

Journal Pre-proof

'Walking the EQUATER': From the CONSORT statement (1996) to better reporting in the 'Science of Botanicals'/Ethnopharmacology

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PII: S0378-8741(25)01593-4

DOI: <https://doi.org/10.1016/j.jep.2025.120901>

Reference: JEP 120901

To appear in: *Journal of Ethnopharmacology*

Received Date: 28 July 2025

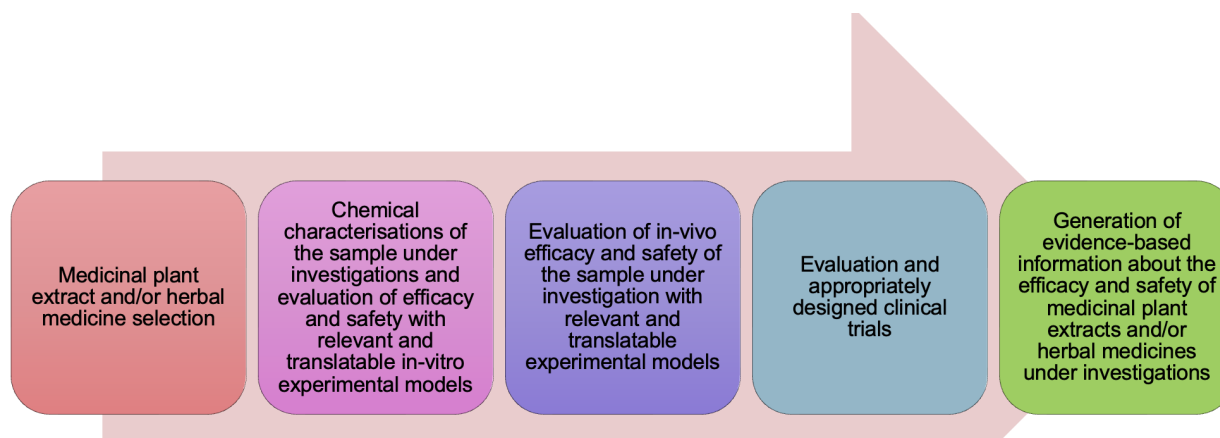
Revised Date: 10 October 2025

Accepted Date: 13 November 2025

Please cite this article as: Jalil, B., Wolfram, E., Baloch, M., Heinrich, M., 'Walking the EQUATER': From the CONSORT statement (1996) to better reporting in the 'Science of Botanicals'/Ethnopharmacology, *Journal of Ethnopharmacology*, <https://doi.org/10.1016/j.jep.2025.120901>.

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- Medicinal plant is a plant species whose parts (such as roots, leaves, bark, seeds, or flowers) contain chemical ingredients, often secondary metabolites, that are used or have the potential to be used for therapeutic, preventive or curative purposes in humans or animals. In other words, it is any plant that can provide bioactive compounds or precursors that can prevent, alleviate, or treat disease.
- Herbal medicine refers to the use of whole plants, plant parts, or plant extracts, such as roots, leaves, flowers, or seeds, as therapeutic agents to prevent, alleviate or treat disease, or to support wellness. It includes preparations made from plants and plant materials that are formulated into finished products, which are administered in suitable doses and forms with attention to safety, efficacy, and traditional or scientific use.

‘Walking the EQUATER’: From the CONSORT statement (1996) to better reporting in the ‘Science of Botanicals’/Ethnopharmacology

‘Walking the Equator’ implies integrating ‘reporting guidelines’ as they are summarised on the Equator Network and understanding the resources relevant for reporting research.

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Abstract

Ethnopharmacological relevance: In the quest for scientific rigour and reproducibility, the CONSORT Statement (1996) and subsequent developments of reporting guidelines have played an important role in improving the comprehensive and standardised reporting and practice in clinical (i.e., health and biomedical) research. However, in ethnopharmacology and the broader science of botanicals, despite the availability of structured guidance, such as the herbal extension of CONSORT and ConPhyMP guidelines, the understanding, implementation, critical assessment and regular use of such reporting standards remain inconsistent and require improvement.

Aims: This review aims to bridge this gap by investigating the historical development and challenges of reporting scientific studies, and provides evidence about the current situation of the application of the herbal extension of CONSORT and ConPhyMP guidelines via case studies

Material and Method: While cross-disciplinary efforts continue to generate new guidelines to overcome the reproducibility crisis in various scientific domains, their application to research on medicinal plant extracts and herbal medicines is worryingly underdeveloped.

Results: Many studies continue to be published without adhering to fundamental, checklist-based criteria, undermining their reproducibility and the broader applicability of their findings. This constrains the potential health benefits and the credibility of ethnopharmacological evidence. Medicinal plant and ethnopharmacological research need more rigorous, standardised, and transparent reporting to effectively 'walk the line' between traditional knowledge systems and modern scientific standards. Hence, the appropriate integration of traditional medicine into the global healthcare system. Such alignment could enable the science of botanicals to achieve more appropriate integration into respective global healthcare systems.

Conclusions: The review provides a detailed insight into the current level of adaptation and implementation of reporting guidelines in the field of botanicals/ethnopharmacology and offers practical recommendations and ways forward.

