世界针灸学会联合会标准

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针灸病例注册登记实施指南

Guideline for registry study on acupuncture and moxibustion clinical

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Foreword

This document is developed in accordance with the technical procedures and rules established by the Standardization Working Committee of the World Federation of Acupuncture-Moxibustion Societies.

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The drafting organization of this document: Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences; Institute of Acupuncture and Moxibustion Research, China Academy of Chinese Medical Sciences; Shenzhen Hospital of Traditional Chinese Medicine.

Members of the drafting panel of this document: Jia Liu, Chao Wang, Hai-bo Yu, Bao-yan Liu, Li-yun He, Xiao-dong Wu, Xiao-hui Zhan, Jia-ping Wu, Xing-xian Huang, Xu-qiang Wei, Yuan-yuan Zhuo, Shao-hong Li, Jin-huan Zhang, Wei-ying Chen, Yu-hai He, Yan-ke Ai, Xiao-ying Lv, Hong-jiao Li, Lin Luo, Qi-zhen Wang, Xue Cao, Xiang-ran Meng, Ming-lin Sun, Hui Deng, Li-hong Yue, Xin Wang, Zheng-li Long, Jia-jia Zhang, Tian-yi Zhao, Yi-fan Bai, Yan Zhang, Rui-jie Sun, Yu-kun Tian, Xin-yi Liu.

Members of the expert committee of this document: Li-xing Lao (USA), Zhao-xiang Bian (China), Fan-rong Liang (China), Yi-ming Li (Switzerland), Cun-zhi Liu (China), Wei-dong Yu (Canada), Amir Hooman Kazemi (Iran), Sanghoon Lee (Korea), Ken Chen (China), Zhi-shun Liu (China), Ji-ping Zhao (China), Hong Xu (China), Xing-fang Liu (China), Kai Qi (China), Jing-jing Wang (China), Ze-lin Chen (China), Xiao-chun Yu (China), Hong Zhao (China).

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Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents.

Introduction

Registry study is an organized system for one or more predetermined scientific, clinical, or policy purposes, uses data collected uniformly by observational research methods to assess the specific outcome[1] of a particular disease, condition, or exposed population. This document is formulated in accordance with *Good Clinical Practice of Acupuncture-moxibustion Research Management*[2] and relevant international rules for clinical trials, based on the principles of the *Declaration of Helsinki*[3] relevant ethical requirements.

The purpose of this document is to ensure the standardization of the acupuncture-moxibustion case registration research process and the credibility of the research results, and to protect the rights and safety of the research subjects, which providing guidelines for the entire process of design, organization, organization implementation, monitoring, inspection, documentation, analysis, summary, reporting and evaluation.

Guideline for registry study on acupuncture and moxibustion clinical

1 Scope

This document provides the key techniques and management requirements for the whole process of acupuncture-moxibutsion registry study.

This document is intended for use by researchers, subjects, quality management personnel, platform developers and other personnel who carry out acupuncture-moxibutsion clinical research using the registration model.

2 Normative references

The content of following documents constitutes an essential provision of this document by means of normative references in the text. For dated references, only the edition corresponding to that date applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

T/CAAM 0006—2022, *Guidelines of quality assessment for clinical trials of acupuncture-moxibustion in the real world*

T/CAAM 0007—2022, *Guideline for registry of acupuncture-moxibustion clinical research*

T/CAAM 0009—2022, *Guidelines of data management specification in clinical trials of acupuncture-moxibustion in the real world*

T/CACM 1371.4—2021, *Technical specifications for real-world studies of traditional Chinese medicine—Ethical review*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
registry

A systematic study that uses primarily observational design to gather data uniformly for assessing a

specific disease, condition, or exposed population outcome with intended scientific, clinical, or policy purposes.

3.2
registry study on acupuncture-moxibustion

Taking acupuncture-moxibustion as the therapy, adopting real world clinical study design, registry study on acupuncture-moxibustion uses the case registry style to collect data and program management, in order to evaluate the safety, clinical efficacy and cost-effectiveness of acupuncture-moxibustion therapy or devices in real clinical practice, describe the application situation and evaluate the quality of service.

4 Establishment of registry study

4.1 Research purpose and hypothesis

To carry out registry study on acupuncture-moxibustion, the main clinical issues should firstly be clarified and scientific hypotheses for research should be built. The purpose of registry study on acupuncture-moxibustion including but not limited to evaluate the safety or effectiveness of acupuncture therapy or acupuncture apparatus, describe the application, and evaluate the quality or capability of service.

