunion. Journal of Ayurveda and Integrative Medicine. 2018;9(3):217-20.

58. Attanayake AP, editor Evaluation of therapeutic effect of triphala katakanpata decoction and assessing the quality of life among diabetes mellitus patients. ICAUST; 2015.

59. Attanayake AP, editor Assessment of fracture healing following Ayurveda treatment in Malunion distal radius comminuted fracture of wrist without removing the internal fixator: a case study ICAUST; 2016; Sri Lanka.

60. Attanayake AP, Silver, Jayaweera J, editors. Healing effect of Sri Lankan traditional and Ayurveda medicine in comminuted fracture over shaft of Tibia following nonunion: a case report. ICAUST; 2017; Sri Lanka.

61. Balasooriya, editor Evaluation of the clinical efficacy of HeAyurvedaenBowitiya leaves [Osbeckiaoctandra] Phanta in the management of Diabetes Mellitus ICAUST; 2016; Sri Lanka.

62. Batvitha, editor A case study on management of Haemorrhoidal prolapse ICAUST; 2018; Sri Lanka.

63. Bavitha, editor Application of Kshara in the management of Fistula in Ano: A case study. ICAUST; 2018; Sri Lanka.

64. Chandrasiri A, Ediriweera E. Effect of El-Vireka, Mudgadi Kashaya and Triphala Udvartana in Athisthaulya (Obesity) - A case study. International Journal of AYUSH Case Reports. 2019;3:32-41.

65. De Silva K, Hapuarachchi S, Harapathdeniya S, Perera P, editors. Evaluation of efficacy of Sihin Midi (Premna integrifolia L) decoction in athistaulya (Obesity) patients. ICAUST; 2017.

66. Dissanayaka, editor A clinical study comparing the efficacy of the decoctions of Gaskaralheba (Achyranthesaspera) and Hathavariya (Asparagus racemosus) in the treatment of Sravi Arshas (bleeding piles). ICAUST; 2017; Sri Lanka;.

67. Dissanayake HNK, editor Comparative clinical study on the efficacy of treatment for Sraviarshas (bleeding piles) using the decoctions of Rathkaralheba (Cyathullaprostrata) and Gaskaralheba (Acyranthesaspera). ICAUST; 2015; Sri Lanka.

68. Farzana M, Sultana A, editors. Effect of Post e Anar and Safoof e Zaj in Hikkathul Farzj: A preliminary study. ICAUST; 2016; Sri Lanka.

69. Fazeenah, editor A case study on Varmghudadadarqiyyah (Thyroid swelling). ICAUST; 2018; Sri Lanka.

70. Fazmiya, Sewwandi, editors. Evaluation of unani treatment modality in myocardial infarction- case study. ICAUST; 2017; Sri Lanka.

71. Fazmiya, editor A prospective of modified Unani therapeutics for Gall Stone (Hasat-e-Mirarah) – Case series. ICAUST; 2015; Sri Lanka.

72. Fernando B, editor A clinical study on the efficacy of Sapta Winsati Guggulu in the management of Sushka Arsa. ICAUST; 2016; Sri Lanka.

73. Gamage K, Welivitigoda C, Kisholorjan S, editors. Management of hyperlipidemia (medhovruddhi) with the use of ayurvedic and traditional medicine: a case study. ICAUST; 2017; Sri Lanka.

74. Gunarathna E, Kulathunga R, editors. Management of Avabhahuka (Frozen Shoulder) Through Sri Lankan Ayurveda Treatment Protocol: A Case Study. ICAUST; 2019; Sri Lanka.

75. Gunarathna E, editor Leech application for management of Inflamed Haemorrhoids: A case study. ICAUST; 2018; Sri Lanka.

76. Gunatilaka HDP, Ediriweera E, Weerasinghe K, Karunarathne H, editors. Clinical evaluation of Sheeta Kashaya of Hibiscus furcatus with and without Vamana Karma with Lindernia pusilla in the cases of Prameha- Madhumeha (Type 2 Diabetes Mellitus). ICAUST; 2015; Sri Lanka.

77. Hasana M, editor Effectiveness of Syzygium cumini (Naval) root decoction of on Diabetics Mellitus (Mathumeaham) ICAUST; 2016.

78. Jabeen A, editor Unani approach to paralysis (Falij) – A clinical contrive ICAUST; 2017; Sri Lanka.

79. Jamaldeen, Rismiya, editors. A case study on effectiveness of dry cupping in frozen shoulder. ICAUST; 2017; Sri Lanka.

80. Ajmeer A, Dudhamal T, Gupta S, Mahanta V. Katupila (Securinega leucopyrus) as a potential option for diabetic wound management. Journal of Ayurveda and integrative medicine. 2014;5:60-3.