1. Background

1.1 The roots of scientific reporting – from antiquity to the EQUATOR Network

Scientific data reporting and scientific publications serve not only to disseminate findings to the scientific community and the public but also to establish the credibility and reliability of knowledge within the research community. Beyond formal requirements such as a clear structure, citations, and statistical rigour, there exists a set of essential requirements and expectations, usually expressed in a guide for authors adopted by publishers and ethical principles (e.g. COPE - <https://publicationethics.org/>), that scientific work must be accurate, reproducible, replicable and reported with integrity. As Karl Popper famously asserted, “Science begins only with the admission, and even the requirement, of the possibility of error” (The Logic of Scientific Discovery, 1934). This principle implies that scientific claims must be presented in a way that allows others to assess, challenge, or replicate them—a hallmark of rigorous scientific practice. A publication is therefore not simply a record of what was done, but an invitation to scrutiny.

The notion that scientific knowledge must be traceable, reproducible, and systematically communicated has endured for over two millennia. The demand for complete, truthful, and transparent scientific reporting, as institutionalised by the EQUATOR Network (Enhancing the Quality And Transparency Of health Research Network <https://www.equator-network.org/>). In order to ascertain the value and reliability of medical and health research, this international initiative aims to promote accurate and transparent reporting of health research.

This approach has deep roots in the philosophy of science, going back to antiquity. Thinkers like Aristotle, Hippocrates, and Galen laid out the basis of principles of science that closely mirror the goals of today’s reporting guidelines: clarity, logical structure, methodological transparency and prerequisites for reproducibility. In his Posterior Analytics (4th century BCE), Aristotle argued that scientific knowledge must rest on first principles and be logically derived from them: “When we think we know the cause on which the fact depends as the cause of that fact and of no other, and further, that the fact could not be other than it is.” (Aristotle Posterior Analytics, Book I.2). In the Hippocratic Corpus (5th century BC), particularly in Epidemics, we find one of the earliest forms of structured clinical observation: “What I see, I describe, so that anyone who reads my report may imagine what I saw.” (Hippocrates/ Epidemics I, 5) Galen strongly emphasised in the second century AC the need for repeatable observations and well-documented procedures in science: “It is foolish to make assertions which one is not able to establish by repeated observation or by demonstrative reasoning.” (Galen translated by Walzer and Owen 1934). He criticised medical practitioners who failed to report their methods, insisting on reproducibility. Later, Francis Bacon laid the foundations of modern scientific empiricism in his Novum Organum, where he emphasised structured observation and also again the significance of comprehensive reporting: one can only improve what one can describe (Bacon/Devey Ed. 1902).

The EQUATOR Network builds on this heritage when it provides structured tools for researchers, editors, and reviewers to ensure research is complete, ethical, and transparent. As Altman and Simera (2016) explained: “Incomplete or inaccurate reporting of research studies is unethical. It can lead to unnecessary studies, inappropriate patient care, and wasted resources.”

Research in a multidisciplinary field such as ethnopharmacology, medicinal plants or modern supplements research is inherently multidisciplinary. Ideally, it should advance toward a transdisciplinary approach. However, this requires the integration of research approaches and concepts from multiple fields. In recent years, there has been an ongoing scientific debate on how to ascertain best practice in research. The CONSORT statement has been a core milestone in this regard. At the same time, these standards are often not adopted as widely as they should be (for example, in the case of the CONSORT herbal). Therefore, there is a need to develop an integrated strategy to ascertain reproducibility and ultimately the applicability of such research.

1.2 Challenges in reporting in the field of traditional medicine¹ and ethnobotany², as well as ethnopharmacology³ and medicine

Research involving medicinal plant uses and their derived extracts and preparations deviates significantly from studies centred on pure synthetic compounds. Typically obtained from diverse sources such as plants, algae, fungi, lichens, or animals, these medicinal resources yield inherently complex extracts comprising several metabolites—some active, partially active, and others entirely inactive. Consequently, researching these extracts poses distinct challenges. Furthermore, the activity of these extracts often influences multiple targets as opposed to a singular target (Heinrich et al., 2020). The variability in the composition of these extracts is contingent upon the preparation method and the specific plant materials utilised, including quality aspects of such products (Heinrich, 2015). This inherent complexity and variability result in significant implications for the reproducibility and interpretation of research findings in pharmacology, toxicology, and clinical studies. Achieving high methodological quality necessitates that research methods and results can be consistently reproduced or replicated. “For most study designs and settings, it is more likely for a research claim to be false than true” (Ioannidis, 2005). This assertion extends to pharmacological studies involving single chemical entities. Ioannidis noted that “research findings might be measures of the prevailing bias” across various scientific fields (Ioannidis, 2005). The lack of reproducibility of methods and results has been a consistent issue in several research areas, including medicinal plant research (Heinrich et al., 2020; Rivera et al., 2014). This has led to the development and publication of a range of best practice guidelines to overcome these challenges, which were then endorsed and supported by the leading Journals as a part of the authors’ requirements (Chan et al., 2025; Hopewell et al., 2025). Attempts and guidelines to overcome the challenges hindering the reproducibility of studies across different fields are continually being developed (Chan et al., 2025; Hopewell et al., 2025). However, the adoption of guidelines related to improving the reproducibility of research concerning medicinal plant extracts and herbal medicines remains limited

¹ Traditional medicine is the “sum of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health and the prevention, diagnosis, improvement or treatment of physical and mental illness” (WHO, 2023).

² Ethnobotany is a conceptually much broader term dealing with useful plants in general (Heinrich and Jager, 2015).

³ Ethnopharmacology only formally introduced in 1967 by Efron et al., who used it in the title of a book on hallucinogens: *Ethnopharmacological Search for Psychoactive Drugs* (Efron et al., 1970; Holmstedt, 1967). It covers a broad range of themes at the interface of pharmacology/toxicology/clinical research with the social sciences, as well as botany and natural product research (Heinrich and Jager, 2025).