4.2 Selection of research method

The design of registry study on acupuncture-moxibustion should be based on the clinical questions, according to the study purpose and the real-world research environment. Research methods include but are not limited to observational studies, such as traditional cohort studies, case-control studies, nested case-control studies, case-cohort studies, cross-sectional studies, as well as registrie-based randomized controlled trials and complex data mining.

4.3 Study protocol

Registry study on acupuncture-moxibustion scheme is the basis for implementation and management. It should be clear, detailed and executable. The contents include but are not limited to: title, research site, research purpose, research population, intervention methods, outcome indicators and their measurement methods, research period, data collection methods and instruction of data platform.

4.4 Quality management

Establish a planned systematic quality management for specific projects to ensure that the implementation of registry study on acupuncture-moxibustion and data collection process are consistent with

the program. For details, see T/CAAM 0006—2022.

4.5 Data management

Data management of registry study on acupuncture-moxibustion is in line with traditional clinical trial data management principles. For details, see T/CAAM 0009—2022. Case registration data can be used as previous data. In data extraction, attention should be paid to completeness, standardization, accuracy and traceability, and sensitive information should be desensitized. For prospective data collection, data collection elements should be determined, and attention should be paid to the timeliness, completeness, standardization, accuracy and traceability of data. Unified data specification and operation standard should be established for multi-source heterogeneous data processing, and the data should be merged after standardized processing.

4.6 Ethics consideration

Registry study on acupuncture-moxibustion follows the ethical principle of "human as object", multi-center and cross-regional ethical review and acupuncture safety should be focused on, and informed consent should be given by participants, patients and data providers. For real-world retrospective studies (where data has been obtained), an application for exemption of informed consent may be made taking into account compliance reasonableness; for real world prospective research (future data), the methods of universal informed consent and conventional informed consent can be adopted. For details, see T/CACM 1371.4—2021.

4.7 Transparency

The research plan should be registered and published on the clinical research platform of acupuncture-moxibustion. The research progress and process shall be made public and subject to supervision and inspection. For details, please refer to T/CAAM 0007—2022.

5 Implementation of registry study

5.1 Database construction

Registry study on acupuncture-moxibustion can create a new database, or use the existing data platform to build a database. If the existing data platform is selected, it should be ensured that it conforms to the purpose and content of the study, and can provide data protection, data storage, data movement, and data verification guarantees.

5.2 Registry recruitment

Recruitment includes the recruitment of medical institutions/research centers, doctors/researchers, patients/subjects. Recruitment plans should be formulated before the start of registration, and

should include recruitment conditions, recruitment methods, recruitment forms, recruitment processes, etc. The medical institutions/research centers and doctors/researchers recruited should ensure that they have the appropriate qualifications, researchers and clinical participants. Research related duties and functions undertaken by units other than those authorized by the institution should be approved and documented.

5.3 Training

Prior to the start of the study, all participants in the study should be trained by personnel who is familiar with the program. The training goal of researchers is to master the implementation plan; patients are trained to give full informed consent and to cooperate with data collection. Training should be carried out throughout the research process and a consistency check should be established for program implementation.

5.4 Clinical implementation

The researcher in the medical institution organized qualified acupuncture-moxibustion doctors to perform treatment on the patients according to the research plan, and record the results in a timely manner. If the patient needs to use acupuncture-moxibustion equipment for treatment by him/herself, the patient should record it in the diary card in time.

5.5 Data collection and reception

In registry studies on acupuncture-moxibustion, the followings shall be implemented in accordance with the provisions of the data management system: collection and management process of data, the system used for data management and collection, the steps and tasks of data management, and the quality assurance measures for data management. Data collection personnel should be authorized by the researcher and be trained. Data collectors collect the outcome indicators of acupuncture-moxibustion treatment in accordance with the research protocol.

5.6 Central quality control

The central quality control system conducts quality control on the multi-center participating research institutions and the entire research process. The researcher authorizes full-time quality control personnel to regularly evaluate the compliance of researchers and patients.

5.7 Organizational management

Registry study on acupuncture-moxibustion should establish a mechanism of project organization and management. Researchers should have specific management regulations on the personnel, files, contracts, and funds involved in the research. When involving cross-border cooperation, the management of research institutions or individuals, the use of funds, the management of equipment, the use and processing of biological samples, and the management of data should comply with the laws,

regulations and policies of the participating countries.

6 Evaluation of registry study

The project evaluation of registry study should be carried out after the registration is completed, including the design, implementation, data analysis, bias control, etc., to evaluate whether the study has achieved the research purpose and maintained good authenticity, accuracy and practicability.

