eCMTA | Evidence-Based Chinese Medicine and Technology Assessment

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Protocol

Exploring study materials and data sharing practices in traditional, complementary and integrative medicine research: a protocol for a cross-sectional study

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Received: June 12, 2025; **Revised:** July 25, 2025; **Accepted:** September 26, 2025

ABSTRACT

Introduction Traditional, complementary, and integrative medicine (TCIM) therapies include those typically considered outside of the purview of conventional medicine. Sharing study materials and data is crucial for enhancing transparency, reproducibility, and data use for secondary data analyses in TCIM research. This cross-sectional study aims to assess the extent to which TCIM study materials and data are made publicly available. **Methods** We will analyze a sample of 400 published TCIM research articles including primary studies (e.g. clinical trials, observational studies, and qualitative research), as well as evidence synthesis studies (e.g., systematic reviews and scoping reviews), which are informed by systematic searches. In analyzing these studies, we aim to assess whether and how researchers shared the data and materials they generated or used in their work, including details on how to access them. This study will be conducted by searching the MEDLINE database using the "Complementary Therapies" medical subject heading; records will be screened for eligibility then a sample of eligible articles will be selected at random. **Discussion** The findings and observations from this analysis will provide insights into current practices and highlight areas for improvement in the transparency and accessibility of TCIM research.

KEYWORDS

complementary medicine, data sharing, integrative medicine, materials sharing, study materials and data, traditional medicine

CITE THIS ARTICLE

Melendez G, Rahman S, Zubrytska O, et al. Exploring study materials and data sharing practices in traditional, complementary and integrative medicine research: a protocol for a cross-sectional study. Evidence-Based Chinese Medicine and Technology Assessment, 2025, 1: 9570014. https://doi.org/10.26599/eCMTA.2025.9570014

1. Introduction

Traditional medicine is defined as "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".[1] Complementary medicine includes "therapies or interventions not taught/used in conventional medicine, used to treat therapy demands that are not met by conventional medicine".[2] Integrative medicine is unique as it is considered a holistic approach that represents "the combination of conventional and unconventional medicine, accounting for the whole person, and preventative maintenance of health".[2] For the purpose of this study, these terms will be collectively referred to as traditional, complementary, and integrative medicine (TCIM).

The wide range of TCIM practices is reflected in the large quantity of terms analyzed in a recent study. Out of an initial 1561 terms, 1494 were ultimately standardized and classified, with the final list comprising 604 distinct complementary and integrative medicine therapies.[3]

This study underscores the broad spectrum of TCIM approaches. More specifically, the 2022 National Health Interview Survey (NHIS) showed that the most commonly used practices among American adults are meditation (17.3%), yoga (15.8%), chiropractic care (11%), massage therapy (10.9%), guided imagery/progressive muscle relaxation (6.4%), acupuncture (2.2%), and naturopathy (1.3%).[4] Understanding these common practices within the American context provides a valuable foundation for exploring TCIM on a global scale. In a broader context, the 2019 World Health Organization (WHO) global report on traditional and complementary medicine reveals regional variation in TCIM use, with up to 99% of populations in Bahrain, Oman, Germany, Myanmar, and Papua New Guinea reporting TCIM practices.[5] Despite high usage rates, each of the six WHO regions highlighted a lack of research data as the greatest challenge in regulating TCIM practices.[5] Member States concluded that there is a critical need to evaluate TCIM research in terms of safety, quality, and efficacy.[5] In addition, the significant

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reliance on TCIM is evident in various Asian countries. For instance, TCIM accounts for around 40% of all health care delivered, and it is used to treat approximately 200 million patients annually in China.[6] Additionally, 69% of the Korean population has used TCIM, and 60%–70% of allopathic doctors in Japan prescribe herbal medicines for their patients.[6] Further research into the barriers to conducting TCIM research has identified obstacles such as competency, bias, and most importantly, access to quality research in the field.[7,8] Additionally, there are challenges in applying TCIM research findings in clinical settings.[8,9] Structural factors affecting TCIM research can be categorized into three main areas: availability, accessibility, and appropriateness.[10] Accessibility is particularly impacted by language barriers. In many Asian countries, a significant portion of original data is recorded in local languages, which limits access and understanding for a global audience.[11] These factors collectively influence the opportunities and capabilities to obtain high-quality evidence. High-quality evidence forms the foundation for reproducibility, as robust and reliable data are essential for validating results across studies and contexts.

