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OBM Integrative and Complementary Medicine

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Original Research

Implementation of General Consent in Swiss Traditional Chinese Medicine Practices: A Cross-sectional Study

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Academic Editor: Peta Stapleton

OBM Integrative and Complementary Medicine
2026, volume 11, issue 2
doi:10.21926/obm.icm.2602017

Received: November 24, 2025
Accepted: May 11, 2026
Published: May 18, 2026

Abstract

Traditional Chinese Medicine (TCM) is often applied in isolated TCM practices, making rigorous research and standardized real-world data collection challenging. The purpose of this study was to implement the general consent (GC) in TCM practices, investigate the issue and the acceptance rate of the GC, and the influencing demographic factors. GC forms were distributed to patients before appointments and collected during their first visits. Logistic regression analyses were performed to investigate demographic factors influencing GC issue and acceptance rates, considering variables such as age, sex, age * sex, and months since implementation. The study enrolled 2,603 patients who sought TCM treatment, of whom 77.5% returned a GC document. Overall, the GC acceptance rate was 1,558/2,603 (59.9%); of those returning the GC, the acceptance rate was 1,558/2,018 (77.2%). The median [IQR] age of patients was 52 years [37, 64], and the number of female patients was around twice that of male patients. Logistic regression analysis showed no association with the GC issue rate for

older age (odds ratio, OR: 1.01, 95% CI: 0.99-1.03, p = 0.474), female sex (OR: 1.31, 95% CI: 0.71-2.38, p = 0.387), the interaction between age and female sex (OR: 1.00, 95% CI: 0.98-1.01, p = 0.379), or months since GC implementation (OR: 1.00, 95% CI: 0.98-1.01, p = 0.615). Similarly, for the acceptance rate, no effects were observed for older age (OR: 1.02, 95% CI: 1.00-1.04, p = 0.120), female sex (OR: 1.25, 95% CI: 0.63-2.46, p = 0.516), or the interaction between age and female sex (OR: 0.99, 95% CI: 0.97-1.01, p = 0.243). Months since GC implementation was associated with a slight decrease in acceptance rate over time (OR: 0.98, 95% CI: 0.97-1.00, p = 0.034). In conclusion, this study successfully implemented the GC in TCM practices and paves the way for real-world studies in the field of TCM. Patient acceptance was high and remained consistent across sex and age.

Keywords
Traditional Chinese Medicine, TCM; general consent; Switzerland

1. Introduction

Traditional Chinese Medicine (TCM) includes a diverse array of treatments aimed at diagnosing and managing illnesses. Its adoption has markedly increased in Western countries, further supported by the World Health Organization's inclusion of TCM diagnostic patterns in the latest update of the International Classification of Diseases code (version 11, accepted in 2019), which serves as the universal benchmark for health diagnostics [1]. In Switzerland, a 2017 survey by the Swiss Federal Statistical Office revealed that 8.5% of respondents (1,592 out of 18,832) had used TCM or acupuncture in the past 12 months [2]. Assuming this survey is representative of Switzerland, a total of 598,655 of 7,043,002 (corresponding to 8.5%) Swiss inhabitants might have used TCM in 2022. Given the widespread TCM presence and its possible significant impact on contemporary healthcare practices and clinical routines, it is crucial to rigorously evaluate and conduct research on the efficacy of TCM therapies across various diseases [3].

To conduct clinical research ethically and effectively, obtaining informed consent (IC) is recognized as a foundational requirement, mandated by national and international standards like the International Conference on Harmonization - Good Clinical Practice [4]. It ensures participants' autonomy by fully informing them about a specific study's objectives, methods, potential benefits, and risks, securing their voluntary agreement [5]. On the other hand, General Consent (GC) is a flexible alternative that addresses some of the impracticabilities of informed consent [6]. It permits the use of participants' data or biological samples obtained during the clinical routine for future yet-to-be-defined research projects by streamlining research processes, enhancing the potential for scientific breakthroughs, and upholding ethical standards through voluntary, informed participation [7, 8].

The widespread adoption of the GC in various research fields and institutions highlights its advantages [9]. In conventional medicine and hospitals, GC has been a standard element of the admissions process for all in- and outpatients [8]. Yet, its utilization within TCM research and practice is lacking compared to the usage of ICs [10]. The varied modalities of TCM, such as herbal medicine and acupuncture, present distinct obstacles for clinical studies due to the personalized

nature of its treatments [11]. Adopting GC in TCM research will play a crucial role in facilitating its progress and addressing the unique challenges it faces.