(Heinrich et al., 2020; Heinrich et al., 2022) and, even more worryingly, poorly understood. Articles focusing on medicinal plant extracts continue to be published without adhering to specific, basic criteria often summarised in checklists. This compromises the reproducibility of these findings and limits their significant beneficial impact and wider interpretations. Examples of problematic research methods and reporting in studies looking into the efficacy or safety of medicinal plant extracts or herbal medicines include poor or no authentication of the material under investigation, the lack of or the poor characterisation of the sample under investigation, including the quantification approach and/or how the sample under investigation was extracted or processed (Heinrich et al., 2022), and how the formulation challenges and pharmaceutical performance in case of final products was considered or assessed (Jalil and Heinrich, 2025).

2. What is 'EQUATOR'?

The EQUATOR Network is an umbrella organisation that brings together researchers, clinicians, medical journal editors, peer reviewers, developers of reporting guidelines, research funding bodies, and other collaborators with a mutual interest in improving the quality of research publications, design, methodology and reporting of research outcomes. It aims mainly to build evidence in the medical community through standardisation and consensus-building, involving stakeholders. Its primary mission is to achieve accurate, complete, and transparent reporting and sound and transparent design of all health research-related studies to support research reproducibility and usefulness. The methodology to build consensus across experts and stakeholders, which is recommended by the EQUATOR Network is a the Delphi survey, which has been first applied in management by researchers of the RAND Cooperation starting in the 1950s (Dalkey and Helmer, 1963)., a not-for profit organisation that evolved from the US Air Force to today's independent think tank. The method was designed to systematically collect and refine expert opinions through a series of structured questionnaire rounds, allowing participants to reassess their views in light of anonymous group feedback. This iterative process aimed to minimise the influence of dominant individuals and reduce bias common in face-to-face group discussions. The core features of the Delphi method—expert anonymity, controlled feedback, and statistical aggregation of responses of either consensus or disagreement—make it particularly suitable for areas where empirical evidence is limited or uncertainty is high. Moher et al. (2010) recommend and explain on this basis an approach with the advantage and methodology to develop Consensus Guidelines in the case of the CONSORT statement in its version of 2010. In the development of clinical research guidelines such as CONSORT and SPIRIT, the Delphi method is widely used to achieve consensus among diverse stakeholders, including clinical experts, methodologists, and patients. For example, the CONSORT 2010 update involved a structured Delphi process to determine which items were most essential for transparent reporting of randomised trials (Moher et al., 2010).

Therefore, using the EQUATOR approach increases the value of health research and helps to minimise avoidable waste of financial and human investments in health research projects. In the last decades, several reporting guidelines have been developed with respect to high levels of disciplines as well as within different areas of research. One of the main benefits of the EQUATOR is that it avoids the duplication of efforts and reporting guidelines. However, it does have the authority to enforce coordination or collaboration (Gattrell et al., 2025). In response, users of checklists are likely to be confused by the proliferation of reporting guidelines and extensions, which can only be exacerbated by duplication (Gattrell et al., 2025). Without

central oversight or a dedicated forum for discourse to ensure guidelines complement each other, the risk of duplication remains.

3. Challenges in the current situation of PROSPERO – a case study

The International Prospective Register of Systematic Reviews (PROSPERO) is an international database of systematic reviews with health-related outcomes that are registered prospectively. It aims to raise awareness of the importance of good research reporting and assist in developing, disseminating, and implementing such good practices using reporting guidelines for different study designs. It also serves as a tool for monitoring the comprehensiveness of reporting of such projects, focusing on health research. The network also actively conducts research in this area.

This prospective registration of protocols in PROSPERO facilitates a streamlined and expeditious process, ensuring comprehensive listing and complete reporting. This proactive approach aims to prevent duplication and reduce the likelihood of reporting bias by enabling a comparison between the completed systematic review and the initially planned protocol (<https://www.crd.york.ac.uk/prospero/#aboutpage>). Therefore, PROSPERO was selected here as a case study to examine the reporting and reproducibility of studies documented in PROSPERO from a pharmaceutical-analytical standpoint. The aim is to understand what level of detail is recorded in the database and whether this enables reproducibility.

We hypothesised that medicinal plant extracts and herbal medicine assessed in systematic reviews and meta-analyses documented on PROSPERO are transparently recorded in terms of methods and findings, to allow reproducibility of the published outputs (i.e., pre-registration of studies enhances the appropriate and transparent reporting of methods and findings later in the published outputs). The case study aimed to synthesise and evaluate the reporting, hence reproducibility of the existing studies (i.e. records) on PROSPERO, by assessing whether they include the minimum criteria listed in the Consensus statement on the Phytochemical Characterisation of Medicinal Plant extracts (ConPhyMP) guidelines checklist, explicitly focusing on reporting medicinal plant material and its initial processing to enhance reproducibility. In the hope of more attention to the challenges and deficiencies evident in the design, methodology, and reporting, but in the registration of studies concerning medicinal plant extracts and herbal medicines.

A comprehensive search was then conducted on the PROSPERO database without constraints on publication timeframe, document type, or publication status. The search strategy incorporated search terms such as "herbal medicine," "medicinal herb, medicinal herbs, medicinal herbal extracts," "medicinal plant, "medicinal plant extracts," "herbal extracts," "plant extracts," and "medical plants". This was to ensure the inclusion of all studies, regardless of when they were registered in PROSPERO. This search was conducted from January 2018 to January 2024. The references of the included studies were also manually reviewed and searched, respectively.