81. Ahmad W, Alam S, Dandroo J, editors. Pyoderman gangrenosum treated with Marham-e-raal – A case series. ICAUST; 2017.

82. BMARI. Case study on Actinomycosis (Kakanantikakushta). In: BMARI, editor. 2017.

83. Edirisinghe E, Ediriweera E, Weerasinghe K. Clinical effect of Sepalika (Nycanthes arbortristis) Niruha Vasti, Sepalika Sudulunu Kashaya and Lakshadilepa on Grudhrasi (sciatica)-A case study. International Journal of AYUSH Case Reports. 2018;2(3).

84. Edirisinghe E, Ediriweera E, Dhamasiri W. Effect of Sapa Vireka Choorna on Vibandha (Mala Adassiya/ Chronic Constipation) – Series of case studies. International Journal of AYUSH Case Reports. 2019;3(3).

85. Lankani A, Ediraweera E. Effect of Sri Lankan traditional medicine Jathiphalaadi Lepa and Heen Demata Yusha Nasya on Manibandha Shoola [Carpal Tunnel Syndrome]- A Case Report. International Journal of AYUSH Case Reports. 2018;2(2).

86. Ediraweera E. A Clinical study on efficacy of Siyakkai (Acacia concinna) Hair Wash on Darunaka (Pityriasis capitis). Journal of Ayurvedic and Holistic Medicine. 2021;2(7).

87. Jayasekara W, Ediraweera E. Effect of Vamana Karma, Triphala Kashaya and Dehigetadi Lepa in treatment of Kitibha (Psoriasis) - A case study. International Journal of AYUSH Case Reports. 2019;3(2):166-76.

88. Jayasundara N, Gunthilaka E, Perera P, editors. Principles of traditional medicine in the management of cancer – A case report. ICAUST; 2014; Sri Lanka.

89. Priyadarshani E, Karunagoda K, Perera P. Therapeutic effects of Sri Lankan Ayurveda treatment regimens for uterine fibroids - A case series. Ayurveda sameeksha. 2016;12:107.

90. Leena I, editor A clinical survey on effect on Maternal stress during pregnancy for Autistic disorders. ICAUST; 2018; Sri Lanka.

91. Mendis R, Wijesinghe W, Attanayake AP, editors. Assessing the therapeutic effect of Kakulu rice flour (KRF) paste for Carpal tunnel syndrome. ICAUST; 2017; Sri Lanka.

92. Navodi W, Ediriweera E, Kumara H. Sri Lankan traditional Virechana Karma with Ehela Peni (Cassia fistula) and application of Kaluwala Alepa (Alpinia malaccensis) in treatment of Sidhma Kushta (Pityriasis versicolor) - A case study International Journal of AYUSH Case Reports. 2017;1(2).

93. Ranasinghe R, Ediriweera E, Officer M, editors. EFFECTS OF DHANYAMLA PARISHEKA IN THE MANAGEMENT OF AMAVATA WITH SPECIAL REFERENCE TO RHEUMATOID ARTHRITIS- A CASE STUDY. ICAUST; 2015.

94. Seneviratne V, Perera P, SD H, editors. Effect on Agni in management of cancer: a case study of Ayurvedic perspective. 1st National Symposium on Sri Lankan Traditional Medicine; 2014; Institute of Indigenous Medicine, University of Colombo, Sri Lanka.

95. Shifra A, editor Efficacy of Unani Management Modalities in Congenital Hypothyroidism - A Case study. ICAUST; 2017; Sri Lanka.

96. Wickramasinghe M, Ediriweera SJJoA. Effect of Rakthamokshana (blood-letting therapy) and Sri Lankan traditional medicine on Siraja Granthi (varicose veins) - A case study. International Journal of AYUSH Case Reports. 2018;2:6-13.

97. Silmiya, editor Efficacy of jawarish-e-kamoon saada in the management of common gastrointestinal complaints: a clinical study. ICAUST; 2015.

98. BMARI. Therapeutic effect of Ayurveda treatment regimens for subfertility – Case Series. 2017.

99. Jayasinghe S, editor A clinical evaluation of triphala churna in the management of medo roga (hyperlipidemia and obesity). ICAUST; 2015.

100. Liyanage R, editor A case study on the management of Obsessive-compulsive disorder with special reference to Butonmada2018.

101. Perera PK, Perera M, Kumarasinghe N. Effect of Sri Lankan traditional medicine and Ayurveda on Sandhigata Vata (osteoarthritis of knee joint). Ayu. 2014;35(4):411-5.

102. Perera P, Kumarasinghe N. Traditional Sri Lankan Medicine Intervention in the Management of Knee Osteoarthritis (Janu Sandhigata Vata): Case Series. INternational Journal of Ayurveda and Pharma Research. 2018;6.

103. Jayasena R, editor A clinical study on the management of Sandhigatavata: A case study. ICAUST; 2018.

104. Jayasinghe J, Kulatunga R, Madushani M, editors. Clinical evaluation of a selective treatment regime on Sandhigatavata. ICAUST; 2018; Institute of Indigenous Medicine, University of Colombo, Rajagiriya, Sri Lanka.

