世 界 针 灸 学 会 联 合 会 标 准

WFAS 009.1—2023

针灸临床研究管理规范

Good clinical practice of acupuncture and moxibustion research

2023-10-09 发布　　2023-12-31 实施

世界针灸学会联合会　　发 布

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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.

This document is endorsed and published by the World Federation of Acupuncture-Moxibustion Societies.

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The development of this document is funded by the National Key Research and Development Program of the Ministry of Science and Technology of the People's Republic of China, under the project Development of International Clinical Guidelines, Technical Operation Specifications and Service Standards for Acupuncture & Moxibustion (No. 2019YFC1712200) and its sub-project International Standards Research on Clinical Research and Service of Acupuncture-Moxibustion (2019YFC1712205); Science and Technology Innovation Project, CACMS, Research on Key Technologies of Real-World Clinical Evaluation and Data Governance Analysis Based on Disease Research (CI2021A00702-02), and Registry Study of TCM Real World Study on Efficacy Evaluation (CI2021A05408).

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

The clinical research evidence of acupuncture-moxibustion is related to the widespread application, development and policy formulation all over the world. For a long period, *Good Clinical Practice* (*GCP*)[1] provided support for evidence quality level of drugs and guideline for researchers. The basic requirements are applicable to acupuncture-moxibustion clinical research, but due to the specificity of acupuncture-moxibustion and the difference of research purpose, it is not entirely appropriate. It is necessary to finalize good clinical practice to require acupuncture-moxibustion clinical research.

The purpose of this document is to regulate the organization and management of clinical research on acupuncture and moxibustion, the protection of the rights and interests of research subjects, research design, requirements of clinical research program, international implementation, etc., to ensure the quality of acupuncture and moxibustion clinical research and the recognition of evidence.

Good clinical practice of acupuncture and moxibustion research

1 Scope

This document specifies the key technical and administrative requirements for the clinical study of acupuncture-moxibustion.

This document is suitable for researchers and medical workers to carry out clinical research on acupuncture-moxibustion, and can also provide reference for assessment and management agencies.

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 0007—2022, *Guideline for registry of acupuncture and moxibustion clinical research*

3 Terms and definitions

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

3.1
clinical study of acupuncture-moxibustion

Research conducted on human subjects that purpose to discover or confirm the clinical efficacy of an acupuncture-moxibustion therapy; and/or to determineadverse reactions, safety and/or effectiveness of an acupuncture-moxibustion therapy.

3.2
manipulator of acupuncture-moxibustion

The person who implements acupuncture-moxibustion measures in acupuncture-moxibustion clinical research.

3.3
efficacy

The maximum expected effect of the intervention under ideal conditions.

NOTE Effecacy emphasizes the role of intervention under ideal conditions purpose. Effectiveness reflects the net effect of the intervention.

3.4
effectiveness

The magnitude of the intervention's effect under actual conditions.

NOTE Effectiveness is the combined result of efficacy and conditions and levels of medical services.

3.5
real world study;RWS

Scientific research activities conducted under routine medical conditions using information generated in the course of daily medical practice.

3.6
multi-regional clinical trials;MRCT

Clinical trials conducted by multiregion researchers in multiple clinical trial centers in different countries or regions with the same protocol.

4 Organization and management

4.1 Sponsor

Acupuncture-moxibustion clinical research may be initiated by government agencies, universities, scientific research institutes, medical institutions, and social organizations. The sponsor should determine the research project in the form of a scientific research project proposal and propose the purpose of acupuncture-moxibustion clinical research. The sponsor also undertakes the responsibilities of organizing and appointed principle researcher, approving research budgets, providing research funding, monitoring research progress, evaluating research results, etc..

4.2 Research process

Acupuncture-moxibustion clinical research generally includes:

a) project determination;

b) research team formation;

c) research design, research plan formulation;

d) ethical review;

e) clinical trial registry;

f) research implementation and quality control;

g) data management or data governance;

h) statistical analysis;

i) research report writing and publishing;

j) data concurrent and sharing;

k) research summary and document management.

4.3 Multi-center management

For multi-center acupuncture-moxibustion clinical research, a clinical research unit with relevant qualifications could be selected as a sub-center according to the research purpose and research content. As a sub-center, the research unit should provide corresponding research conditions, organize research training, take necessary measures to ensure research quality, and complete research tasks as promised. Specialized personnel are responsible for coordinating all centers, conducting technical management, quality supervision, coordinating tasks and organizing training. MRCT should meet the local scientific research requirements, and corresponding measures should be taken according to the impact of different languages and cultures on the research quality.