An additional targeted search focused on specific herbal medicines, specifically those relevant in Europe. The

aim was to gain insights into the reporting practices, especially for medicinal plants with representation in existing studies. The search strategy incorporated search terms, such as “black cohosh (*Actaea racemosa* L.)”, “Echinacea (*Echinacea angustifolia* DC.)”, “feverfew (*Tanacetum parthenium* (L.) Sch.Bip.)”, ginseng (*Panax ginseng* C.A.Mey.)”, “gingko (*Ginkgo biloba* L.)”, “lavender (*Lavandula angustifolia* Mill)”, “pelargonium (*Pelargonium sidoides* DC)”, “rhodiola (*Rhodiola rosea* L.)”, “saw palmetto (*Serenoa repens* (W.Bartram) Small)” and “St John’s Wort (*Hypericum perforatum* L.)”. This search was conducted from November 2015 to November 2023. The aim was to determine the number of studies published for each herbal medicine and to assess their reporting and reproducibility (see Table 1 in the supplementary materials for more details).

The methodology for assessing the studies recorded on PROSPERO (i.e., reproducibility of PROSPERO studies) included evaluating the presence of specific critical criteria adapted from the ConPhyMP guidelines (Heinrich et al., 2022). It is a consensus statement/checklist that guides researchers in reporting the starting plant materials and the chemical methods used to define the chemical compositions of the plant extracts in such studies (<https://ga-online.org/best-practice/>).

The critical criteria for this evaluation encompassed the name of the plant material used and chemical characterisation. More specifically, in terms of starting plant material and the extraction process, we scored the included studies with regard to: 1) herbal species used; 2) defined botanical drug taxonomy; 3) Dose and duration of treatment stated; 4) Defined extract and extraction process; and 5) Defined finished product (see Table 2 in the supplementary material for more details).

In terms of plant material used and the availability of chemical analysis, we scored the included studies with regard to: 1) medicinal plant species used; 2) defined chemical species; 3) conducted phytochemical analysis; 4) described phytochemical analysis; and 5) use of reference standards (see Table 3 in the supplementary material for more details).

This scoring system was conducted in line with the ConPhyMP guidelines (Heinrich et al., 2022), where five or more criteria in the included PROSPERO studies indicated high, three or four criteria suggested moderate, and two or fewer criteria indicated poor methodological quality in line with the ConPhyMP guidelines checklist.

The exploration of PROSPERO using the specified criteria identified a total of 1727 studies. After eliminating 9 duplicate articles, 1619 articles were excluded for reasons such as being discontinued, ongoing, or completed but unpublished studies. Additionally, 22 articles were excluded for not incorporating herbal medicine in their inclusion criteria, and 12 articles were excluded for reasons including language (7 in Chinese), preprint status (2; without peer reviews), and lack of relevance (3). Consequently, the eligibility assessment considered sixty-five (65) published articles, all of which were included in the study. Within 3-6 years from registration on PROSPERO, 1,424 records remain under review. The selection process of the study is presented in the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) Flow Diagram (Figure 1).

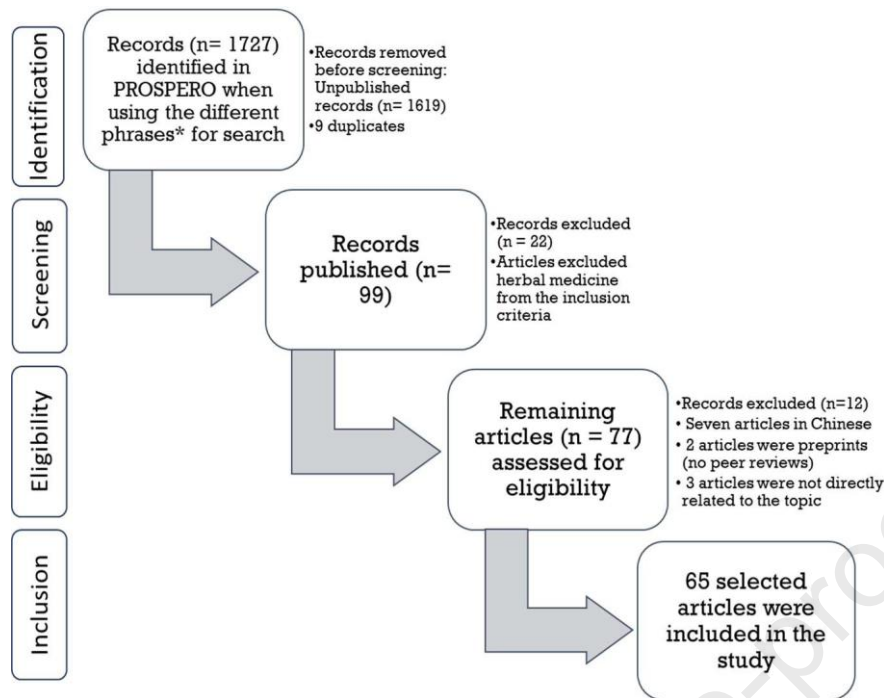


Figure 1: PRISMA Flow diagram of the study's selection and inclusion process (Page et al., 2021).

Out of the 65 recorded articles subjected to analysis, only five adhered to the ConPhyMP guidelines. Our results show that approximately 80% of the recorded studies concerning medicinal plant extracts lack fundamental reproducibility criteria, such as poor methodological quality and limited adherence to reporting standards (Table 2 and 3 in supplementary materials).