105. Gamage K, editor Efficacy of Acupuncture on Osteoarthritis of the knee joinr. ICAUST; 2018; Sri Lanka.

106. Jayawardhane N, editor Therapeutic Efficacy of Janu-Vasti and the Traditional Local Application in the Management of Sandhigata Vata (Osteoarthritis) ICAUST; 2016.

107. Perera A, editor Therapeutic Effects of Sri Lankan Traditional Medicine and Ayurveda Treatment Regimes on SandhigathaVata (Osteoarthritis) – A case series. ICAUST; 2015; Sri Lanka.

108. Sewwandi, editor Case studies with seleted treatment regimen in the management of sandhigatavata ICAUST; 2015; Sri Lanka.

109. Silva D, editor Clinical evaluation of Shirodhara and MatraVasti with Baladi Yoga on fatigue after stroke (Pakshaghata). ICAUST; 2015.

110. Perera, editor Improvement of certain hematological values in a patient with Polycythemia (rubra) vera following Ayurveda treatment: A case report. ICAUST; 2015.

111. Sajeewani, editor Role of Shatavari Ksheera Basti in the management of Gharbha Kshaya (IUGR), A case study. ICAUST; 2015.

112. Dwivedi A, editor Managment of benign prostatic hyperplasia-an Ayurvedic approach. . ICAUST; 2016.

113. BMARI. A preliminary study on prevalence of proteinuria and abnormal serum creatinine levels among the patients attended for Ayurveda Treatments. In: (BMARI) BMARI, editor. Sri Lanka2017.

114. BMARI. Impact of clinically effective Ayurveda treatment on liver and kidney functions of psoriasis patients. In: Institute BMAR, editor. 2017.

115. BMARI. A clinical study of Virechana karma with *Dimorphocalyx Glabellus* Decoction of vasaguluchyadi and Aniththadilepa in the management of Psoriasis. In: Institute BMAR, editor. 2017.

116. BMARI. Clinical study of Nimbadilepa with pinda oil in the management of thickness condition of SidhmaKushta (psoriasis). In: Institute BMAR, editor. Sri Lanka2017.

117. Fazeenah A, editor An observational study on the therapeutic effect of polyherbal formulae in the management of (Daa us Sadaf) Psoriasis vulgaris ICAUST; 2016.

118. Mahesh, Parappagoudra, Navodayraju, editors. Case report on management of Kushta (Psoriasis) with Virechana Karma (Induced Purgation) and Rasayana (Rejuvenation) therapy. . ICAUST; 2017.

119. Pramodani, editor A Study on the Efficacy of traditional shirolepa in the management of Scalp Psoriasis. ICAUST; 2015.

120. Dewanarayana, editor A comparative clinical evaluation of Vasaguduchyadi decoction and Aniththadi Lepa with and without Virechana Karma with Weliwenna in the management of Kitibha (psoriasis). ICAUST; 2015.

121. Ariyaratne S, editor Effect of Unmadagajakesari Rasa on Astavidha Manobhavas of Kaphaja Unmada. ICAUST; 2016.

122. Ariyaratne S, editor Effect of unmadagajakesari rasa on kaphaja unmadama. ICAUST; 2015.

123. Liyanage C, editor Effectiveness of Navarakizhi on Sith peralum Umathuwa. ICAUST; 2015.

124. Raesuddeen, editor Case study on Zoaf-eKulya (renal failure). . ICAUST; 2015.

125. Ranasinghe P, editor Therapeutic potentials of Dhanyamla (A fermented cereal) against Amavata. ICAUST; 2018.

126. Ranasinghe P, editor Comparative evaluation of DhanyamlaVasti and Kayaseka in the management of AmavataWsr to Rheumatoid Arthritis. ICAUST; 2015.

127. Nishshanka, editor Clinical study on Bala KorandaTaila (BKT) matravasti and Eranda Saptaka Kashaya (ESK) in the management of Gridrasi. ICAUST; 2016.

128. Vidanapathirana P, editor A Comparative Clinical Study on the Effect of Chitrakadi Oil matravasti and Sinhasyadi Decoction Orally in the management of Gridhrasi (Sciatica). ICAUST; 2016.

129. Nishshanka, editor Clinical study on Bala Koranda Taila (BKT) matravasti and Eranda Saptaka Kashaya (ESK) in the management of Gridrasi. ICAUST; 2016.

130. Salma, editor A case study on Da ul Faqaa (Pemphigus vulgaris). ICAUST; 2015.

131. Perera, Dissanayake HNK, Jayakody JR, editors. Selective Ayurveda treatment modality for Lichen Planus (vishajakushta) – A case study. ICAUST; 2017.