This study introduces the GC within the context of TCM research, aiming to reconcile TCM's traditional approaches with modern ethical standards. This initiative seeks to streamline the research process in TCM, facilitating wider research activities and deeper investigation into real-world TCM's effects and mechanisms while maintaining ethical integrity through informed, voluntary participation.

The purpose of this study was to investigate the GC issue rate, which refers to how often the GC was distributed, and the GC acceptance rate, which represents the proportion of patients who accepted the GC, as well as the demographic factors influencing these rates during the first two years of its implementation in TCM practices.

Successful implementation of the GC in TCM practices will enable practice-based research projects in clinical research, a highly warranted and understudied medical field.

2. Materials and Methods

This cross-sectional study was conducted from the 1st of January 2023, to the 31st of December 2024, at ten TCM practices owned by the company TCM Ming Dao or MediQi. The individual TCM practices were situated in Switzerland in Aarau, Baar, Baden, Bad Ragaz, Bad Zurzach, Chur, Lenzburg, Uster, Wil, and Zug. Those practices implemented the general consent document and collected and stored the documents internally. For this project, each practice provided the SWISS TCM UNI anonymized data for the current analysis. The SWISS TCM UNI is an accredited Swiss University focusing on the education, research, and practice of Traditional Chinese Medicine.

2.1 Study Population

This study included all patients who sought TCM treatment at any of the outpatient practices at TCM Ming Dao in 2023 and 2024, as well as those visiting any MediQi practices from May 1, 2024, until the end of 2024. All participating practices adhered to standardized treatment protocols and employed certified TCM providers, ensuring a consistent quality of care across sites. Two TCM providers were licensed medical doctors. There were no specific age, sex, or literacy requirements for inclusion (calculated as of the date of the first TCM treatment). Eligible participants were required to be conscious patients (in the case of patients aged under 18, their legal guardians) capable of understanding the nature and implications of the German or English GC version.

2.2 Data Collection and Data Management

In case a patient contacted the TCM practice secretary and arranged a TCM treatment, the GC and other administrative documents were sent by mail to the patient. During the patient's admission and the first visit, the GC was discussed, if required, and the completed and signed GC was collected by the secretary's office. In case the patient returned no GC, the practice secretaries were instructed to remind the patient once. If the GC was still not returned, no additional reminders were sent. As part of the daily routine, the secretary's offices of the practices entered the GC information into an internal file containing all new patients seeking TCM therapy. The patient's

decision to accept or reject the GC was not communicated to the TCM providers, and neither decision affected the anticipated TCM treatment.

2.3 Outcomes

The primary outcome of this study was the overall GC acceptance rate over the first two years of its implementation. The secondary outcome was the issue rate, defined as the frequency with which the GC was issued. The overall objective was to assess the factors influencing the GC issue and acceptance rates.

2.4 Statistical Analysis

Descriptive statistics for patients who agreed, declined, or did not return and incorrectly completed GCs were performed. A GC was not issued or invalid (GC status = not issued/invalid) if the forms were not handed out to the patients or not returned to the secretary or if the document contained missing information, i.e., missing signature of the patient. Results are presented in median (interquartile) or absolute numbers and percentages. All cases with missing or incomplete General Consent documentation - including unsigned forms, partially completed documents, or forms not returned to clinic staff - were systematically classified as 'Not issued/invalid'. The primary outcome, the overall GC acceptance rate, was calculated by the number of patients agreeing to the GC divided by the total number of new patients seeking TCM. The 95% confidence interval of the primary outcome was calculated using the Clopper-Pearson binomial confidence interval. In additional analyses, GC acceptance was stratified by sex and age group and analysed.

Logistic multivariable regression analyses to investigate whether demographic characteristics, or the months since GC implementation, were predictors for the GC issues and the GC acceptance were performed. To address potential sources of bias, patients were prospectively enrolled, and regression models were adjusted for clinically relevant confounders (age, sex, time since implementation). In the first model, the dependent binary variable was the issued GC, i.e., a valid GC document returned to the secretary versus no GC issued/invalid GC. In the latter, GC acceptance (Yes, No, excluding the not issued/invalid GC) was the dependent binary variable. Age, sex (men, women), and the interaction between age and sex were independent predictors. Both models included age, sex (men, women), the interaction between age and sex, and months since GC implementation as independent predictors. The interaction between sex and age was also analyzed to evaluate how the impact of age on GC acceptance and GC issuance rates might vary by sex. Patients with missing age or sex data were excluded from multivariable regression analyses.