4.4 Contract management

Clinical collaboration activities should be in the form of contracts/agreements with legal effects, through the confirmation of the relevant institutions and the person in charge of research to clarify the research tasks, rights and obligations, and funding allocation of each party. The contract/agreement should be archived.

4.5 Fund management

Research funding should be dedicated, and the content of funding management included in the clinical cooperation agreement should comply with relevant national policies and regulations, and the financial management requirements for the budget and implementation of the project funds. The financial staff should routinely manage and record the use of funding. It should finish the required financial audit at the end of the study.

4.6 Archives management

All data (such as video, images, sound recordings, texts, electronic documents, etc.) generated in clinical acupuncture-moxibustion research should be numbered and stored in separated file cabinets. It shall be kept and managed by specially assigned person; it shall actively accept the inspection of quality control department. The original data files of acupuncture-moxibustion clinical research shall be allowed to be inspected directly by the relevant supervisors, inspectors, members of the ethics committee and management departments. At the end of the study, all data should be kept for at least 5 years.

4.7 Intellectual property management

The intellectual property rights related to patents, papers, scientific and technological achievements that may form in the clinical study of acupuncture-moxibustion should be clearly stipulated before the start of the study, including the holders, authors, coauthors, correspondence authors and authors ranking principles, and related documents should be signed.

5 Protection of rights and interests of research objects

5.1 Ethics principle

Acupuncture-moxibustion clinical research should conform to the basic principles of clinical research ethics and medical ethics in the declaration of Helsinki issued by the world medical congress[2], and strive to maximize the benefits and avoid harm to the research objects on the premise of justice and respect for personality.

5.2 Independent ethics committee (IEC)

The acupuncture-moxibustion clinical research plan shall be reviewed and approved by the ethics committee. The ethics committee shall be composed of more than 5 members, including members of medicine, non medicine, law and other units, and shall have members of different genders. The review of acupuncture-moxibustion clinical research protocols should be attended by acupuncture-moxibustion professionals or independent acupuncture-moxibustion consultants.

5.3 Research implementation and revision

Acupuncture-moxibustion clinical research should be implemented only after obtaining the approval of the ethics committee. In the implementation process, the revised research plan should be submitted in time in accordance with the requirements of the ethics committee, and serious adverse events should be reported to the ethics committee and project leader department.

5.4 Informed consent

Provide written informed consent signed by the research subject, which should meet the general requirements of the informed consent, and explain the alternative treatments and procedures or processes that may be available; research subjects can refuse to participate in the study or withdraw from the study at any time without being penalized or losing treatment they would have received.

5.5 Ethics of real world study

Real world study using clinical medical record information and related database materials should also be reviewed and approved by the ethics committee. The content and form of the patient's informed consent should conforming the medical ethics requirements. Special attention should be paid to the protection of patient privacy and intellectual property rights of medical information.

5.6 Ethics of international multicenter clinical trials

For international multicenter clinical trials, a joint ethical review mechanism should be established, which requires the approval of the ethics committee of the center as well as the ethics committee of the location, and the respective review responsibilities should be clearly defined. The local ethics committee should fully consider all influencing factors to ensure that the subjects meet the ethical requirements and avoid double standards between different countries or regions.

6 Research design

6.1 Content of research design

The design of acupuncture-moxibustion clinical research mainly includes medical design, statistical design, ethical design and management design. According to the characteristics of acupuncture-moxibustion clinical research, there should be special analysis and control measures for the compliance of researchers and research subjects and various biases that may arise.

6.2 Purpose

The medical design of acupuncture-moxibustion clinical research should clarify the research purpose and clinical practical questions to be solved. Pilot study should be conducted and the research team should accumulate the research experience. Based on the present evidence and purpose to set up scientific, feasible clinical research hypothesis.

6.3 Methodology

The clinical research of acupuncture-moxibustion should adopt a step-by-step research method. According to the maturity of the acupuncture-moxibustion intervention program, acupuncture-moxibustion clinical research is divided into the clinical discovery phase, the optimization and improvement phase, the verification phase, the clinical promotion application and re-evaluation stage of the intervention program.