132. Musmira, editor Effect of Roghan e khas on over granulation tissue formation in post episiotomy wound – A case study. ICAUST; 2015.

133. Perera, editor Successful Ayurvedic treatment modality for Prurigo nodularis (type of vishaja kushta) – A case study. ICAUST; 2015.

134. Hewageegana AU, editor Development of a substitute oil for VipadikaharaGritaTaila and its evaluation against Vipadika skin disease (A case study. ICAUST; 2015.

135. Farzana M, editor A Successful Pregnancy Outcome after Repeated Spontaneous Abortion Due to Myoma (Sala'e laifiya) -A Case Report. ICAUST; 2015.

136. Meher, Gopikrishna, editors. A comparative clinical study to evaluate the effectiveness of nyagrodhadi lepa & manjisthadi lepa on ankle sprain: a case stud. ICAUST; 2017.

137. Nithyapriya, editor The Varma therapy management for Sulukku (Sprain)- Traditional method: Observational Study. ICAUST; 2015.

138. Jayasinghe J, editor Case series on effect of Ayurvedic Treatment Regimens for Vadyathva (Sub fertility). ICAUST; 2015.

139. Kumari, editor A clinical evaluation of the effect of Shothahara compound on Shotha. ICAUST; 2015.

140. Raesuddeen, editor Case study on Synovitis. ICAUST; 2015.

141. Kalawana O, editor Clinical study on Beejadushtijanya Pandu (Thalassemia major) in children and it's management with Musta-thriphaladi avaleha and Gandhakadi yoga. ICAUST; 2018.

142. Karunarathna W, editor A preliminary study on local effect of traditional herbal remedy used in traumatic nail injuries. ICAUST; 2016.

143. Rajeev R, editor Clinical Evaluation of Sivappukukilthaila paste with Panchathuvarpikasayamin the management of wound. ICAUST; 2016.

144. Gunarathna E, editor Effect of leech therapy on diabetic foot ulcer - a case study. ICAUST; 2016.

145. Samaranayake, Pushpakumra, editors. Case study on Kshara Application in Diabetes Foot Ulcer. ICAUST; 2017.

146. Pathirana J, editor Management of Urolithiasis with reference to Ayurvedic concepts: A case study. ICAUST; 2018.

147. Priyadarshani E, editor Therapeutic Effects of Sri Lankan Ayurveda Treatment Regimes for Uterine Fibroids – A Case series. ICAUST; 2015.

148. Rumaiza, editor Pessary treatment for uterine prolapse and health-related quality of life: a case study. ICAUST; 2016.

149. BMARI. Wound healing effect of traditional herbal formulation (Pachchennai oil) on Varicose ulcer. In: Institute BMAR, editor. Sri Lanka2017.

150. Kumaradharmasena L, editor An Ayurvedic approach of computer vision syndrome and management with Tripalaghrit Akshitharpana: A case study. ICAUST; 2018.

151. Surangi K, editor Ayurvedic management of Macular odema (3rd patalagathatimira): A case study. . ICAUST; 2018.

152. BMARI. A case study on management of chronic wound with polyherbal formulation. In: Institute BMAR, editor. 2017.

153. Sing L, editor). Effect of Ayurvedic therapies in the management of infected wounds. ICAUST; 2017.

154. Ralapanawa DMPUK, Jayawickreme KP, Ekanayake EMM, Kumarasiri PVR. A study on the knowledge and attitudes on advanced life support among medical students and medical officers in a tertiary care hospital in Sri Lanka. BMC Res Notes. 2016;9(1):462-.

155. Prashan A, Kalpani B, Pathirage P, Chathura W. Knowledge and Attitudes on First aid among Advanced Level Students in Gampaha Educational Zone, Sri Lanka. Research Square. 2021.

156. Perera W, Perera P, Ambagahawita A, Wijesundara C, Bandaranayaka K, editors. People's knowledge, attitude and practices towards dengue infection and prevention in a semi-urban area, Sri Lanka. iCAUST; 2018; Sri Lanka.

157. Wijesinghe W, Pilapitiya S, Hettiarchchi P, Wijerathne B, Siribaddana S. Regulation of herbal medicine use based on speculation? A case from Sri Lanka. Journal of traditional and complementary medicine. 2017;7(2):269-71.

158. Stanieri A, Butler-Henderson K, Sahama T, Perera P, Silva D, Pelonio D, et al. A visual grid to digitally record an Ayurvedic Prakriti assessment: a first step toward integrated electronic health records-Open Access Repository2018. 11-7 p.

159. BMARI. Ayurveda Research from 1980 to 2016. In: Institute BMAR, editor. Nawinna2017a.

160. Kalyani M, editor A study of dispensing ayurvedic drugs on consumer satisfaction: special reference to puttalam district in Sri Lanka. ICAUST; 2017; Sri Lanka.

