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**Review Article**

# Quality Assessment of Cohort Studies in Complementary and Alternative Medicine: A Scoping Review Over Two Decades

***Mojtaba Norouzi*** [1], ****Ali Akbar Haghdoost*** [2]

1. *Department of Biostatistics and Epidemiology, Faculty of Public Health, Kerman University of Medical Science, Kerman, Iran*
2. *HIV/STI Surveillance Research Center, and WHO Collaborating Center for HIV Surveillance, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman, Iran*

***Corresponding Author:** Email: ahaghdoost@gmail.com

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**Abstract**

**Background:** We aimed to investigate the subject matters and the quality of publications detailing the findings of cohort studies within the realm of complementary and alternative medicine (CAM).

**Methods:** A scoping review was conducted on cohort studies in the CAM field up to the conclusion of 2023. The evaluation of their quality was carried out utilizing the 'Strengthening the Reporting of Observational Studies in Epidemiology' (STROBE) checklist. Moreover, an analysis of their research settings and associated variables, including publication year, type of disease, intervention method, and study field, was conducted.

**Results:** Overall, 215 articles were identified. The majority of these cohorts, approximately 42.3%, originated from Taiwan, with stroke and cardiovascular diseases emerging as the most prevalent outcomes of interest. The mean STROBE score was 1.38 (SD=0.57) out of 2. The lowest scores were associated with the methods and funding sections. Methodologically, the principal weaknesses were linked to sample size, loss to follow-up, and bias control.

**Conclusion:** The frequency of cohort studies in CAM was limited, predominantly concentrated in a few countries. Chinese medicine and acupuncture were the main intervention methods, while other CAM interventions received less focus. Furthermore, the quality of these studies was deemed unsatisfactory in most cases.

**Keywords:** Scoping review; Quality assessment; Cohort studies; Complementary therapies

## Introduction

The cohort study design, as an applicable method, is commonly employed in research, with its outcomes ranking second only to randomized controlled trials (1). Cohort investigations allow researchers to gain insights into the outcomes or natural progression of a disease or condition within a specific study population (2). Despite cohort studies being more susceptible to bias and confounding compared to RCTs (3), they remain popular in the field of Complementary and Alternative Medicine (CAM). This is because cohort studies offer high external validity and can more accurately depict the impacts of CAM interventions (4). Furthermore, they do not face certain limitations present in interventional studies, such as ethical considerations, high costs, and con-

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straints on the size or duration of follow-up (5, 6).

Cohort studies in the realm of CAM possess unique characteristics. In this field, CAM interventions are regarded as exposure factors when conducting cohort studies (7). These studies typically center on disease prognosis (8), efficacy assessment (9), economic evaluation (10), and adverse events (11) when evaluating CAM interventions.

Although there is no single accepted tool for evaluating study quality (12), it is crucial to evaluate the overall quality of studies (13). Insufficient reporting obstructs the ability to make well-informed decisions, which could have serious repercussions when ineffective or harmful treatments are supported, ultimately leading to a waste of research endeavors (14). The "Strengthening the Reporting of Observational Studies in Epidemiology" (STROBE) guideline is currently a commonly used tool for assessing the quality of observational studies (15). Many journals have incorporated the STROBE statement as submission guidance to enhance the quality and transparency of health research (16, 17).

A scoping review is an appropriate approach for defining the subject, domain, context, idea, or problem being examined. The primary aim of conducting a scoping review is to identify and chart pertinent evidence (18). Scoping reviews, as an alternative, have become increasingly popular, when systematic reviews may not fully achieve the intended objectives (19). Scoping reviews provide various benefits, such as synthesizing a growing literature to pinpoint research gaps and highlight areas for future studies. Moreover, they are suitable for addressing exploratory research questions (20).

To the best of our knowledge, no review has been done to analyze the subject and report the quality of cohort studies in the CAM field. Recognizing the deficiencies in these articles can facilitate progress toward standardized reporting. In this study, we utilized a scoping review to conduct descriptive statistics and evaluate the reporting quality of cohort studies in CAM using the STROBE criteria.

## Methods

A scoping review study was conducted to examine the topic and assess the quality of cohort studies in CAM. We defined six steps in our scoping review: 1) search strategy; 2) searching databases; 3) assessment of inclusion and exclusion criteria; 4) assessment of reporting quality; 5) data collection; 6) analysis.

### *Search strategy*

We combined two sets of keywords to search the databases. The first set defined different types of interventions in CAM, and the second set defined cohort studies as follows: (acupuncture OR ayurveda OR homeopathy OR naturopathy OR chinese OR chiropractic OR osteopathic OR massage OR dance OR tai chi OR yoga OR herbal OR electromagnetic OR reiki OR qigong OR meditation OR biofeedback OR hypnosis OR reflexology OR persian OR irani OR iranian OR dancing OR complementary OR alternative) AND (cohort studies OR longitudinal studies OR prospective OR retrospective). On February 9, 2024, we searched the main international and persian databases such as PubMed, ISI Web of Science, Scopus, Google Scholar, Science Information Database SID (WWW.SID.ir), and MagIran (WWW.Magiran.com). English articles that were published from 1947 to December 31, 2023, were extracted.