To estimate the association between predictors and outcomes, adjusted odds ratios (ORs) with 95% confidence intervals (CIs) were calculated using multivariable logistic regression. Patients with missing age or sex data were excluded from multivariable regression analyses. These ORs account for the influence of all included covariates, ensuring that the reported associations reflect the independent effects of each predictor. The months since implementation were calculated as the difference between the patient's first visit and January 1, 2023, for Ming Dao patients, and May 1, 2024, for MediQi patients, when the GC was first introduced.

Statistical analyses were performed with STATA version 15 (StataCorp, College Station, TX, USA) and RStudio version 4.3.3. A p-value below 0.05 was considered to reflect statistical significance.

2.5 Ethics Statement

Anonymous data does not require informed consent from participants or approval from the ethics committee according to local law [12]. The GC has been adapted from the Swiss Ethics template [13] and was approved by the Ethics Committee of Northwest-Central Switzerland (No. AO_2023-00017) (see GC in the Appendix). The GC was available in German and English. This study adhered to STROBE guidelines (STrengthening the Reporting of OBservational studies in Epidemiology) [14].

3. Results

3.1 Population Overview

As reported in Table 1, a total of 2,603 patients visited the ten practices from January 2023 to December 2024, with Bad Zurzach accounting for 38.0% of all visits, followed by Baden (17.7%), Lenzburg (13.0%), Bad Ragaz (7.4%), Zug (6.7%), Uster (5.1%), Chur (3.2%), Baar (3.0%), Wil (2.9%), and Aarau (2.8%). Out of the total amount of records, in 585 of 2,603 (22.2%) of the cases, the GC was either not issued (567 of 585 [96.9%] due to language issues, other reasons remain unknown), or the patient did not provide a valid GC document (18 of 585 [3.1%]). The remaining 2,018 of 2,603 (77.5%) signed a GC, of which 1,558 of 2,018 (77.2%) agreed, and 460 of 2,018 (22.8%) declined. Among all new patients, a positive GC was obtained from 1,558 of 2,603 cases (59.9 with a 95% CI of 57.9 to 61.7%) (Table 1).

Table 1 Demographic characteristics of new patients seeking TCM therapy in 2023 and 2024.

Variable	New patients	Consented	Declined	Not issued/invalid
N (Overall)	2,603 (100)	1,558 (59.9)	460 (17.7)	585 (22.5)
N (signed GC)	2,018 (100)	1,558 (77.2)	460 (22.8)	-
Sex (n, %)				
Male	835 (32.1)	513 (61.5[1])	133 (15.9[1])	189 (22.6[1])
Female	1,676 (64.4)	1,000 (59.7[1])	301 (18.0[1])	375 (22.4[1])
Unknown	92 (3.5)	45 (48.9[1])	26 (28.3[1])	21 (22.8[1])
Age, years	51 [37, 64]	52 [37, 65]	50 [37, 60]	52 [37, 63]

Values are presented in numbers (proportions) or median [interquartile range].

[1]These proportions were calculated in relation to the total number of new patients with the corresponding sex, i.e., 513 out of 835 (61.5%) male patients consented.

3.2 Demographics

Around two-thirds of the new patients seeking TCM treatment in 2023 were female; 59.7% gave their consent, and 18.0% declined the GC (Table 1, Figure 1). Similar proportions of GC status were found in male patients (n = 835, 61.4% consented, 15.9% declined).