161. Wimalasooriya W. Effect of an indigenous food supplement "Suwa poshini" on nutritional status of pre-school children in Galle district-A prospective community trial. In ICAUST. 2016.

162. Priyadarshi SS, editor Application of Rasayana for paediatric population. ICAUST; 2015; Sri Lanka.

163. Kavtiha, editor A study on lifestyle of elders in J/283 Gramaniladari division (idaikkadu), Sri Lanka. ICAUST; 2015; Sri Lanka.

164. Fatima, editor Evaluation of traditional food "Kitchadi" on weight gain among the preschool children of four gravatte division in Galle. ICAUST; 2015; Sri Lanka.

165. Liyanage RP, Hettige SS, Karunarathne H, editors. Ayurvedic Management of Bipolar affective Disorder; a Case Report. Ayurveda: Inspiring Health and Happyness, Proceedings of 5th International Conference on Unani, Ayurveda, Siddha and Traditional Medicine; 2017; Insitute of Indigenous Medicine, University of Colombo, Sri Lanka.

166. Waratenne, editor A study of Sri Lankan cuisines with special reference to Ashtha Aaharavidhi Visheshayatana. ICAUST; 2015.

167. Lakmali, editor A study of clinical risk management in Ayurveda teaching hospitals in Sri Lanka. ICAUST; 2015; Sri Lanka.

168. Thillany, Sathiyaseelan, editors. Study on the Dominance of Arogyam and Intellectual activities in Guna changes among the Elders in shanthinilayam, Kaithady. ICAUST; 2015; Sri Lanka.

169. Pathiraja, editor The Application of International Human Rights Standards as a mechanism to protect the rights of the people living with HIV/AIDS: A Sri Lankan Perspective. ICAUST; 2017; Sri Lanka.

170. Jayasinghe, Kulatunga, Ratnapala, editors. Identification of association between risk factors and serum cholesterol. ICAUST; 2017; Sri Lanka.

171. Silva, Thathparan, editors. Analytical survey of patients attending to swithra (vitiligo) clinic. . ICAUST; 2017; Sri Lanka.

172. Lakmali, editor A Study of the factors influencing for the patterns of consumer behavior in the medical sector. ICAUST; 2015; Sri Lanka.

173. Fonseka, editor Role of Diabetic Retinopathy Screening. ICAUST; 2015; Sri Lanka.

174. Jayalal, editor Study on the Need of Stress Management in Ayurveda Health Care System in Sri Lanka. ICAUST; 2015; Sri Lanka.

175. Loganathan, editor A study of distribution of "Diagnosed hypertension" in Mathagal J/151 Grama Niladhari division during from April to June 2012. I. ICAUST; 2015; Sri Lanka.

176. Zabir, editor Knowledge, Attitude and Preventive Measures of Breast Cancer among Maligawatta Area Women. ICAUST; 2015; Sri Lanka.

177. Sandamali, editor Prevention of suicide (with especial reference to "sumithrayo" in panduwasnuwara western d.s. in kurunegala district). ICAUST; 2015; Sri Lanka.

178. Munasinghe, editor Effect of obesity on quality of certain semen parameters of Sri Lankan males. ICAUST; 2015; Sri Lanka.

179. Rathnakara, editor Prevalence of respiratory disorders of children, attending the Ayurveda Teaching Hospital, Colombo. ICAUST; 2015; Sri Lanka.

180. Wickramasinghe A, editor Comprehensive survey of patients attending to the orthopedic clinic in Ayurveda teaching hospital, Borella. ICAUST; 2015; Sri Lanka.

181. Kumari, editor An assessment of the perception of stress in type 2 diabetic patients in accordance with perceived stress scale (PSS 10). ICAUST; 2015; Sri Lanka.

182. Nayanathara, editor Prevalence of risk factors for non-communicable diseases in the selected population of urban areas in Thalawathuhenpita - North GramaNiladari divisions in Kelaniya District Secretariat Division of Gampaha District of Western Province, Sri Lanka and to develop a training programme with reference to Ayurveda medical system. ICAUST; 2015; Sri Lanka.

183. Niranjan, editor A study of Management practices for preventing Non-Communicable Diseases in Elderly population in Trincomalee urban council area. ICAUST; 2015; Sri Lanka.

184. Samarakoon, editor A study on effective distribution of Ayurveda drugs in Eastern Province of Sri Lanka. ICAUST; 2015; Sri Lanka.

185. Nizamdeen, editor Prevalence of Diabetes and Impaired Fasting Glucose (IFG) in adult population in the Kadawathsathara, Galle District. ICAUST; 2015; Sri Lanka.

186. Perera P, Silva K, Chandra N, editors. Health seeking behavior among patients with knee osteoarthritis in Sri Lanka: A hospital based survey. Conference proceedings Population Association of Sri Lanka , Annual Scientific Sessions , . Population Association of Sri Lanka: Annual Scientific Sessions; 2017; Univeristy of Colombo: Sri Lanka.