### *Inclusion and exclusion criteria*

This scoping review encompassed cohort studies investigating specific facets of CAM. Exclusion criteria comprised randomized trial designs, other observational studies, systematic reviews and meta-analyses, guidelines, letters to the editor, conference abstracts or articles, and animal experiments.

### *Reporting quality assessment*

The quality of the articles was evaluated using the STROBE checklist (15), which is a tool designed to assess the reporting quality of observational studies. The STROBE Statement includes a

checklist with 22 essential items that should be included in the reporting of observational studies. These items cover various sections of the article, such as the title and abstract, introduction, methods, results, discussion, and additional information like funding. While 18 items are common to all three study designs, there are four design-specific items that have different versions. Some items require specific information for cases and controls in case-control studies, or for exposed and unexposed groups in cohort and cross-sectional studies. Although there is a unified checklist, separate checklists tailored to each of the three study designs are also available. The tools and metrics used to assess the quality of the articles were based on a ratio scale. Each case was scored on a scale ranging from zero to two: zero indicating "not reported," one indicating "inadequately described," and two indicating "adequately described" (21). All items were assigned equal importance, and if certain items were not relevant to a particular study, they were labeled as "not applicable."

### *Bias control*

To guarantee a thorough examination of the available evidence in our scoping review, we took into forms of bias that may arise in such reviews and implemented strategies to address them, as mentioned below:

Selection bias is a concern in scoping reviews, as it can arise from an incomplete or biased search strategy that overlooks relevant studies. To control this issue, we incorporated two sets of keywords in our search strategy and included all relevant terms. Additionally, we incorporated "grey literature" in our extensive research. Another possible bias in scoping reviews is reporting bias, which occurs when researchers choose to report specific outcomes or analyses from a study. To mitigate the effects of reporting bias, we employed clear and systematic approaches for selecting studies, extracting data, and conducting analysis. Furthermore, there were no conflicts of interest.

### *Choosing and assessing the articles*

The articles underwent a two-stage selection and evaluation process: an initial screening based on title and abstract, followed by a full-text review of potentially relevant articles. Rigorous training was provided to two data collection personnel to reduce human errors, and reviewers possessed expertise relevant to the scoping review topic. Training was also conducted on proper data extraction techniques to minimize subjective interpretations. Two reviewers independently assessed the retrieved studies, and any discrepancies in the findings were resolved through deliberation with a third expert to reach a consensus. To evaluate agreement and consistency between two reviewers Kappa statistics were employed, resulting in a kappa coefficient of .8. In addition, we utilized a standard checklist (STROBE) to prevent instrumental errors and misclassifications.

### *Collecting data*

In this research, data concerning the variables of publication year, type of disease, method of intervention, study field, control selection method, outcome, follow-up period, and geographic distribution of articles were documented.

### *Statistical Analysis*

Each STROBE checklist item was analyzed to determine the frequency, relative frequency, mean, and standard deviation (SD) of the scores using Stata version 14.2 (Stata Corp, College Station, TX, USA). The geographical distribution of articles in CAM was visualized using ArcMap version 10.8. To evaluate the degree of self-correlation among the studies and the potential for clustering, we utilized Moran's overall test. Additionally, we selected six classes and manual methods to map and separate various regions. Data trend was analyzed using the Join Point Regression Program (ver. 5.2.0.0). A *P*-value of less than 0.05 was considered statistically significant. Additionally, the frequency of studied diseases in CAM was displayed using MAXQDA ver. 2018.

## Results

Overall, 68,695 articles were initially identified. Following the removal of duplicates and screening based on the title and abstract, 620 articles were retained for full-text review. Ultimately, 215 articles were deemed eligible for inclusion (Fig. 1).