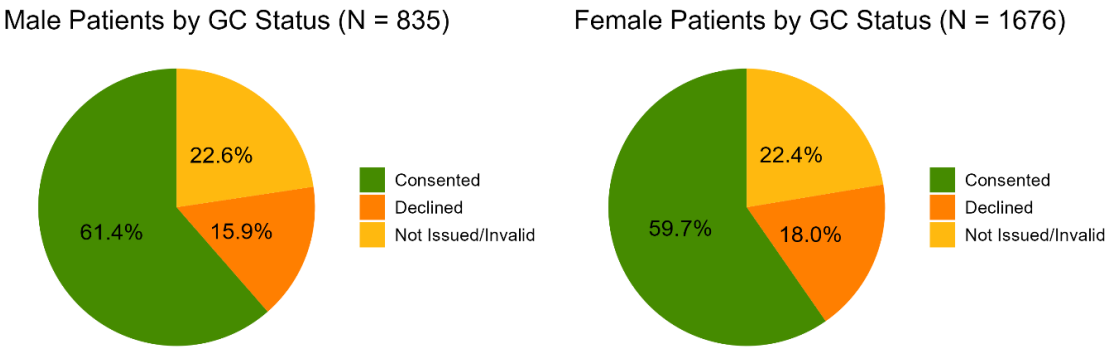

Figure 1 Sex-related General Consent (GC) categorization.

The median [interquartile] age of all new patients was 52 [37, 64] years old. The relationship between age and GC acceptance rate is illustrated in absolute years and as a proportion in Figure 2 and Figure 3. The logistic regression analysis revealed that neither sex nor age was associated with the GC acceptance rate (Table 2 and Table 3). Among 2,603 total patients, 92 (3.5%) had missing age or sex data. Of these, 71 (3.5% of the 2,018 patients with issued GC documentation) had valid consent forms despite the missing demographic information.

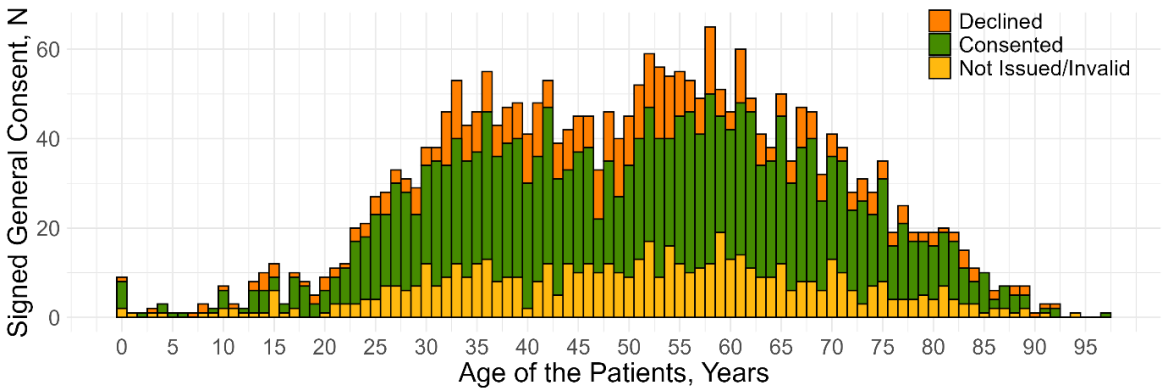

Figure 2 Absolute distribution of GC status (accepted, declined, not issued/Invalid) across all patient ages.

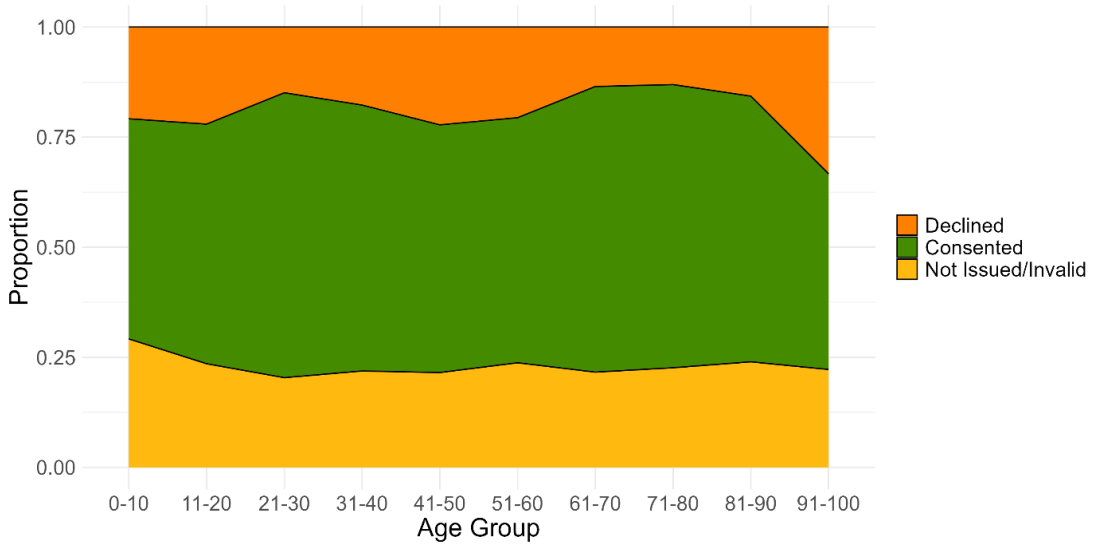

Figure 3 Proportional GC status distribution by age decade (grouped in 10-year intervals).