187. Stranieri A, Butler-Henderson K, Sahama T, Perera PK, Da Silva JL, Pelonio D, et al. A visual grid to digitally record an Ayurvedic Prakriti assessment; a first step toward integrated electronic health records. J Tradit Complement Med. 2016;7(2):264-8.

188. Sridharan K, Sivaramakrishnan G. Clinical trials in Ayurveda: Analysis of clinical trial registry of India. Journal of Ayurveda and integrative medicine. 2016;7(3):141-3.

189. Bhatt S, Nimkar SJJoD, Sciences M. Clinical research in Ayurveda: a preliminary review of 225 papers published in Indian Ayurveda journals. 2015;14(2):43-50.

190. Medagama AB, Bandara R, Abeysekera RA, Imbulpitiya B, Pushpakumari T. Use of Complementary and Alternative Medicines (CAMs) among type 2 diabetes patients in Sri Lanka: a cross sectional survey. BMC complementary and alternative medicine. 2014;14:374.

191. Pilapitiya S, Siribaddana SJCoip. Current Comments Issues in clinical trials in complementary and alternative medicine. 2013;11:1-2.

192. Masic I, Miokovic M, Muhamedagic B. Evidence based medicine - new approaches and challenges. Acta informatica medica : AIM : journal of the Society for Medical Informatics of Bosnia & Herzegovina : casopis Drustva za medicinsku informatiku BiH. 2008;16(4):219-25.

193. Sackett D, Strauss D, Richardson W, Rosenberg W, Haynes RJNY. Evidence-based medicine: how to practice and teach EBM (2 edn.) Churchill Livingstone. 2000.

194. Understanding Evidence Based Medicine [Available from: https://bestpractice.bmj.com/info/toolkit/

https://www.cebm.ox.ac.uk/resources.

195. Ijaz N, Rioux J, Elder C, Weeks J. Whole systems research methods in health care: A scoping review. Journal of Alternative & Complementary Medicine. 2019;25(S1):S21-S51.

196. Flower A, Witt C, Liu JP, Ulrich-Merzenich G, Yu H, Lewith G. Guidelines for randomised controlled trials investigating Chinese herbal medicine. Journal of ethnopharmacology. 2012;140(3):550-4.

197. WHO. General guidelines for methodologies on research and evaluation of traditional medicine. World Health Organization; 2000.

198. Liu L, Leung EL, Tian X. Perspective: The clinical trial barriers. Nature. 2011;480(7378):S100.

199. Riley DS, Barber MS, Kienle GS, Aronson JK, von Schoen-Angerer T, Tugwell P, et al. CARE guidelines for case reports: explanation and elaboration document. Journal of clinical epidemiology. 2017.

200. Mosihuzzaman M, Choudhary MI. Protocols on safety, efficacy, standardization, and documentation of herbal medicine: UPAC Technical Report Pure and Applied Chemistry. 2008;80(10):2195-230.

201. Chawla R, Thakur P, Chowdhry A, Jaiswal S, Sharma A, Goel R, et al. Evidence based herbal drug standardization approach in coping with challenges of holistic management of diabetes: a dreadful lifestyle disorder of 21st century. Journal of diabetes and metabolic disorders. 2013;12(1):35.

202. He T-T, Ung COL, Hu H, Wang Y-T. Good manufacturing practice (GMP) regulation of herbal medicine in comparative research: China GMP, cGMP, WHO-GMP, PIC/S and EU-GMP. European Journal of Integrative Medicine. 2015;7(1):55-66.

203. Ayurveda Act, No. 31 of 1961, in Gazette No. 13,301 of I4th September, 1962.

204. Ernst E. Toxic heavy metals and undeclared drugs in Asian herbal medicines. Trends Pharmacol Sci. 2002;23(3):136-9.

205. Anonymous. Quality of herbal remedies. The rules governing medicinal products in the European Community Volume III Guidelines on the quality, safety and efficacy of medicinal products for human use. Luxembourg: Office for Official Publications of the European Communities,1989. p. 31-7.

206. [Available from: http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/CriticalPathInitiative/CriticalPathOpportunitiesReports/ucm113411.pdf2017, June 9.25.

207. Jayawardena MH, de Alwis NM, Hettigoda V, Fernando DJ. A double blind randomised placebo controlled cross over study of a herbal preparation containing Salacia reticulata in the treatment of type 2 diabetes. Journal of ethnopharmacology. 2005;97(2):215-8.

208. Ayurveda Do. Ayurveda Pharmacopoeia. Sri Lanka; 1961.

209. Israel BA, Schulz AJ, Parker EA, Becker AB. Review of community-based research: assessing partnership approaches to improve public health. Annual review of public health. 1998;19:173-202.

210. Wallerstein N, Duran B. Community-based participatory research contributions to intervention research: the intersection of science and practice to improve health equity. Am J Public Health. 2010;100 Suppl 1(Suppl 1):S40-6.