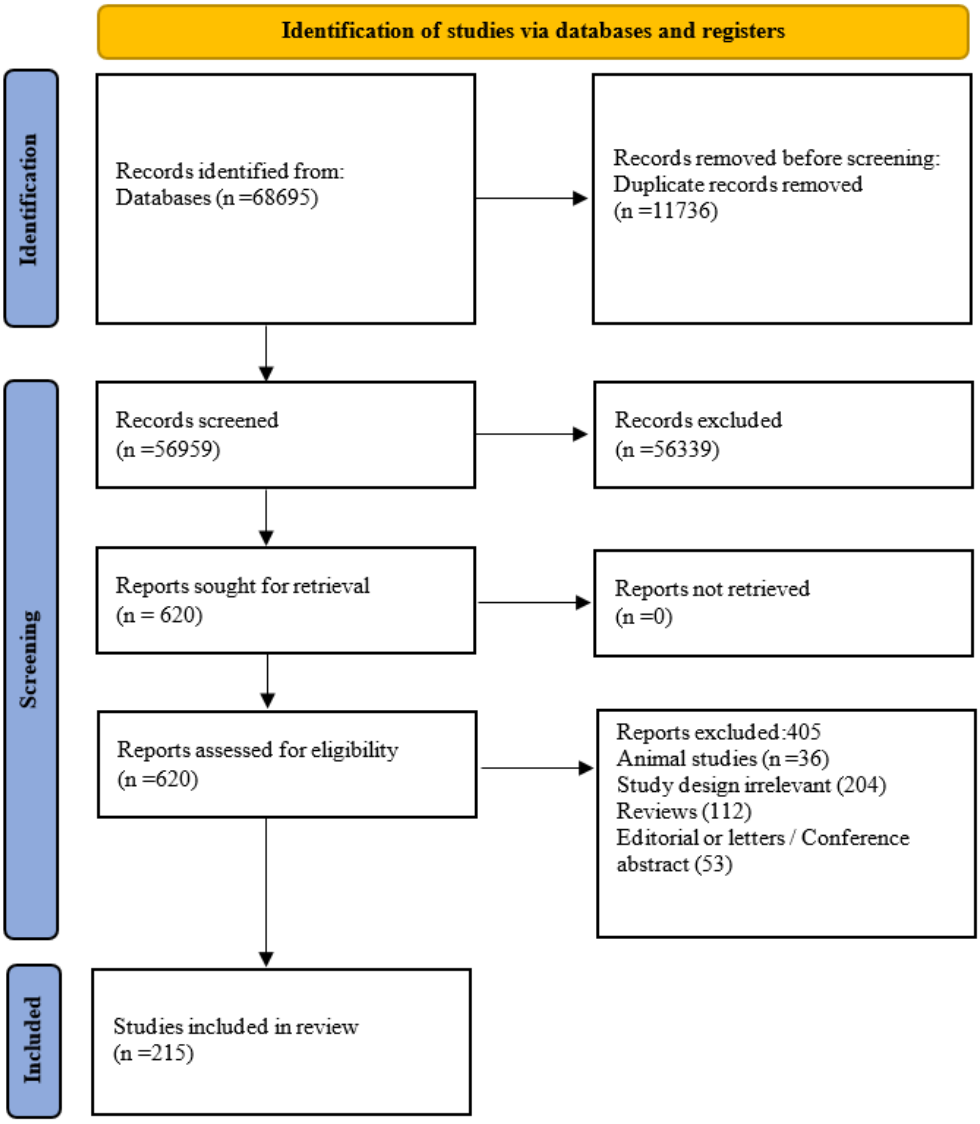


**Fig. 1:** PRISMA flow diagram for selection of eligible studies

A descriptive examination of the articles was conducted. The predominant intervention methods discussed in the cases were Chinese medicine and acupuncture. Additionally, the most extensively researched area pertained to neoplasms (Fig. 2). Furthermore, the predominant control selection method used was blank control, with the primary objective of the studies being to assess the effect of the intervention (Fig. 3).

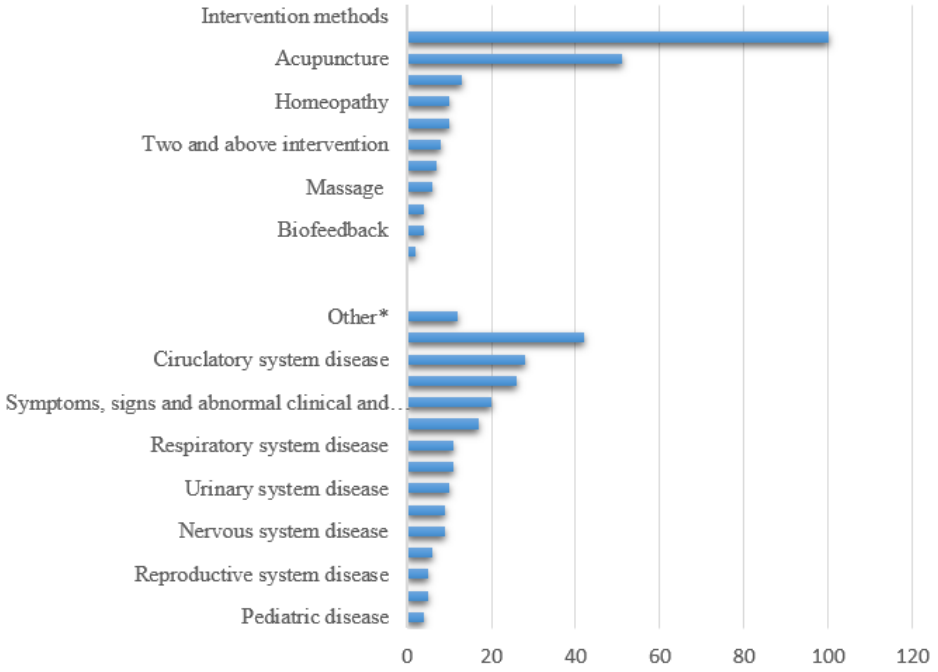


**Fig. 2:** The main characteristics of complementary and alternative medicine cohort studies up to the end of 2023

*Quality of life (2 articles), Insomnia (2 articles), Dementia (1 article), Rehabilitation (3 articles), Adverse drug reactions (1 article), Chronic disease (2 articles), Financial impact (1 article).