Table 2 Logistic regression – General Consent implementation: not issued/invalid vs. issued. (only male and female).

Variable	Odds ratio	95% confidence interval	p-value
Age, per one-year increase	1.01	0.99 to 1.03	0.474
Female sex (*reference: male*)	1.31	0.71 to 2.38	0.387
Female * Age	1.00	0.98 to 1.01	0.379
Months since GC implementation	1.00	0.98 to 1.01	0.615

N = 2511.

Table 3 Logistic regression – General Consent status (excluding not issued/invalid, i.e., analyzing the issued ones): consented vs. declined (only male and female).

Variable	Odds ratio	95% confidence interval	p-value
Age, per one-year increase	1.02	1.00 to 1.04	0.12
Female sex (*reference: male*)	1.25	0.63 to 2.46	0.516
Female * Age	0.99	0.97 to 1.01	0.243
Months since GC implementation	0.98	0.97 to 1.00	0.034*

N = 1947.

3.3 Months Since GC Implementation

Logistic regression analysis revealed that months since GC implementation were not significantly associated with the GC issue rate (OR: 1.00, 95% CI: 0.98-1.01, p = 0.615) (Table 2). When analyzing the acceptance rate (accepted vs. declined), months since GC implementation was associated with a slight decrease in the acceptance rate over time (OR: 0.98, 95% CI: 0.97-1.00, p = 0.034) (Table 3, Figure 4).

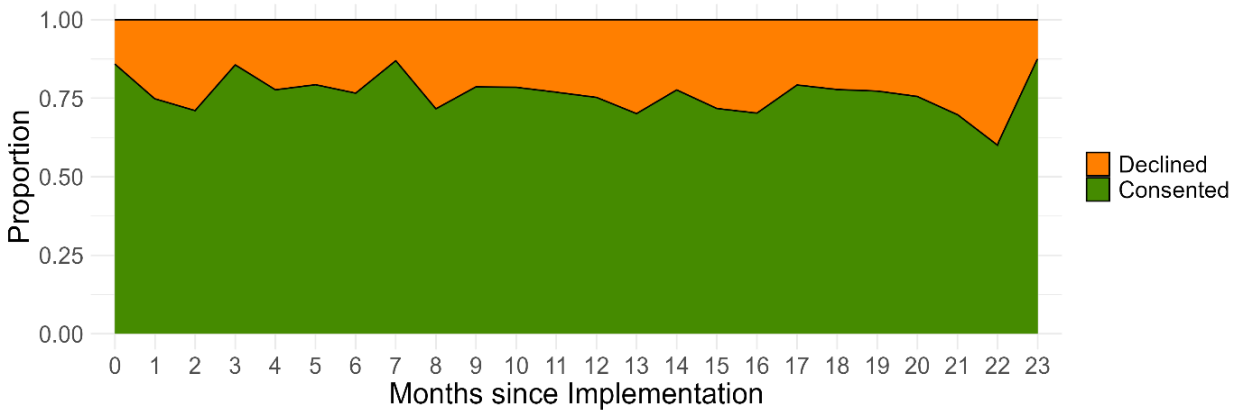

Figure 4 Proportional distribution of 'Consented' and 'Declined' general consent statuses over time since implementation.

4. Discussion

The current study found that GC implementation in TCM practices is feasible, and that the GC acceptance rate remains high. Importantly, the GC acceptance rate in these TCM practices was

independent of age and sex, suggesting that future TCM research, depending on the GC acceptance rate, will not be biased by age or sex. These findings might encourage other TCM practices to implement the GC, facilitating future practice-based TCM research using patient data obtained in daily clinical routine.