211. Vaudano E. The innovative medicines initiative: a public private partnership model to foster drug discovery. Comput Struct Biotechnol J. 2013;6:e201303017-e.

212. Fani Marvasti F, Stafford RS. From Sick Care to Health Care — Reengineering Prevention into the U.S. System. New England Journal of Medicine. 2012;367(10):889-91.

213. So AD, Gupta N, Brahmachari SK, Chopra I, Munos B, Nathan C, et al. Towards new business models for R&D for novel antibiotics. Drug resistance updates : reviews and commentaries in antimicrobial and anticancer chemotherapy. 2011;14(2):88-94.

214. Maxfield KE, Buckman-Garner S, Parekh A. The role of public–private partnerships in catalyzing the critical path. J Clinical translational science. 2017;10(6):431-42.

215. Data Protection Scheme for Assessed Listed Medicines.

216. WIPO. A LEGAL FRAMEWORK FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE IN SRI LANKA.; 2009.

217. Strengthening the Reporting of OBservational studies in Epidemiology (STROBE) [Available from: https://www.strobe-statement.org/index.php?id=strobe-home.

Annex 1

Reporting observational studies – STROBE statement (217)

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any pre-specified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations and relevant dates, including periods of recruitment, exposure, follow-up and data collection
Participants	6	(a) *Cohort study* — Give the eligibility criteria and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study* — Give the eligibility criteria and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study* — Give the eligibility criteria and the sources and methods of selection of participants
		(b) *Cohort study* — For matched studies, give matching criteria and number of exposed and unexposed *Case-control study* — For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		(b) Describe any methods used to examine subgroups and interactions
		(c) Explain how missing data were addressed
		(d) *Cohort study* — If applicable, explain how loss to follow-up was addressed *Case-control study* — If applicable, explain how matching of cases and controls was addressed *Cross-sectional study* — If applicable, describe analytical methods taking account of sampling strategy
		(e) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study — e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study* — Summarize follow-up time (e.g. average and total amount)
Outcome data	15*	*Cohort study* — Report numbers of outcome events or summary measures over time
		Case-control study — Report numbers in each exposure category or summary measures of exposure
		Cross-sectional study — Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done — e.g. analyses of subgroups and interactions, and sensitivity analyses

Discussion		
Key results	18	Summarize key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalizability	21	Discuss the generalizability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

Annex 2

Template for writing a clinical trial research report

Template for clinical research article (www.springer.com)

Manuscript preparation: Authors of randomized clinical trials must adhere to the CONSORT guidelines; authors of descriptive or observational studies must adhere to STROBE guidelines; and complete the STROBE checklist at the end of the template.

Title page

- Title: Your title should contain no more than 80 characters including spaces.
- Running title: Provide a running title less than 40 characters including spaces.
- Provide highest academic degree for all the authors.
- Academic affiliations
- Conflict of interest statement: Any and all personal or institutional financial support related to the study must be noted here; see guidelines for format.
  - If any author has consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.; if so, please note.
  - If you or any author have received or may receive any personal payment or in-kind benefit or other professional benefits from a commercial entity (e.g. serve as a consultant), please note, "Each author () certifies that he or she has or may receive payments or benefits from a commercial entity () related to this work", and note the initials of those authors who received funding in and the source in the parentheses.
  - If any author has directly received research funding and/or has potential conflicts of interest, state, "One or more of the authors () has received funding from" and note the source and the initials of those authors who received funding in the parentheses.
  - If the institution of the authors has received any sort of support related to the work, state, "The institution of the authors () has received funding from" and note the source and the initials of those authors who received funding in the parentheses. If no author has received any financial support please, note, "Each author certifies that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article."
- Ethical Board Review statement: Institutional ethical board review is required for any study involving humans, human material or data or animals; a statement of approval must be noted here; see guidelines for format

- Work performed at [insert name of institution or institutions in the case of authors from multiple institutions]
- Word Count (Introduction through Discussion): Generally, limit manuscripts to fewer than 3000 words.
- Corresponding author: Provide complete contact information for corresponding author, including phone, FAX and e-mail address.

Abstract

Your abstract must be structured with the following five sections and contain fewer than 250 words.

Background:

Questions/purposes:

Patients and methods:

Results:

Conclusions:

Level of evidence: Below abstract provides a level of evidence and study description for your primary research question (see website for guidelines). The study descriptions include one of the four types as found in the guidelines. An example of the format is: "Level of evidence: Prognostic study, level II-1 (retrospective study). See the guidelines authors for a complete description of levels of evidence."

Introduction (maximum of 500 words)

All manuscripts must contain an introduction, typically 3-4 paragraphs.

Prepare text and introduction in a question/purpose format: First question or purpose must be designated as a primary research question for assigning a level of evidence. Generally, formulate no more than 2-4 questions or purposes; each should be sufficiently important that their answers would also appear in the abstract.