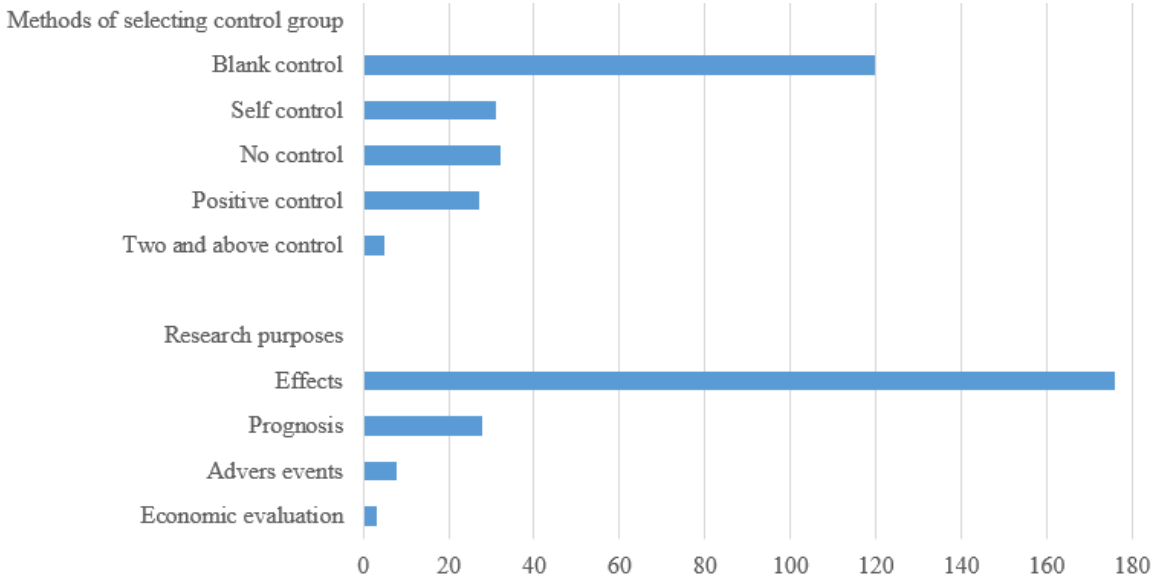


**Fig. 3:** The frequency of control group selection methods and research objectives in cohort studies on complementary and alternative medicine until the end of 2023

The majority of cohort studies were conducted retrospectively, with an average follow-up period of 47 months. Retrospective-prospective studies had the highest average sample size. Out of the studies included, only five reported no significant association between CAM interventions and outcomes (Table 1).

**Table 1:** Frequency and average related to results, type of study, follow-up period, and sample size of complementary and alternative medicine cohort studies up to the end of 2023

| Study design | Number (%) | Average follow-up (months) | Average sample size | Non-significant result |
|---|---|---|---|---|
| Prospective | 75 (34.9) | 55.09 | 28433 | 3 |
| Retrospective | 94 (43.7) | - | 12907 | 1 |
| Retrospective-Prospective | 46 (21.4) | 39.36 | 16740 | 1 |
| Total | 215 | 47.22 | 19360 | 5 |

The majority of cohort studies in the CAM field were carried out in Taiwan (42.33%), with China following closely behind at 21.86%. There were no studies conducted in Africa or South America (Fig. 4).