Sharing study materials and data enhances the understanding and reproducibility of scientific literature. In research, "sharing" involves making materials and data available to facilitate understanding, replication, and analysis of studies.[12] Open science is a movement that promotes transparency, accessibility, and collaboration in research by making scientific knowledge openly available.[13] Sharing study data, analytic code, and research materials is an open science practice that supports verification and promotes accountability.[13] This enables other researchers to validate findings, explore new questions, and build upon existing studies. In the context of TCIM research, adopting open science practices can therefore improve the visibility, reliability, and impact of scientific studies.

Recent years have seen a notable shift toward open data, as funding agencies and journals increasingly require data availability statements and mandates for data management and sharing plans. The 2022 WHO policy on sharing and reuse of health-related data for research purposes outlined the FAIR principles, which stand for Findable, Accessible, Interoperable, and Reusable.[14] These principles emphasize that research outputs, including both datasets and study materials, should be organized and documented in ways that promote transparency, reproducibility, and reuse by other researchers. The WHO policy further specifies that publications must include data availability statements with links to underlying or extended data, as well as any relevant study materials or software required to understand and reproduce the research.[14] Similarly, the 2023 NIH Data Management and Sharing Policy requires researchers to plan for broad and appropriate sharing of scientific data, while also recognizing that associated documentation and study materials are essential for effective reuse.[15] Together, these policies underscore the growing expectation that both data and study materials should be made available to maximize transparency and reproducibility.

Publishers can play an important role in facilitating and enforcing data sharing. However, studies in the broader biomedical literature have found that many journals have not yet implemented data sharing policies, and requirements vary widely,[16] highlighting the challenges of standardization across journals. Similarly, a recent audit in the field of TCIM has shown considerable variability in journal requirements for open science. The audit found that out of 19 TCIM journals the mean Transparency and Openness Promotion Factor score was 2.95, with 21% of journals scoring 0 and the remainder ranging between 1 and 8.[17] This highlights the inconsistent adoption of open science practices across the field.

Sharing study materials refers to providing the essential resources needed to understand, replicate, and validate research findings. Study materials are defined as resources or instruments used to generate data, including but not limited to questionnaires, interview guides, protocols, and analytic code.[12] Sharing analytic code, such as scripts used for statistical analysis, is important because it enables transparency and reproducibility in data processing and interpretation.[12] Likewise, sharing materials such as interview guides and survey instruments facilitates consistency in data collection across different studies and allows for comparative analyses.[12] Comprehensive documentation, such as protocols detailing study procedures and analysis plans outlining statistical methodologies, ensures methodological rigor and offers a framework for evaluating research outcomes.[12] Collectively, sharing study materials strengthens transparency, replication, and the overall reliability of research.

Data sharing is defined according to the National Library of Medicine's data glossary as the practice of making data available by researchers to peers and readers, increasing transparency, reproducibility, and the impact of the research data presented.[18] For the purpose of this study, we define data as raw data and data that requires further analysis. The sharing of this data is crucial, as it allows for the verification of findings, enables meta-analyses, and contributes to the broader scientific community's understanding. For instance, pseudonymized data from clinical trials allows other researchers to verify findings and conduct meta-analyses.[19] In systematic reviews, results are often shared to support evidence synthesis and policy decisions.[19] Observational studies may share anonymized patient data or survey responses to enable further analysis and validation of study outcomes.[19] In the present study, these operational definitions of study materials and data will be used to distinguish between the two in eligible articles.

These study material and data sharing practices play a crucial role in advancing research by broadening both the scope and depth of available knowledge.[20] However, the extent to which researchers share study materials and data differ greatly across different fields of study, and understanding these practices is crucial as they directly impact the dissemination and reproducibility of research findings. To address this, the present study aims to conduct a cross-sectional analysis of primary research articles and reviews informed by systematic searches on TCIM. By identifying study material and data sharing practices across this field, we seek to provide insights into current trends and inform future efforts to enhance transparency and accessibility in TCIM research.