Despite numerous studies on informed consent and ethical considerations [10, 15-18], there has been no work on GC in TCM research. The current results showed a considerable acceptance rate (59.9%) of GC among all incoming new patients. This is 21.1% higher compared to a study on GC implementation at the University Hospital Zurich (USZ) [8] (59.9% vs. 38.8%) ($P < 0.001$, two-sample test of proportions), thanks to the much lower rate of not issued or invalid GCs (22.2% vs. 51.3%) ($P < 0.001$, two-sample test of proportions). Out of those who returned a valid GC document, 77.2% consented to participate. This was comparable to the 79.7% of the returned and agreed GCs at the USZ [8]. These findings and high acceptance rates suggest that patients are open to research participation beyond conventional medical frameworks and centralized hospital settings. They show a similar willingness to provide patient data for complementary medicine research in a decentralized setting like TCM practices.

During the study period, the number of female patients seeking TCM treatment was twice that of male patients. This greater presence of the female population in TCM usage is consistent with findings from a study conducted in Taiwan, where the 1-year prevalence of TCM use was 31.8% among women and 22.4% among men, among 14,064 eligible participants [19]. Although specific studies on TCM usage in Europe are lacking, studies have shown that women generally seek complementary and alternative medicine (CAM) treatments more frequently than men. More specifically, a study from Norway indicated that 42% of those reporting CAM usage were female compared with 24% male [20]. Similarly, a broader and more recent study in Europe showed that 21.5% of female and 13.9% of male participants reported usage of CAM [21].

Despite the higher proportion of female patients seeking TCM therapies, the GC acceptance rate remained independent of sex and age (Table 3). This finding differs from the GC study conducted at the University Hospital Zurich, which found that age was positively associated and female sex was negatively associated with GC acceptance rate. These differences highlight that GC acceptance rates might depend on the settings and are not generalizable across different fields of medicine. Nevertheless, the absence of a correlation between sex and age and the GC acceptance rate is a promising finding, suggesting that future TCM research based on GCs will likely not be biased by sex or age.

One of the strengths of this study is its pioneering implementation of GC in TCM practices, successfully bridging traditional medical practices with modern ethical standards. It paves the way for practice-based TCM research in the real-world setting. The successful implementation provides a framework for other practices and institutions to adopt similar practices. The study has several limitations affecting its overall robustness and generalizability. The focus on the German-speaking part of Switzerland limits the generalizability of the findings to broader populations or to different geographic and cultural contexts. The logistic regression model primarily considered age, sex, and months since implementation, excluding other potentially influential factors like socioeconomic status, practice location, education level, and specific health conditions. Although the above-mentioned and investigated influencing factors were not relevant to GC acceptance rate, they might be relevant in other study and practice settings.

5. Conclusion

This study successfully implemented the GC in TCM practices in Switzerland. Findings revealed that the GC implementation was feasible and that patients, regardless of age or sex, demonstrated a high GC acceptance rate, paving the way for highly warranted real-world medical research in TCM. A successful GC implementation might encourage other practices to adopt the GC, facilitating practice-based, real-world research in TCM. Establishing a network of TCM practices willing to participate in research, along with nationwide implementation of the GC and standardized entry and exit forms, will enable novel and highly warranted research in TCM.

Abbreviations

CAM	Complementary and Alternative Medicine
GC	General Consent
IC	Informed Consent
TCM	Traditional Chinese Medicine
USZ	University Hospital Zurich

Author Contributions

XW completed the statistical analysis, designed and made the graphs/figures, and wrote the first draft of the manuscript. XL and BC structured and acquired the data. RB and SP assisted with the GC implementation and acquisition of the data. MF supervised the planning, conduct, and completion of the project, and assisted XW with statistical analysis. KM supported XW for statistical analysis, designed and made the graphs/figures, and assisted with writing the manuscript. MF and YL conceptualized and designed the project. All authors critically reviewed and approved the final manuscript.

Funding

The project did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Competing Interests

All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. The co-authors Yiming Li, Saroj Pradhan, and Ralf Bauder are employed at the TCM Ming Dao AG. No other potential conflict of interest was disclosed.

Data Availability Statement

Anonymized data as well as analytical code underlying the presented analyses are available from the corresponding author upon reasonable request.

AI-Assisted Technologies Statement

Regarding the AI, Grammarly was used for basic grammar correction and language refinement in the preparation of this manuscript. All scientific content, data interpretation, and conclusions were developed independently by the author. The authors have thoroughly reviewed and edited the AI-assisted text to ensure its accuracy and accept full responsibility for the content of the manuscript.

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