In addition, almost 90% of the recorded studies covered specific herbal medicines, including *Actaea racemosa* L. (black cohosh), *Echinacea angustifolia* DC. (echinacea), *Lavandula angustifolia* Mill. (lavender), *Rhodiola rosea* L. (rhodiola) and others that do not reach publication after being registered for 3-5 years on PROSPERO. Furthermore, many of these that reach publication have a poor methodological quality and/or reporting of the findings (Table 1 in supplementary materials).

For every herbal medicine listed, 8%-10% of the articles registered on PROSPERO have reached publications. Out of 20 recorded studies on rhodiola, for example, only one reached publication. Similarly, out of 80 recorded studies on lavender, only eight reached publication. For the remaining 17 studies on rhodiola, which are still under review, the oldest was registered in 2020 and the newest in 2023. The two studies that had completed reviews but were not published had been registered in PROSPERO in May 2021 and October 2022. These articles are relatively new and might still reach publication, so it is necessary to follow up on their status in the upcoming five years. For lavender, out of the 47 articles still under review, four were registered between 2017 and 2018. However, the remaining ones were registered starting in 2020. Similarly, the status of these studies may be updated in the next two years. For echinacea, one of the studies under review was registered in 2019, and the rest started in 2020. For the studies with completed reviews but not published, one was registered in 2018, and the other was registered in 2023. For black

cohosh, out of the eight articles still under review, two were registered in 2016, while the others were registered by 2020.

Most published articles on the herbal medicines of interest (black cohosh (*Actaea racemosa* L.), lavender (*Lavandula angustifolia* Mill), echinacea (*Echinacea angustifolia* DC.), pelargonium (*Pelargonium sidoides* DC.), rhodiola (*Rhodiola rosea* L.), saw palmetto (*Serenoa repens* (W.Bartram) Small)) have a low-point score. This is because most of the articles showed gaps in adequately characterising the chemical composition as well as the extraction methods (Table 1).

These results highlight the issues and challenges associated with the registration process of studies involving medicinal plant extracts and herbal medicines. In this context, the question arises why a high number of articles get recorded on PROSPERO while few (less than 5%) reach publication? One reason could be that many articles have been under review on PROSPERO for several years without having an update on the status. Other reasons imply some issues and challenges with the registration review process, e.g., lack of transparency in terms of the methods and outcomes provided during the study registration on PROSPERO, specifically related to the phytopharmacological studies. Overall, within 3-6 years of the study registration on PROSPERO, 83% remain under review, 13% is not published/review discontinued, and only 4% is published.

However, several limitations exist; for example, articles published in Chinese were not assessed for reproducibility, and the PROSPERO database was the primary database searched and used as a case study for inclusion in this study. This study also builds on the development and interpretation of the ConPhyMP guidelines, including their limitations, which may have influenced the thinking and interpretation of this study. Many articles are still under review, having been registered on PROSPERO by 2020, and might be published in the next 3-5 years. Moreover, it is essential to note that the ConPhyMP guidelines tool was published in 2022 (Heinrich et al., 2022) (see section 5).

4. Broader implications of reporting standards in clinical and health research

4.1 CONSORT and SPIRIT - guidelines and extensions assuring scientific quality in clinical research

The CONSORT (Consolidated Standards of Reporting Trials) (Hopewell et al., 2025) and SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) (Chan et al., 2025) guidelines are cornerstone tools to improve the comprehensive reporting, transparency, and reproducibility of randomised controlled trials and their protocols. Since SPIRIT addresses the rational design of studies, it assists CONSORT in what and how results have to be presented to the public and the scientific community. Both guidelines – the one before and the other after a clinical trial- ensure that the assessment, the evaluation, and the publication of clinical data are of high quality, reported in detail and support evidence of clinical outcomes.

CONSORT was first published in 1996 (Begg et al., 1996) to address the inadequate reporting of Randomised Controlled Trials (RCTs). It was updated in 2001 and again in 2010, with the latest revision being developed for 2025 to harmonise with SPIRIT updates (Hopewell et al., 2025; Tunn et al., 2024). SPIRIT was introduced in 2013 to complement CONSORT by providing guidance on the minimum content for a clinical trial protocol. Like CONSORT, it is undergoing revision for a 2025 update, aligning both checklists to improve reporting consistency (Chan et al., 2025; Tunn et al., 2024).

4.2 CONSORT herbal extension statement 2006 and an evaluation of its wider adoption

CONSORT and SPIRIT guidelines are endorsed by major medical journals and regulatory bodies (Chan et al., 2025; Hopewell et al., 2025). They are also the basis for various extensions tailored to specific interventions, e.g. the herbal CONSORT extension. In 2004, a CONSORT extension for herbal medicine was issued, complementing the general CONSORT statement that was designed for allopathic medicine (Gagnier et al., 2006). Since herbal preparations consist of a spectrum of compounds derived from plants that are subject to natural variations, an extension of the 22-item checklist general CONSORT statement was necessary. In Gagnier et al. (2006) the authors explain that they did not amend but adapt 9 of the 22 checkpoints to assure the reporting of important data that is specific to clinical research with herbal medicine.