2. Methods

2.1. Ethical approval

This study will involve a review of peer-reviewed literature only; it will not require ethics approval or consent to participate.

2.2. Open science statement

The protocol, study materials, and raw and analyzed data will be made available via Open Science Framework (OSF).[21] The final manuscript detailing our findings will also be posted as a preprint prior to submission to a journal.

2.3. Approach

We will search for and select primary research articles and review articles informed by systematic searches from MEDLINE found via the "Complementary Therapies" medical subject heading (MeSH) (Appendix 1). A random sample of 400 eligible articles will be analyzed to assess study material and data sharing practices. The data extraction form will be piloted with 20 articles, and any necessary adjustments will be made based on the results of the pilot extraction.

2.4. Sampling framework and eligibility criteria

A search strategy was developed to include primary research, as well as reviews informed by systematic searches published in English within the MeSH heading "Complementary Therapies" on MEDLINE via OVID in accordance with the eligibility criteria. Included studies must be published in English and specifically focus on TCIM, in accordance with an operational definition of TCIM informed by a systematic search developed by Ng et al. (2022).[3] Preliminary searches were conducted using MEDLINE to identify the most common study types in the relevant literature. These searches revealed

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that randomized controlled trials, observational studies, qualitative studies, and reviews informed by systematic searches (e.g. systematic reviews, scoping reviews) are the most prevalent in TCIM literature. Additionally, these study types have established reporting guidelines available through the EQUATOR Network,[22] which help ensure consistency and rigor in their evaluation and inclusion in this review. Based on their prevalence and the availability of standardized reporting criteria, these study types were selected for inclusion in this review.

We will exclude case reports, study protocols, case series, commentaries, and letters to the editor from our audit, as these types of reports generally do not generate study materials or data. Additionally, we will exclude any studies that do generate data but do not fall within the four study types included in our analysis. Furthermore, to ensure precise and reliable results, the required sample size was calculated using the sample size for a proportion equation.[23] Assuming a worst-case scenario proportion of 50%, a 95% confidence level, and a 5% margin of error, the required sample size was determined to be 384.16. For the sake of practicality, the sample size will be increased to 400.

2.5. Screening

The search strategy is expected to return approximately 1400 articles. These articles will be randomized using the RAND function on Microsoft Excel for Microsoft 365 (Microsoft Corporation, Redmond, WA).[24] To balance the screening workload, we will take the first 900 randomized articles (300 per reviewer) for title and abstract screening, which will be conducted independently and in duplicate by a team of three researchers (GM, OZ, and SR) working in pairs. Full text screening will then be performed in Excel, with all articles being screened independently and in duplicate, and conflicts resolved through discussion. From the pool of eligible articles that result from screening, we will select 400 articles for data extraction, consistent with our pre-specified sample size calculation (see "sampling framework and eligibility criteria"). If fewer than 400 eligible articles are identified, all eligible articles will be included, and the reduced sample size will be reported as a limitation. If more than 400 are eligible, the first 400 in the randomized order will be selected to preserve the random sampling strategy.

2.6. Data collection

A pilot extraction will be conducted on the first twenty eligible articles from the sample, independently and in duplicate, using a standardized data extraction form. This step will ensure that all information is systematically captured. Any challenges encountered during the pilot extraction will be addressed, and necessary adjustments to the form will be made before proceeding with data extraction. The final data extraction will proceed with the 400 eligible articles from full-text screening. Following the pilot, we will establish a standardized set of labels for the extracted items, enabling consistent categorization and comparisons across data and material sharing.

Once piloting is complete, the material and data sharing practices of eligible studies in the sample will be documented. This process will begin by accessing the and recording the title, digital object identifier, journal name, author names, year of publication, and the country of the corresponding author. We will also record the modality studied, and if multiple modalities are included, all applicable modalities will be listed. Modalities will be categorized based on the National Cancer Institute framework as mind–body therapies, biologically based practices, manipulative and body-based practices, energy healing, whole medical systems, and general complementary and alternative medicine.[25] If multiple modalities are included in a study, all applicable categories will be listed. The study type, as reported by the author will also be noted, including randomized controlled trials, observational studies, qualitative studies, and review articles informed by systematic searches. Subsequently, information regarding the availability of study materials and data will be examined. As stated in the "Introduction" section, study materials are defined as the tools and resources used to generate data (e.g., questionnaires, protocols, analytic code), while data are defined as the outputs of those tools (raw or analyzable datasets). These definitions will be used to identify whether eligible articles share study materials, data, or both.