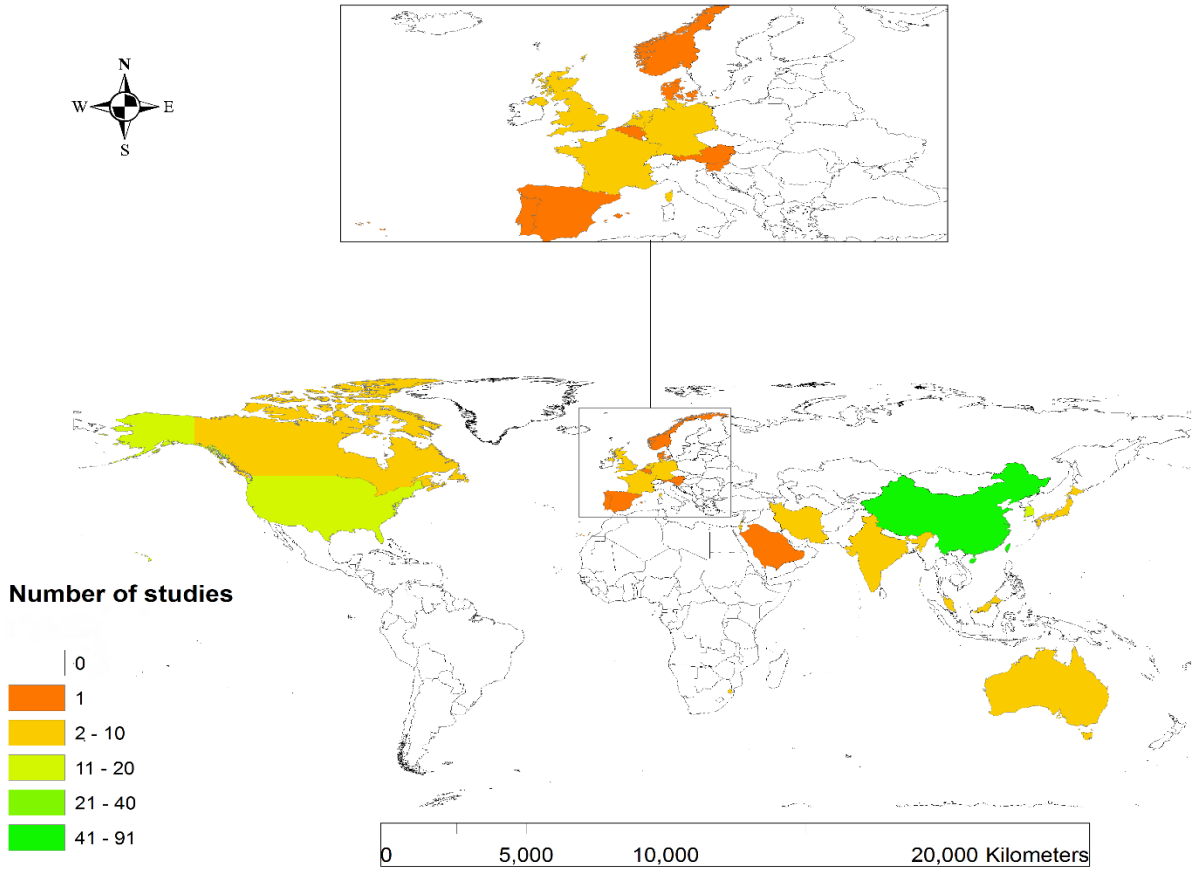


**Fig. 4:** Geographical distribution of complementary and alternative medicine cohort studies up to the end of 2023

### *Moran's overall test*

Moran's index correlation (0.004) was close to zero, with a non-significant *P*-value (0.306). This suggests that the distribution of studies follows a random pattern.

The diseases that received the most research attention were stroke (6.05%), cardiovascular diseases (3.72%), diabetes (3.25%), colorectal cancer (2.79%), and AIDS (2.79%) (Fig. 5).

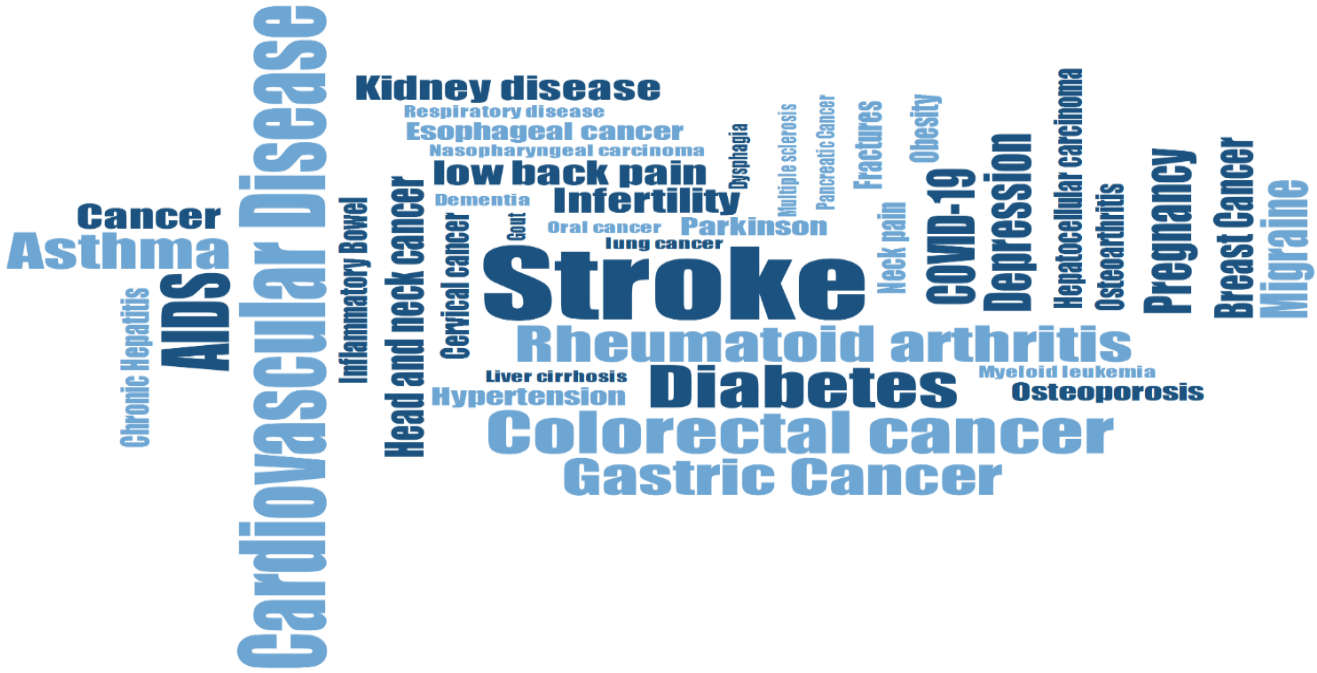


**Fig. 5:** Frequency of diseases studied in complementary and alternative medicine cohort studies up to the end of 2023

The evaluation of the articles was conducted qualitatively using the STROBE checklist. The mean score across all articles was 1.38 ± 0.57 out of two. The introduction section received the highest average STROBE score, while the other information and methods sections scored lower. Missing data, study size, sensitivity analyses, bias, and loss to follow-up all received mean scores below one. Within the methods section, the variable item achieved the highest mean score. Only the "summarize follow-up time" item scored below one in the results and discussion sections. More than 53% of the studies provided sufficient information for the funding item. Item 16c was not applicable to any of the studies, and items 11 and 16b were not applicable to the majority of the studies (Table 2).