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[3] Yang Liran,Qiu Renzong. *World Medical Association Declaration of Helsinki—Ethical principles for medical research involving human subjects*[J]. Medicine and Philosophy (Humanities and Social Medicine),2009,30(5):74-75.

前　言

本文件依据世界针灸学会联合会标准工作委员会制定的技术流程和规则研制。

本文件由世界针灸学会联合会(World Federation of Acupuncture-Moxibustion Societies，WFAS)归口并发布。

本文件起草单位：中国中医科学院中医临床基础医学研究所、中国中医科学院针灸研究所、深圳市中医院。

本文件主要起草人：刘佳、王超、于海波、刘保延、何丽云 、武晓冬、詹晓惠、吴佳苹、黄杏贤、魏绪强、卓缘圆、李少红、张金焕、陈伟英、何玉海、艾艳珂、吕晓颖、李洪皎、雒琳、王启桢、曹雪、孟祥然、孙铭璘、邓辉、岳俐宏、王馨、龙政莉、张家嘉、赵天易、白轶凡、张燕、孙睿婕、田煜坤、刘心怡。

本文件专家委员会委员：劳力行(美国)、卞兆祥(中国)、梁繁荣(中国)、李一明(瑞士)、刘存志(中国)、于卫东(加拿大)、Amir Hooman Kazemi(伊朗)、Sanghoon Lee(韩国)、陈恳(中国)、刘志顺(中国)、赵吉平(中国)、徐红(中国)、刘兴方(中国)、齐凯(中国)、王京京(中国)、陈泽林(中国)、喻晓春(中国)、赵宏(中国)。

本文件的制定得到了中华人民共和国科技部-国家重点研发计划中医药现代化研究重点专项项目国际针灸临床实践指南、技术操作规范和服务标准的研制(项目编号：2019YFC1712200)中国际针灸临床研究服务标准研制(课题编号：2019YFC1712205)；中国中医科学院科技创新工程课题中基于疾病研究的真实世界临床评价及数据治理分析关键技术研究(CI2021A00702-02)、中医药真实世界疗效评价病例注册登记研究(CI2021A05408)的基金支持。

请注意本文件的某些内容可能涉及专利。本文件的发布机构不承担识别专利的责任。

引　言

注册登记研究是一个有组织的研究过程，用于一个或多个预先确定的科学、临床或政策目的，使用通过观察研究方法统一收集的数据来评估特定疾病、状况或暴露人群的特定结局[1]。本文件依据《针灸临床研究管理规范》[2]及国际临床试验相关规则，按照《赫尔辛基宣言》[3]原则及相关伦理要求制定。

本文件的目的是保证针灸病例注册登记研究过程的规范性及研究结果的可信性，保护研究对象的权利和安全，对设计、组织、实施、监督、检查、记录、分析、总结、报告和评价等整个过程提供指导方针。

针灸病例注册登记实施指南

1 范围

本文件提供了针灸病例注册登记研究的全过程关键技术及管理要求。

本文件适用于采用病例注册登记模式开展针灸临床研究的研究者、受试者、质量管理人员、平台开发技术者等人员使用。

2 规范性引用文件

下列文件中的内容通过文中的规范性引用而构成本文件必不可少的条款。其中，注日期的引用文件，仅该日期对应的版本适用于本文件；不注日期的引用文件，其最新版本（包括所有的修改单）适用于本文件。

T/CAAM 0006—2022 真实世界针灸临床研究数据质量评估规范

T/CAAM 0007—2022 针灸临床研究注册指南

T/CAAM 0009—2022 真实世界针灸临床研究数据管理规范

T/CACM 1371.4—2021 中医药真实世界研究技术规范 伦理审查

3 术语和定义

下列术语和定义适用于本文件。

3.1

注册登记 registry

为达到一种或多种预定的科学、临床或政策目的，主要利用观察性研究方法，统一收集数据来评估某一特定疾病、状况或暴露人群特定结局的系统性研究工作。

3.2

针灸病例注册登记 registry study on acupuncutre-moxibustion

以针灸疗法为干预手段，采取真实世界临床研究设计，采用病例注册登记形式开展数据收集和项目管理，以评估针灸疗法或针灸器械在真实临床实践中的安全性、临床疗效、成本效益，描述应用情况，评价服务质量。