Among the points included item 4 addresses the herbal interventions. It seems to have been the most demanding to find a consensus, since the details are the important points that make the reporting of the herbal intervention so special: Details such as the herbal product name, plant part used, preparation type, source and authentication of the plant material, pharmaceutical quality (e.g., drug extract ratio (DER), solvents and extraction conditions), dosage, and purity testing must be included. These requirements recognise that herbal products differ from conventional drugs, especially when formulations are made specifically for a study or involve crude plant materials. The guideline uses "where applicable" to accommodate the diversity of herbal practices while promoting standardised and transparent reporting. Also, items 6 (outcomes), 15 (baseline data), 20 (Discussion interpretation) 21 (Generalizability) and 22 (Overall evidence) needed to be adapted: For herbal medicine trials, outcome measures (item 6) should align with the intervention and reflect its theoretical foundations. Reporting should include baseline data on other medications, herbal products, or complementary therapies (item 15). When interpreting results (item 20), researchers should consider the specific product and dosage tested, as well as existing evidence on that exact formulation. Generalizability (item 21) should address how the trial product relates to those used in clinical or self-care settings. Finally, interpretation of overall evidence (item 22) should include a broader discussion of how the findings compare with trials of similar herbal products, recognising the diversity in formulations and practices.

Concerning the evaluation of success, studies have shown that adherence to CONSORT and SPIRIT leads to better reporting of clinical trials and protocols. In neuro-oncology, for example, trial protocols showed ~79% adherence to SPIRIT and trial reports ~75% adherence to CONSORT (Suppre et al., 2023). A web impact analysis found that CONSORT and SPIRIT have broad but fragmented online presences, suggesting room for improved digital dissemination and user engagement (Orduña-Malea et al., 2023). Tools trained on SPIRIT

and CONSORT items (like the SPIRIT-CONSORT-TM dataset) now enable automated assessments of trial transparency, pushing the field toward AI-supported quality control (Jiang et al., 2025). A systematic scoping review identified over 100 specific suggestions for improving the 2010 and 2013 guidelines, which are informing the upcoming 2024 revisions (Nejstgaard et al., 2023).

Unfortunately, clinical investigators adopted the herbal extension of the CONSORT statement to a very limited degree. Several of the authors involved in the 2006 herbal extension evaluated the reporting compliance in publications and concluded there was “underreporting” (Gagnier et al., 2011) and thus less than anticipated. Ten years later, only one publication has addressed this lack of use directly in the indication of rheumatology.

In the systematic review of *Crocus sativus* L. (saffron) supplementation in rheumatic disease trials, the authors identified significant shortcomings in how the included randomised controlled trials adhered to the CONSORT guidelines for herbal interventions. Most notably, most trials failed to report essential details about the herbal products used, such as the exact dosage, composition, and standardisation of active compounds like crocin and safranal. Only one study fully complied with these standards, using validated methods to quantify active ingredients (Shakiba et al., 2018). This lack of transparency severely limits reproducibility and the ability to compare results across studies. Another key issue was poor reporting of adverse events, with two of five trials omitting this information entirely, despite known risks associated with herbal treatments. Additionally, most studies did not control for critical confounding factors such as diet, physical activity, and treatment adherence, which are essential in influencing disease outcomes. Due to these methodological flaws and inconsistencies, the authors concluded that the current evidence base is too limited and heterogeneous to draw reliable conclusions about the effectiveness of saffron in rheumatic diseases. They emphasise the need for future trials to follow CONSORT Herbal to improve comprehensive reporting of design and data, and reproducibility and thus credibility rigorously.

An unpublished first assessment of randomised clinical trials concerning well-known herbal medicines derived from herbal substances such as *Echinacea purpurea* and *Curcuma longa* showed that the guidelines are neither followed nor referenced in the publications, and fall short in many checkpoints. These dramatic findings suggest yet another dimension of the problem: hundreds of clinical trials. This often leads to monographs and assessment reports, e.g. from the herbal medicinal product committee of the European Medicine Agency (EMA-HMPC) and the European Scientific Cooperative of Phytotherapy (ESCOP), highlighting that the extract or herbal preparation used in the clinical trial has not been “further specified” (ESCOP 2021) or “no further details available” (EMA-HMPC 2013). This is the case for *Echinacea purpurea*.

Fei and Liu (2008) stated the first time that the herbal extension of CONSORT in the version of 2006 came short on specific requirements for Traditional Chinese Medicine (TCM), since it was based on the Western view on medical outcomes, which are not one-to-one comparable to the medical treatment system of TCM. Shortly after, in the same year, the same authors proposed an adaptation of the original herbal CONSORT checklist for TCM (Fei and Liu, 2008). It took another 9 years until, in 2017, an official extension of CONSORT named “CONSORT-CHM Formulas” addressing specifically Traditional Chinese Medicine was published – not only in English (Cheng et al., 2017c), but also in traditional Chinese (Cheng et al., 2017b) and simple Chinese

(Cheng et al., 2017a). Using this guideline, the herbal extension that previously also covered herbal use in traditional medicine systems was replaced with regard to TCM.

Since the publication, several evaluations have been undertaken (e.g. a review by Wang et al. (2024)), which shows that the TCM scientific community is actively following and peer reviewing the use of the guideline, but there remain major quality challenges in designing and reporting on TCM preparations. In other ethnomedical systems, the acknowledgement and awareness are still low. In case of Ayurveda, in 2008, when the CONSORT - herbal extension had only recently been published, the checklist was taken up and evaluated (Narahari et al., 2008). It was challenging to adapt to traditional systems, which rely on the herbal intervention and a more holistic and personalised view on illness and healing. It was discussed and documented in a workshop (Tillu, 2010) and later analysed in depth in a comprehensive review (Patwardhan, 2014). Reports from other traditional and ethnomedicine systems (e.g. Africa, South America) to address reporting guidelines tailored to the requirements of their local ethnomedicine systems have, to the best of our knowledge, not yet been initiated.