Joint point regression analysis indicated a statistically significant increase in the number of CAM cohort studies from 2003 to 2020 ($P<0.05$). However, from 2020 to 2023, there has been an insignificant decrease ($P=0.733$). Additionally, the average annual percent change (AAPC) of 18.5 shows a significant upward trend from 2003 to 2023 ($P<0.001$). While there is a significant improvement in the quality of CAM cohort studies ($P<0.001$), it is deemed insufficient (Fig. 6 and Table 3).

**Table 2:** Frequency and mean score of complementary and alternative medicine cohort studies up to the end of 2023 based on the STROBE checklist (The mean score is calculated on a scale of 2)

| Number | Item* ( Average ± SD) | Number of articles Applicable for item Frequency (%) | Not reported item Frequency (%) | Inadequately reported item Frequency (%) | Adequately reported item Frequency (%) | Average ± SD |
|---|---|---|---|---|---|---|
| Title and abstract (1.75 ± 0.51) | | | | | | |
| 1a | Indicate the study's design | 215 | 24 (11.16) | 28 (13.02) | 163 (75.81) | 1.65 ± 0.67 |
| 1b | what was done and what was found | 215 | 0 (0.00) | 31 (14.42) | 184 (85.58) | 1.85 ± 0.35 |
| Introduction (1.93 ± 0.26) | | | | | | |
| 2 | Background/rationale | 215 | 0 (0.00) | 12 (5.58) | 203 (94.42) | 1.94 ± 0.23 |
| 3 | Objectives | 215 | 2 (.93) | 13 (6.05) | 200 (93.02) | 1.92 ± 0.30 |
| Method (1.10 ± 0.54) | | | | | | |
| 4 | Study design | 215 | 0 (0.00) | 44 (20.47) | 171 (79.53) | 1.79 ± 0.40 |
| 5 | Setting | 215 | 0 (0.00) | 46 (21.40) | 169 (78.60) | 1.78 ± 0.41 |
| 6a | Participants: Give the eligibility criteria | 215 | 0 (0.00) | 40 (18.06) | 175 (81.40) | 1.81 ± 0.39 |
| 6b | Participants: matched studies | 114 | 3 (2.63) | 23 (20.18) | 88 (77.19) | 1.74 ± 0.49 |
| 7 | Variables | 215 | 0 (0.00) | 22 (10.23) | 193 (89.77) | 1.90 ± 0.30 |
| 8 | Data sources/ measurement | 215 | 0 (0.00) | 23 (5.73) | 192 (94.27) | 1.89 ± 0.31 |
| 9 | Bias | 215 | 111 (51.63) | 64 (29.77) | 40 (18.60) | 0.67 ± 0.77 |
| 10 | Study size | 215 | 178 (82.79) | 13 (6.05) | 24 (11.16) | 0.28 ± 0.65 |
| 11 | Quantitative variables | 28 | 0 (0.00) | 21 (75.00) | 7 (25.00) | 1.25 ± 0.44 |
| 12a | control of confounding | 215 | 121 (56.28) | 69 (32.09) | 25 (11.63) | 0.55 ± 0.69 |
| 12b | subgroups and interactions | 215 | 134 (62.33) | 43 (20.00) | 38 (17.67) | 0.55 ± 0.78 |
| 12c | missing data | 215 | 166 (77.21) | 36 (16.74) | 13 (6.05) | 0.29 ± 0.57 |
| 12d | Loss to \|follow up | 133 | 104 (78.20) | 18 (13.53) | 11 (8.27) | 0.30 ± 0.61 |
| 12e | sensitivity analyses | 215 | 156 (72.56) | 25 ( 11.63) | 34 (15.81) | 0.43 ± 0.75 |
| Result (1.50 ± 0.57) | | | | | | |
| 13a | numbers of individuals | 215 | 3 (1.40) | 40 (18.60) | 172 (80.00) | 1.79 ± 0.44 |
| 13b | reasons for non-participation | 215 | 45 (20.93) | 77 (35.81) | 93 (43.26) | 1.22 ± 0.77 |
| 13c | flow diagram | 215 | 77 (35.81) | 2 (0.93) | 136 (63.26) | 1.27 ± 0.96 |
| 14a | characteristics of study participants | 215 | 0 (0.00) | 18 (8.37) | 197 (91.63) | 1.92 ± 0.28 |
| 14b | number of participants with missing | 215 | 10 (4.65) | 58 (26.98) | 147 (68.37) | 1.64 ± 0.57 |
| 14c | Summarize follow-up time | 140 | 89 (63.57) | 33 (23.57) | 18 (12.86) | 0.49 ± 0.71 |
| 15 | Outcome data | 215 | 0 (0.00) | 24 (11.16) | 191 (88.84) | 1.88 ± 0.32 |
| 16a | Give unadjusted estimates | 215 | 8 (3.72) | 36 (16.74) | 171 (79.53) | 1.76 ± 0.51 |
| 16b | Report category boundaries | 62 | 0 (0.00) | 35 (56.45) | 27 (43.55) | 1.44 ± 0.50 |
| 17 | Other analyses | 18 | 1 (5.56) | 7 (38.89) | 10 (55.56) | 1.50 ± 0.62 |
| Discussion (1.60 ± 0.66) | | | | | | |
| 18 | Key results | 215 | 37 (17.21) | 60 (27.91) | 118 (54.88) | 1.38 ± 0.76 |
| 19 | Limitations | 215 | 42 (19.53) | 9 (4.19) | 164 (76.28) | 1.57 ± 0.80 |
| 20 | Interpretation | 215 | 2 (0.93) | 29 (13.49) | 184 (85.58) | 1.85 ± 0.39 |
| 21 | Generalizability | 215 | 23 (10.70) | 42 (19.53) | 150 (69.77) | 1.59 ± 0.68 |
| Other information (1.11 ± 0.97) | | | | | | |
| 22 | Funding | 215 | 9 (41.86) | 11 (5.12) | 114 (53.02) | 1.11 ± 0.97 |