If a study material sharing statement is available, its exact wording will be extracted and the statement will be categorized. We will assess whether the authors have openly shared any study materials, including code where applicable, and document what was shared, their type, and where they are available (limited to supplementary files, repositories, within the manuscript, or other external locations). We will also record whether the materials can be accessed, or if not openly accessible, whether they are available upon request. For studies that do not share materials, we will record whether a justification is provided, including the specific reason or noting if it is not applicable.

Similarly, for data sharing, we will check if a data sharing statement is available, record its exact wording and categorize the statement. We will assess if the authors have shared any data, where is the data available (limited to supplementary files, repositories, or other external locations), whether it can be accessed or is available upon request if not openly accessible, and what data was shared along with its type. If data is not shared, we will note whether a justification is provided and the reason for it, if specified. Two reviewers (GM and OZ) will independently extract all information, and any disagreements will be resolved through a consensus discussion with a third reviewer (SR).

Lastly, it should be noted that we will only be using publicly available data (i.e. the data and materials sharing statements tied to the articles themselves) for this study. We will not be reaching out to the authors of the articles included in our study for any reason, and as such no approval will be sought from our local research ethics board.

2.7. Data analysis

Flowcharts depicting what we predict to be all possible study material and data sharing scenarios for any given eligible article are shown in Figure 1 and Figure 2, respectively. Once data extraction is finalized, the findings will be categorized to identify possible patterns and differences in material and data sharing practices within the sample of TCIM articles. Descriptive statistics will be used to describe the prevalence of material and data sharing practices. For quantitative data, the mean and standard deviation (SD) will be reported. For binary data, frequencies (N) and percentages (%) will be presented. We will also compare sharing practices across TCIM modalities, countries, and study types. Where sufficient statistical power is available, inferential analyses will be applied to test for significant differences.

3. Discussion

The objective of this study is to conduct a cross-sectional audit of primary research articles and reviews informed by systematic searches on TCIM to identify study material and data sharing practices across this field. Through data extraction and subsequent analysis of the sample, the study will aim to summarize and interpret material and data sharing practices in TCIM research, to determine how information is shared and made available to readers.

3.1. Study implications

The findings from this study will have important implications for future developments in the field of TCIM. By identifying current practices in material and data sharing, this study will provide insights into the transparency and accessibility of TCIM research. The results of this cross-sectional analysis will highlight where improvements are needed to enhance transparency. This, in turn, can facilitate greater reproducibility, validation of research findings, and secondary use of research data. Enhanced transparency can also improve trust among researchers, healthcare providers, and patients, leading to increased use and integration of TCIM practices in conventional healthcare.[13]

Additionally, improved data sharing practices can encourage collaboration among researchers, accelerate TCIM advancements, and ultimately lead to better healthcare outcomes for patients relying on TCIM therapies.[13] This