A case study on ginger root Hook et al. (2025) highlights the challenges faced by organisations like ESCOP in summarising evidence for monographs, especially when many clinical trials suffer from poor methodological quality. Recent reviews show that only a small fraction of ginger-related trials meet the required standards, pointing to persistent trial design and reporting issues (Anh et al., 2020; Crichton et al., 2022). Key issues include limited reporting on participant demographics, such as sex and ethnicity. These gaps are concerning, given unknown sex-based differences in drug responses, yet women remain underrepresented in trials and often lack sex-disaggregated data analysis. CONSORT's extension guidelines for sex and gender equity in research (SAGER) further highlight the need to improve transparency in these domains (Heidari et al., 2016). In addition, inconsistent or even no reporting on the ginger preparations was found; therefore, no information was given on standardisation or constituents. Therefore, the clinical data is of known value in such cases. Thus, CONSORT should be seen as a baseline for transparent reporting and a framework that must evolve with scientific and societal demands.

Furthermore, a keyword search for CONSORT: [("Journal of Ethnopharmacology"[Journal]) AND ((Clinical) OR (RCT))] within the Journal of Ethnopharmacology showed 4299 hits (search as of 21st of June 2025). However, only 117 hits were found when searching "CONSORT", while the search for SPIRIT could not distinguish between the word spirit, which has in ethnobotanical or pharmacological research two meanings: alcoholic preparation or a spiritual and cultural context of treatment and healing. About 18 of the 117 articles were reviews, while the other publications are mainly clinical studies. About 14 of these hits cite the herbal extension of CONSORT Gagnier et al. (2006). Only one refers to the EQUATOR Network (Vora et al., 2024). However, this search strategy may have limitations, e.g., using clinical as a keyword may also provide search results/hits related to in vivo or in vitro research or studies, mainly when these terms are included in the title and/or in the text of these studies.

5. ConPhyMP guidelines as a framework and its potential integration into research practice

Reproducibility is at the core of all areas of natural sciences and even more central in those areas where an impact on human health is the main aim (see section 4). To date, numerous pharmacological, clinical and toxicological studies, which report non-reproducible data, have been published. At the centre of the problem is a lack of description of what is studied - a 'black box' approach. Many research groups are unaware of these challenges. Simultaneously, there is a lack of academic chemical and pharmacognostic expertise in many pharmacological and clinical research groups, resulting in studies which, at best, are non-reproducible but which can also result in false decisions, for example, if toxicological or pharmacological claims are made about an extract and this is then taken to the next level (e.g. raising concerns about the safety of a specific botanical preparation or drug). The ConPhyMP guidelines (Heinrich et al., 2022) were developed by an international team of experts in chemistry, analytical sciences, ethnopharmacology, pharmacognosy, and other related fields, utilising a process that facilitates strong stakeholder input. The starting point was an online survey, which enabled the researchers to understand what is possible to implement most widely. Therefore, this guideline, once it is more widely implemented, will enable the impact of basic and applied research on healthcare. The concept was inspired by the CONSORT statement (Begg et al., 1996), which has significantly improved the reporting of clinical research. Similarly, the ConPhyMP statement can improve the reporting of the plant material under study, increasing the research impact in such diverse fields as drug discovery from natural products (e.g., using bioassay-guided fractionation), pharmacovigilance, and basic research on the mechanism of action of herbal medicines.

The implementation by academic journals is a key early step and remains an ongoing task, which first and foremost requires raising the awareness of all stakeholders in the problem and how it can be solved. The ConPhyMP guidelines (Heinrich et al., 2022) provide the basis for this, with the open-access ConPhyMP tool (Heinrich and Jalil, 2023) offering a novel approach to facilitate the implementation of the guidelines to the wider scientific community. It enables experts in other fields to use the guidelines by providing a clear and easy way to assess a manuscript. It directly impacts the relevant industries (e.g., pharmaceutical, cosmetic, and health food) and generally ascertains that research can improve health in all societies. The approach enables a wider acceptance of research by all stakeholders, including the general public.

These guidelines have bridged gaps in experimental design, enabling clearer interpretation of results and fostering collaboration among researchers. Its development and implementation are also novel in the context that there is a 'no size fits all' approach, which means understanding and considering the challenges faced by researchers based in low- or limited-resource countries, where access to equipment is limited. In the ConPhyMP guidelines, medicinal plant extracts are classified into one of three types, capturing species importance and regulatory status. Therefore, rather than relying solely on chemical criteria, the guidelines are based on the importance of a plant as a medicine (as defined by its inclusion in a pharmacopoeia) and its importance in international trade (e.g., as a food supplement). For each extract type, a different level of phytochemical characterisation is required.

Ultimately, the ConPhyMP guidelines contribute to advancing human health by ensuring that research on medicinal plant extracts is planned, conducted and reported with greater precision and transparency, leading to more effective and safer medicinal plant extracts/natural products derived medicines and therapies.