* Items 16c (relative risk into absolute risk), was not applicable to all studies

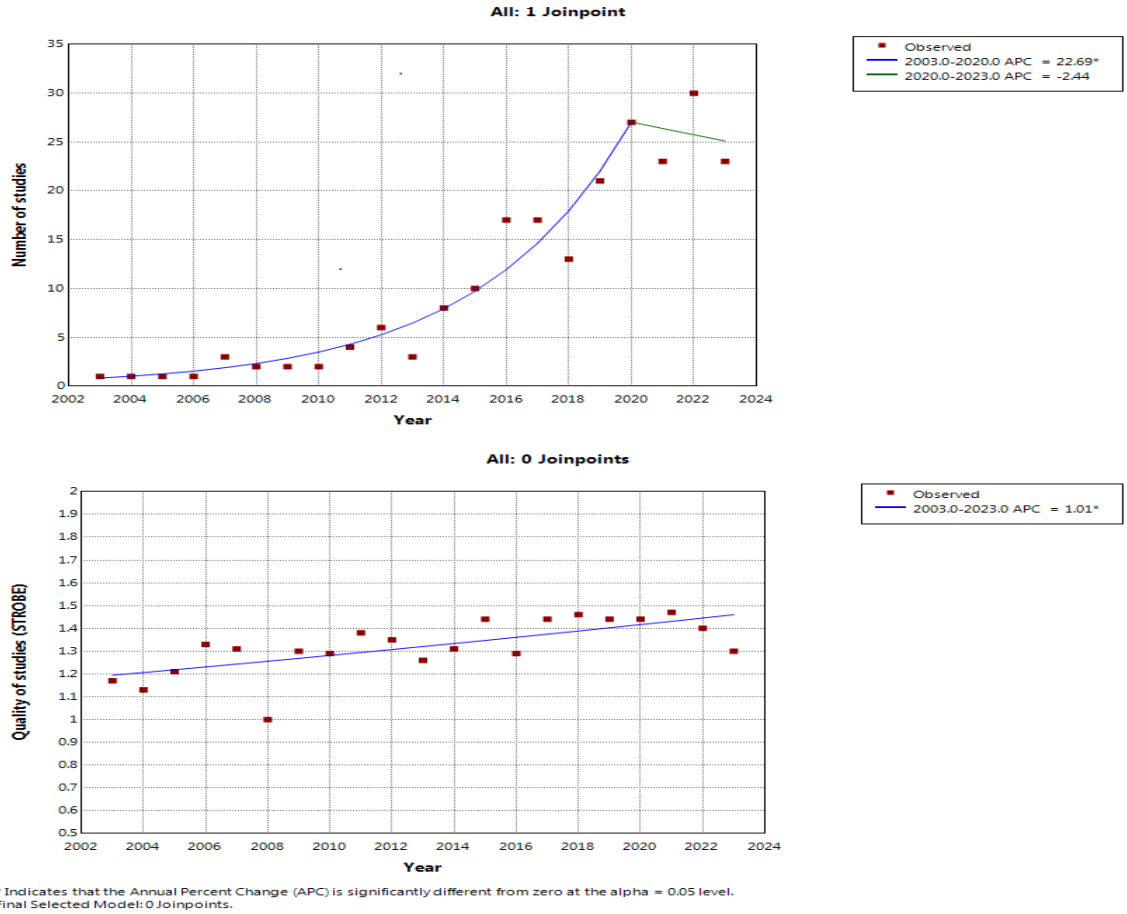


**Fig. 6:** The trend in the number of complementary and alternative medicine cohort studies along with their quality up to the end of 2023

**Table 3:** Join point analyzes of the number of complementary and alternative medicine cohort studies along with their quality up to the end of 2023

| Annual Percent Change (APC) | | | | | |
|---|---|---|---|---|---|
| | | Years | APC | 95% CI* | *P*-value |
| Number of studies | Segment 1 | 2003-2020 | 22.7 | 20.3-33.8 | 0.002 |
| | Segment 2 | 2020-2023 | -2.4 | -22.3-14.4 | 0.733 |
| Quality of studies | Segment 1 | 2003-2023 | 1.1 | 0.4-1.6 | < 0.001 |
| Average Annual Percent Change (AAPC) | | | | | |
| | | Years | AAPC | 95% CI | P- Value |
| Number of studies | Full range | 2003-2023 | 18.5 | 16.5-24.5 | < 0.001 |
| Quality of studies | Full range | 2003-2023 | 1.1 | 0.4-1.6 | < 0.001 |

*CI, confidence interval

## Discussion

This study found a significant rise in CAM cohort studies, focusing on stroke and cardiovascular disease outcomes. Chinese medicine and acupuncture were the primary interventions studied, while other CAM methods received less attention. Most studies were conducted in Taiwan and

China, with no studies from Africa or South America. Evaluation based on STROBE criteria revealed subpar reporting quality on crucial aspects like missing data, study size, sensitivity analyses, bias, and loss to follow-up. Items 11, 16b, and 16c of the STROBE checklist were deemed not applicable for most studies.