4 注册登记项目建立

4.1 研究目的与假说

开展针灸病例注册登记，应明确主要临床问题，根据研究目的形成研究的科学假说。针灸病例注册登记目的包括但不限于：评价针灸疗法或针灸器械的安全性或有效性，描述应用情况，评价服务质量或服务能力。

4.2 研究方法选择

针灸病例注册登记研究的设计应根据提出的临床问题，基于研究目的，依托真实世界的研究环境而

制定。研究方法包括但不限于观察性研究，如传统的队列研究、病例对照研究、巢式病例对照研究、病例-队列研究、横断面研究，也可基于注册库设计随机对照试验和进行复杂的数据挖掘。

4.3 研究方案

针灸病例注册登记方案是实施与注册管理的依据，应清晰、详细、可执行。内容包括但不限于：题目、研究场所、研究目的、研究人群、干预方法、结局指标及其测量方法、研究周期、数据收集方式及数据平台使用方法等。

4.4 质量管理

针对具体项目建立有计划的系统性质量管理体系，保证针灸病例注册登记的实施和数据的采集过程均保持与方案的一致性，质量管理要求按照 T/CAAM 0006—2022 执行。

4.5 数据管理

病例注册登记数据管理符合传统临床试验数据管理原则，数据管理要求按照 T/CAAM 0009—2022 执行。病例注册登记数据可采用既往数据，在数据提取中应注意完整性、规范性、准确性、可溯源性，并对敏感信息采取脱敏处理；对前瞻性数据收集应确定数据收集元素，应注意数据的及时性、完整性、规范性、准确性、可溯源性；多源异构数据处理应建立统一的数据规范和操作标准，对数据进行规范化处理后再进行合并。

4.6 伦理考虑

针灸病例注册登记遵从“以人类为对象”的伦理学原则，应重点关注多中心及跨地域伦理审查和针灸安全性问题，参与者、患者及数据提供方都应进行知情同意。对真实世界回顾性研究（已获取数据）可在考虑合规合理性下申请免除知情同意；对真实世界前瞻性研究（未来数据）可采用泛知情同意、常规知情同意方式。伦理审查按照 T/CACM 1371.4—2021 执行。

4.7 透明化

研究方案在针灸临床研究平台进行注册及公开发表，研究进展及研究过程公开并接受监督和检查，透明化要求按照 T/CAAM 0007—2022 执行。

5 注册登记项目实施

5.1 数据库构建

针灸病例注册登记可新建数据库，也可使用已有的数据平台搭建数据库。如选择已有的数据平台，应保证其符合研究的目的和内容，并能提供数据保护、数据存储、数据移动、数据核查保障。

5.2 登记招募

招募内容包括医疗机构/研究中心、医生/研究者、患者/受试者的招募。招募计划应在注册登记开始前制定，应包括招募条件、招募途径、招募形式、招募流程等内容。其中招募的医疗机构/研究中心和医生/研究者应确保其具备相应资质，研究者和临床参研机构授权以外的单位承担研究相关的职责和功能应当获得批准并有文件记录。

5.3 培训

研究开始前，应有熟悉方案的人员对参与研究的全部人员进行培训。研究者的培训目标是熟练掌

握实施方案；患者的培训目的是充分知情同意且能配合数据采集。培训应贯穿研究全过程，并制定方案执行一致性的检查。

5.4 临床实施

医疗机构中研究者组织具有资质的针灸医生按照研究方案对患者/受试者进行针灸治疗，并及时记录。如果需要患者自行使用针灸器械治疗，可采用日记卡形式由患者进行及时记录。

5.5 数据采集与接收

针灸病例注册登记的数据采集与管理流程、数据管理与采集所使用的系统、数据管理各步骤及任务，以及数据管理的质量保障措施应按照数据管理体系的规定执行。其中数据收集人员应获得研究者授权并经过培训，数据收集人员按照研究方案对针灸治疗的结局指标进行收集。

5.6 中心质量控制

对多中心病例注册登记研究，应对各中心全程进行质量控制，研究者授权专职质量控制人员对研究者和患者对方案的依从性进行评估。

5.7 组织管理

针灸注册登记应建立项目组织管理机制，研究者对参加研究的人员、档案、合同、经费有明确的管理规定。设计跨区域/跨国合作时，伦理要求、管理要求、经费使用、生物样本的使用及处理方式应符合当地法律、法规及政策要求。

6 注册登记研究评估

病例注册登记研究的项目评估应在登记完成后进行，评估内容包括设计、实施、数据分析、偏倚控制等，评价该研究是否达到研究目的，并保持了良好的真实性、准确性和实用性。

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