6. Recommendations for improving the current process and the way forward

We here propose the following recommendations for improving research practice and reporting:

- Considerable efforts need to be made to adopt, implement, and promote the respective guidelines, for example, better support and encourage the consistent use of ConPhyMP, CONSORT, and SPIRIT guidelines and, as needed, specific reporting standards across ethnopharmacology, traditional medicines, medicinal plants, and natural products research and sciences to ensure clarity, transparency, and reproducibility in research.
- Improving the editorial and peer review process, for example, journal editors and peer reviewers should actively ensure adherence to reporting guidelines during manuscript evaluation and publishing.
- Funders should prevent research and research resource waste; for example, Research funders should take responsibility for ensuring that funded projects commit to comprehensive reporting standards and contribute to the global goal of reducing research waste.
- The research community needs to raise awareness across disciplines, esp. in the field of ethnopharmacology. For example, increase awareness and dissemination of reporting guidelines across diverse research communities.
- We need to bridge traditional and modern knowledge systems. We need to acknowledge the unique challenges in applying standard guidelines to ethnopharmacological research and facilitate the development of context-specific adaptations.
- terminology in search and reporting must be clearly defined and standardised: This will help address ambiguities in keyword indexing in ethnopharmacological literature to improve discoverability and compliance tracking.
- We should foster cross-disciplinary collaboration: Encourage cooperation between ethnobotanists, pharmacologists, clinicians, regulators, and methodologists to harmonise reporting standards across varied practices and knowledge systems.

In conclusion, walking the EQUATOR, or more precisely, using the tools available via this network, and critically engaging with them, will be a key step to improve the standardization of reporting of clinical trials and clinical research in herbal medicine.

Credit Authorship Statement

Banaz Jalil: Conceptualisation, data curation, methodology, project administration, writing – original draft, writing – review and editing; Evelyn Wolfram: Data curation, methodology, writing – original draft, writing – review and editing; Manael Baloch: Investigation, writing – original draft, writing – review and editing; Michael Heinrich: Conceptualisation, data curation, methodology, supervision, writing – original draft, writing – review and editing.

Declaration of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

List of abbreviations

CONSORT: Consolidated Standards of Reporting Trials

ConPhyMP: Consensus statement on the Phytochemical Characterisation of Medicinal Plant extracts

EMA: European Medicines Agency

EQUATOR: Enhancing the Quality And Transparency Of health Research Network

ESCOP: European Scientific Cooperative of Phytotherapy

HMPC: Herbal Medicinal Products Committee

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

RCT: Randomised Controlled Trials

PRISMA: Preferred Reporting Items for Systematic reviews and Meta-Analyses

PROSPERO: International Prospective Register of Systematic Reviews

Journal Pre-proof

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Table 1: Recorded articles on PROSPERO for pharmacologically important and widely used herbal medicines (articles on PROSPERO from Nov 2015 to Nov 2023)						
Name of species	MPNS internationally accepted species name (not based on the data in PROSPERO)	Number of records	Review ongoing	Review published	Review completed not published	Review discontinued
Aloe Vera	<i>Aloe vera</i> (L.) Burm.f. [Asphodelaceae]	72	63 (2 excluded)	8	1	-
Black cohosh	<i>Actaea racemosa</i> L. [Ranunculaceae]	10	9 (1 excluded)	1	-	-
Cannabis CBD (Cannabidiol hemp)	<i>Cannabis sativa</i> L. [Cannabaceae]	952	780	92	71	9
Calendula	<i>Calendula officinalis</i> L. [Asteraceae]	16	14	2	-	-
Chamomile or camomile	<i>Matricaria chamomilla</i> L. [Asteraceae]	34	30 (2 excluded)	4	-	-
Curcumin/turmeric	<i>Curcuma longa</i>	362	318 (1 excluded)	32	12	-
Echinacea	<i>Echinacea purpurea</i> (L.) Moench [Asteraceae]	15	11 (1 excluded)	2	2	-
Feverfew	<i>Tanacetum parthenium</i> (L.) Sch.Bip. [Asteraceae]	3	2	-	-	1
Garlic	<i>Allium sativum</i> L. [Amaryllidaceae]	92	80 (5 excluded and 1 duplicate)	7 (1 excluded)	4	1
Ginger	<i>Zingiber officinalis</i> Roscoe [Zingiberaceae]	210	183 (67 excluded / 6 duplicates)	17 (9 excluded)	8 (2 excluded)	2
Ginkgo	<i>Ginkgo biloba</i> L. [Ginkgoaceae]	92	85 (7 excluded)	4 (1 excluded)	3	-
Ginseng	<i>Panax ginseng</i> C.A.Mey. [Araliaceae]	176	170 (10 excluded/ 2 duplicate)	2	4 (1 excluded)	-
Lavender	<i>Lavandula angustifolia</i> Mill. [Lamiaceae]	80	69 (21 excluded / 1 duplicate)	10 (2 excluded)	1 (excluded)	-
Pelargonium	<i>Pelargonium graveolens</i> L'Hér. [Geraniaceae]	2	1	1	-	-

Rhodiola	<i>Rhodiola rosea</i> L. [Crassulaceae]	20	17	1	2	-
Saw Palmetto	<i>Serenoa repens</i> (W.Bartram) Small [Arecaceae]	11	9 (1 excluded)	-	2	-
St. John's wort	<i>Hypericum perforatum</i> L. [Hypericaceae]	22	16	4	2 (1 exclud ed)	-

Highlights

- Inconsistent use of reporting guidelines: Despite the existence of structured frameworks like CONSORT and ConPhyMP, their implementation in ethnopharmacological research remains irregular, affecting scientific rigour and reproducibility.
- Poor adherence to standardised reporting undermines the credibility and broader applicability of findings, thus limiting the integration of traditional medicine into global healthcare systems.
- Call for improved standards: The review underscores the urgent need for more rigorous, standardised, and transparent reporting practices in botanical and ethnopharmacological research, offering practical recommendations for progress.

Declaration of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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