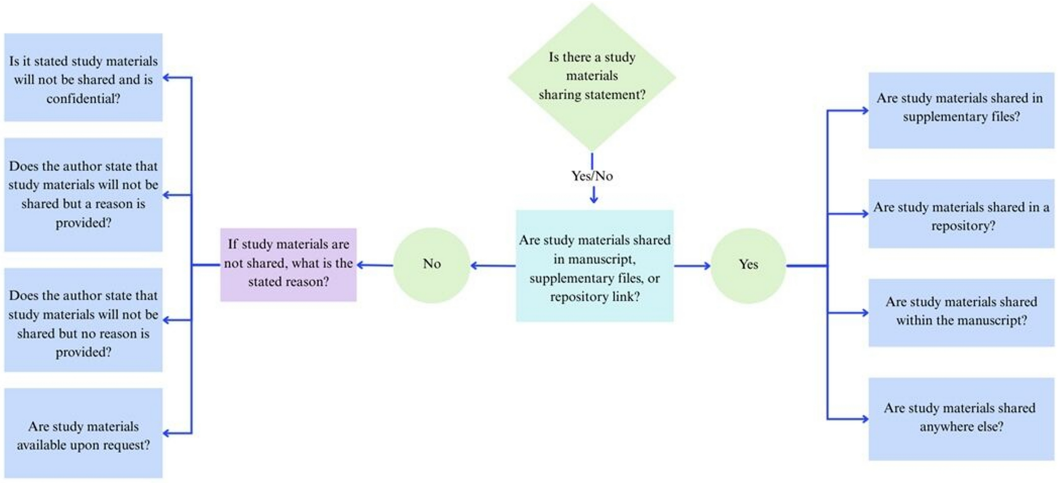


Figure 1 Study materials sharing outcomes for eligible articles

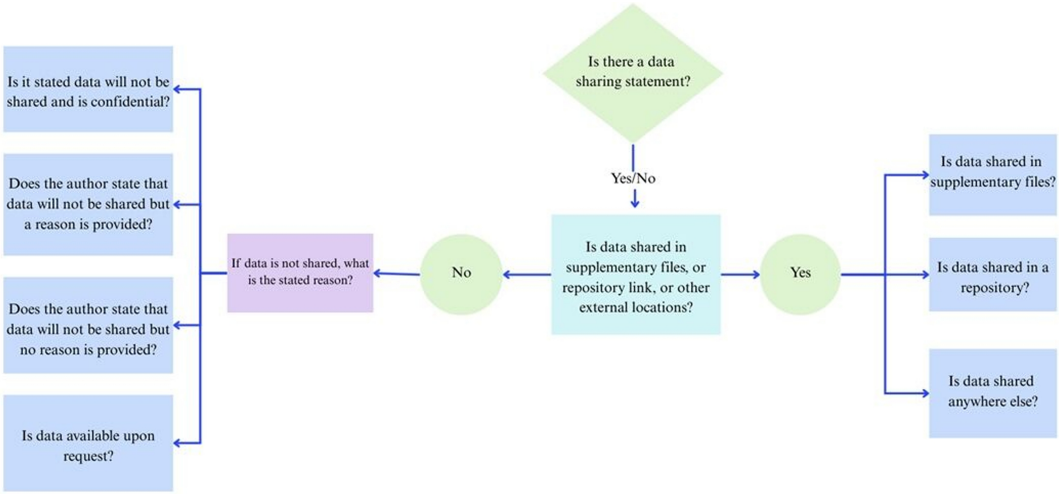


Figure 2 Study data sharing outcomes for eligible articles

study will also serve as a gauge for the levels of materials and data sharing across TCIM research. We will provide a breakdown of the number of articles across different TCIM modalities to compare material and data sharing practices. These comparisons can identify specific areas within TCIM research that may require improved sharing practices. Understanding these variations can help tailor strategies to enhance sharing practices where they are most needed, ultimately promoting the overall quality of TCIM research.

Moreover, sharing study materials and data enhances the understanding and reproducibility of scientific literature, yet challenges persist in its implementation. A recent cross-sectional study on TCIM research found that TCIM researchers face several barriers to sharing study materials and raw data, including concerns about unintended use of secondary data (37%), misinterpretation of the data (32%), intellectual property control (31.7%), patient privacy (29%), and a lack of knowledge in data preparation (25.9%).[12,26] These challenges are not unique to TCIM but are common across many research fields. As a result, these barriers in study materials and data sharing practices may be impacting the dissemination of knowledge and slowing the advancement of the field. Therefore, this study will provide an opportunity to analyze the current practices of study material and data sharing in the context of TCIM research and offer insights into how these practices can be improved, ultimately enhancing data sharing and fostering greater transparency in the field.

Furthermore, our protocol can serve as a proof of concept for researchers in other fields, demonstrating the feasibility and applicability of our approach beyond TCIM. By offering a novel framework for analyzing material and data sharing, this protocol provides a unique research method that can be adapted and applied to various disciplines. Its distinctive methodology, with a strong emphasis on improving transparency and accessibility in research, has the potential to enhance reproducibility and promote more rigorous research practices in fields where data sharing is essential for advancing knowledge and improving outcomes.