Cohort studies offer the ability to test hypotheses that may not be feasible in randomized clinical trials (22). This characteristic has led to the consideration of cohort studies in CAM. Similar to the research conducted by Duan et al. (4), there has been a noticeable increase in the utilization of cohort studies in CAM in recent years. Cohort studies are valuable for tracking patterns and shifts in CAM usage over time (23), which is why they have become a significant tool in CAM research in recent years.

Several studies have highlighted the global use of CAM for treating various diseases over the past decade (24-26). The use of CAM in treating patients with stroke and cardiovascular diseases was significant in this study, as well as in previous research (27-29). Various factors, including the particular condition or illness, the individual's health status, and their current medications, influence patients' readiness to incorporate CAM into their treatment regimen, either as a supplement or alternative (30).

Cohort studies focusing on these conditions can serve as valuable resources for clinical practice and form the basis for future clinical trial investigations. This study similar to other studies (4, 31) shows that using of Chinese medicine is rising. Furthermore, the number of systematic reviews and meta-analyses on acupuncture confirm that using of this intervention is rising (32). Chinese medicine and acupuncture are likely prevalent due to compelling research findings, their potential to complement other treatments, their ability to address various conditions, and minimal adverse effects.

The distribution of cohort studies in the research mirrored the findings of a previous study (4), except for Taiwan having the highest representation and a lack of research conducted in Africa continent and South America. Reasons for using complementary and alternative medicine vary globally (33), along with differences in cultural values and healthcare practices (34), which can impact the utilization of CAM and the approach to related research. Registries are structured data systems that enable the prospective gathering and application of observational and clinical data (35). One possible explanation for the increase in cohort studies in Taiwan and China could be the presence of diverse databases that facilitate the implementation of cohort studies in CAM (36-40). Additionally, the utilization of CAM is significant in these nations; for instance, in Taiwan, the prevalence of CAM treatment recommended or prescribed by both Western medicine practitioners and traditional Chinese medicine practitioners is relatively high (41, 42).

The documentation of CAM usage in Africa is not well-documented, with many CAM users choosing not to disclose their CAM practices to healthcare providers (43). The majority of African countries do not have a registration system for herbal medicines, as highlighted in a WHO report. Additionally, the lack of research data and insufficient financial support for CAM research in the African region and the region of the Americas pose significant challenges to conducting studies in this area (44).

The evaluation of observational studies should be more rigorous compared to clinical trials (45), highlighting the need to report comprehensive details in the method (46). Similar to previous research (47, 48), the quality of reporting in the methods section was a notable concern in this study.

In this section, the reporting quality of key elements such as missing data, study size, sensitivity analyses, bias, and loss to follow-up scored below one. Similar to previous studies (46, 49), missing data was infrequently reported in this study. While the presence of missing data can impact the generalizability of the findings, it is crucial to calculate the sample size to ensure adequate recruitment of participants and detect significant differences (50). However, similar to other research (13, 51), concerns were raised regarding the reporting of sample size calculations in this

study. Sensitivity analyses serve as a measure of the study's robustness against unmeasured confounding variables (52). Yet, akin to other studies (49, 53), the reporting percentage of sensitivity analyses was notably low in this study. Bias has the potential to influence the findings derived from studies (3), underscoring the importance of considering potential sources of bias. However, in this study, as in other studies (47, 54), the reporting of bias was suboptimal.

Similar to the previous study (4), items 11, 16b, and 16c of the STROBE checklist were deemed not applicable for the majority of studies, suggesting that these items may not be suitable for evaluating CAM studies.

## Limitations

This study had some limitations. Firstly, the quality assessment of the articles relied solely on the content provided by the authors without seeking additional information. Secondly, due to a lack of evidence, all checklist items were given equal weight.

## Conclusion

In recent years, there has been a significant increase in the use of cohort studies to assess the impact of CAM interventions. However, the overall quality of reporting in CAM cohort studies is a cause for concern and requires greater transparency. Future studies should focus on enhancing the methodology section and ensuring better adherence to STROBE guidelines during implementation. Failure to improve reporting practices may limit the interpretation and reliability of study results. It is crucial for researchers, health policymakers, and journals to be familiar with and adhere to the STROBE checklist recommendations. Additionally, providing training in statistical methods for researchers and developing a STROBE extension specifically for CAM cohort studies should be considered.

## Journalism Ethics considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

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## Data availability

Data related to this article can be obtained from the corresponding author on request.

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## Conflict of interest

There is no conflict of interest between the authors.

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