One paragraph of background, one or two of rationale and a **final paragraph only stating the questions or purposes of the study.**

Patients and methods

Authors must provide all relevant material in the STROBE guidelines at the end of the template and complete the checklist. Generally, use the following order:

Study design

Relevant patient demographics

Power analysis (if more than one cohort)

Description of treatment or surgery

Description of postoperative treatment

Description of follow-up routine

Description of outcome measures

Statistical analysis, if any; the description of a statistical analysis must reflect the questions and study design.

Results (maximum of 500 words)

Begin with any paragraphs needed to persuade the reader of the validity of your methods if using new or unvalidated methods or to report general findings of interest (e.g. complications) not related to a specifically posed questions. Then, in the subsequent paragraphs, ensure a one-to-one correspondence of questions raised in the Introduction and answers provided in Results.

Next provide one paragraph for each explicit question.

You may end with a paragraph or two of unanticipated results or a description of complications.

Discussion (maximum of 1000 words)

Begin with a restatement of background and rationale, then state your questions or purposes.

Briefly explore each major study limitation.

Then compare and/or contrast your results with observations or data from the literature. **Write one paragraph of comparisons for each question or purpose.** When comparing substantial amounts of data from the literature, provide a table or tables of comparative data noting outcome times, where relevant.

End with a synthesis of your results and those in the literature rather than only conclusions from your own data.

Acknowledgments: Note any non-financial acknowledgments. Begin with, "The authors wish to thank..."

Annex 3

Template for writing a case report

CARE Checklist of information to include when writing a case report

Topic	Item	Checklist item description	Reported on Line
Title	1	The diagnosis or intervention of primary focus followed by the words "case report"	
Key Words	2	2 to 5 key words that identify diagnoses or interventions in this case report, including "case report"	
Abstract (no references)	3a	Introduction: What is unique about this case and what does it add to the scientific literature?	
	3b	Main symptoms and/or important clinical findings	
	3c	The main diagnoses, therapeutic interventions, and outcomes	
	3d	Conclusion—What is the main "take-away" lesson(s) from this case?	
Introduction	4	One or two paragraphs summarizing why this case is unique **(may include references)**	
Patient Information	5a	De-identified patient specific information.	
	5b	Primary concerns and symptoms of the patient.	
	5c	Medical, family, and psycho-social history including relevant genetic information	
	5d	Relevant past interventions with outcomes	
Clinical Findings	6	Describe significant physical examination (PE) and important clinical findings.	
Timeline	7	Historical and current information from this episode of care organized as a timeline	
Diagnostic Assessment	8a	Diagnostic testing (such as PE, laboratory testing, imaging, surveys).	
	8b	Diagnostic challenges (such as access to testing, financial, or cultural)	
	8c	Diagnosis (including other diagnoses considered)	
	8d	Prognosis (such as staging in oncology) where applicable	
Therapeutic Intervention	9a	Types of therapeutic intervention (such as pharmacologic, surgical, preventive, self-care)	
	9b	Administration of therapeutic intervention (such as dosage, strength, duration)	
	9c	Changes in therapeutic intervention (with rationale)	
Follow-up and Outcomes	10a	Clinician and patient-assessed outcomes (if available)	
	10b	Important follow-up diagnostic and other test results	
	10c	Intervention adherence and tolerability (How was this assessed?)	
	10d	Adverse and unanticipated events	
Discussion	11a	A scientific discussion of the strengths AND limitations associated with this case report	
	11b	Discussion of the relevant medical literature **with references**.	
	11c	The scientific rationale for any conclusions (including assessment of possible causes)	
	11d	The primary "take-away" lessons of this case report (without references) in a one paragraph conclusion	
Patient Perspective	12	The patient should share their perspective in one to two paragraphs on the treatment(s) they received	
Informed Consent	13	Did the patient give informed consent? Please provide if requested	**Yes** ☐ **No** ☐

Member States of the WHO South-East Asia (SEA) Region have prioritized attention to research in traditional medicine and supported substantial research activity to promote evidence-based traditional medicine practices. Many research reports have been published in national and international journals. However, despite many such research studies in countries, these have not been analysed systematically in terms of topic, area of research, and issues, challenges and gaps. On account of this, research findings are inadequately reflected in policy guidance on the development of traditional medicine and its appropriate integration with the public health care delivery systems.

This publication provides a detailed account of traditional medicine research status in Sri Lanka during 2014–2019 with reference to research activities, types of clinical research, main health conditions studied, and the gaps, issues and challenges relating to clinical research in traditional medicine. It also enumerates the existing principles and practices for conducting research, including code of conduct, ethics, monitoring and evaluation, regulatory systems, reporting and dissemination, legal frameworks for protecting intellectual property rights, and administrative procedures.

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