3.2. Strengths and limitations

This study has several methodological strengths. Firstly, the use of the MeSH heading "Complementary Therapies" increases the likelihood of identifying eligible TCIM articles, as these headings are allocated to articles by information specialists,[27] enhancing the comprehensiveness and relevance of our sample. Additionally, the application of our operational definition of TCIM and human screening further ensures that included studies align with our eligibility criteria. A further strength of this audit is its focus on common study types in the relevant literature that adhere to established reporting guidelines,[19] enhancing methodological transparency and reliability. Additionally, each article will be cross-referenced against a systematically developed operational definition of TCIM to further verify its eligibility, ensuring that our inclusion criteria are clear.[3] To standardize our data extraction process, we will pilot 20 eligible articles. Any discrepancies identified during this

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pilot phase will be resolved through comparison and discussion. Data extraction will be performed independently and in duplicate to ensure reproducibility and enhance the reliability of the extracted data, minimizing the risk of bias and errors.

With respect to study limitations, although our study includes a five-year time parameter, it is limited by its cross-sectional design, which examines the search data at a specific moment in time. This restricts the generalizability of our findings beyond the included time period. Consequently, trends and changes in study material and data sharing practices over a longer period may not be captured. Additionally, the inclusion criteria restrict the study to articles published in English. This language limitation will exclude relevant TCIM research articles published in other languages, potentially limiting the comprehensiveness of our findings and their applicability to non-English-speaking contexts. Furthermore, the focus on the common study types in the relevant literature limits the inclusion of other valuable research, such as basic research (e.g. cell lines, animal models etc.) as well as less common study designs, which could offer additional insights. This choice reflects our aim to capture widely applicable findings while enhancing methodological transparency and reliability. Similarly, while we are taking a random sample of articles that aims to be representative, it may not wholly capture the diversity and breadth of the TCIM field. TCIM is a dynamic and evolving field, with varying definitions and boundaries, whereby disagreements about their categorization exists even among experts.[3] As such, our sample may not fully encompass all relevant TCIM research or fully reflect TCIM material and data sharing practices.

Another limitation concerns the difficulty of determining whether authors shared data or materials fully or only partially. Internal research processes and raw data are often conducted and stored privately, making it difficult to verify the completeness of what is shared. For this reason, our analysis focused on whether sharing occurred, rather than attempting to assess the comprehensiveness of the data or materials provided.

4. Conclusion

This study will provide an important overview of how and to what extent study materials and data are shared in TCIM research. By examining a broad sample of published primary studies and evidence syntheses, we aim to identify current practices and common barriers to transparency in this field. Our findings will contribute to the ongoing dialogue on open science and inform efforts to improve reproducibility, data reuse, and methodological rigor in TCIM. Ultimately, this work will help lay the foundation for more open, accessible, and trustworthy TCIM research practices moving forward.

Funding

The writing of this protocol was unfunded.

Author Contribution Statement

Gabriela Melendez: Investigation, writing – original draft, and writing – review & editing. **Shahreen Rahman:** Investigation, writing – original draft, and writing – review & editing. **Olena Zubrytska:** Investigation, writing – original draft, and writing – review & editing. **Florian Naudet:** Methodology, investigation, and writing – review & editing. **Livia Puljak:** Methodology, investigation, and writing – review & editing. **Claudia M. Witt:** Methodology, investigation, and writing – review & editing. **Linda Lidan Zhong:** Methodology, investigation, and writing – review & editing. **David Moher:** Methodology, investigation, and writing – review & editing. **Holger Cramer:** Methodology, investigation, and writing – review & editing. **Jeremy Y. Ng:** Conceptualization, methodology, investigation, visualization, writing – original draft, writing – review & editing, and supervision.

Declaration of Competing Interest

The authors declare no competing interests, with the exception of Prof. Linda Lidan Zhong, Prof. Holger Cramer, and Prof. Jeremy Y. Ng. As Editorial Board Members of *Evidence-Based Chinese Medicine and Technology Assessment*, they were excluded from the peer review and decision-making process for this article.

Electronic Supplementary Material

The online version contains supplementary material available at https://doi.org/10.26599/eCMTA.2025.9570014.

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