The design of clinical research at each stage should establish appropriate research objectives and research hypotheses according to the specific conditions of clinical research elements such as intervention measures, intervention effects, intervention targets, other existing standardized intervention methods, and environmental factors in clinical research. A reasonable and appropriate design should be carefully selected based on factors such as acupoints or stimulation sites, stimulation methods, and human conditions that affect the effects of acupuncture-moxibustion. The description of acupuncture-moxibustion intervention should clearly describe the method of acupoints locating, the operation technique and the standard of instruments. International, national or industry standards should be adopted preferentially. The intervention measures of the control group should also provide specific methods, selection basis, and sources. For the control method to be used as “sham acupuncture-moxibustion” or “placebo acupuncture-moxibustion”, a small sample of clinical pre-experiments can be used to confirm its preset control effect. Internationally or nationally recognized efficacy evaluation indicators should be adapted.

6.4 Statistical analysis

Statistical design should first select evaluation indicators that can accurately reflect the clinical effect, are of great importance, can be quantified and measured, and are recognized in the professional field. A detailed plan for the implementation of the assessor’s blind method should be formulated. Appropriate data acquisition and management methods should be selected according to acupuncture-moxibustion clinical research. The statistical analysis plan should be made, and the design of subgroup analysis should be planed in advance. Factors such as the implementation of acupuncture operation, the dynamics of acupuncture points or stimulation sites, sensitization characteristics, the correlation between acupuncture effects and human body status should be fully considered on the design type, sample size and evaluation indicators.

The method of sample size estimation should be clarified, and the determination of pretest sample size can be considered in four aspects: feasibility, precision, sum of trials, sum sample size and standard effect size of interventions. For the estimation of sample size of international multicenter clinical trials, factors such as the regulatory system of each region, compliance with statistical requirements, epidemiological characteristics of the disease and representativeness of sample selection should be considered. Appropriate data acquisition and management methods should be selected according to the clinical research stage of acupuncture-moxibustion. For real world study, data collection conditions or platforms and data collection standards should be clearly defined, and full consideration should be given to reducing and controlling bias.

6.5 Ethics

The ethical design should be based on the requirements that the rights and interests of the research object can be fully guaranteed, and the clinical research can be carried out effectively, and the benefits and potential risks of the research object should be analyzed in depth. Measures should be taken to deal with the possible accidents such as acupuncture-moxibustion in dangerous areas and prepare corresponding treatment plans. According to the characteristics of the population in clinical research of acupuncture-moxibustion at different stages, the corresponding informed consent should be drafted. The informed consent form should be localized to the characteristics of the population in different regions to protect the rights of the subjects.

6.6 Management

In the design of clinical research management, should formulate reliable and effective management measures for the specific reasons that affect compliance, and minimize case shedding; make detailed plans for the management, training and actual mastery level of researchers, operators and index evaluators, and assure the consistency evaluation of training effect; develop standardized operating procedures for clinical implementation of acupuncture-moxibustion, and have clinical quality monitoring measures to ensure the expected effects of group-level clinical intervention.

Acupuncture-moxibustion is a complex intervention process of doctor-patient interaction. In the management design, the influence of the interaction between the researcher and the research object on the clinical research results of acupuncture-moxibustion should be carefully analyzed, and corresponding management measures should be formulated to ensure the comparable baseline of the research and the reliability of the research results.

7 Clinical research program

7.1 Protocol

The acupuncture-moxibustion clinical research protocol is the basis for acupuncture-moxibustion clinical research training, implementation and quality control, supervision and inspection, as well as acupuncture-moxibustion clinical research information disclosure. It should be drafted by the research director on the basis of the research objectives and research contents jointly agreed by the research director and the research sponsor, and implemented after being approved by the ethics committee.

During the research, if needed research protocol could be changed. Major changes must be approved by the ETHICS committee before implementation, and the revised proposal should be put on record with the research sponsor.

7.2 Protocol registration

The acupuncture-moxibustion clinical research protocol should be registered in public trial registration platform, and publish the purpose, design and main content. It was suggested to published registered trial protocol in publications for the clinical research transparency. Protocol registration requirement should accord with T/CAAM 0007—2022.

7.3 Content of protocol

The basic contents of the clinical research protocol for acupuncture-moxibustion are as follows, which can be appropriately adjusted according to the research scale, research purpose, and requirements of the project-initiating department:

- research topics;
- names and qualifications of research sponsors, research leaders, research undertaking units, statistical units and their heads, data management units and their heads, monitoring units and their heads, researchers, research sites;
- research abstracts;
- research background;
- research purpose;
- research design types;
- sample size and calculation basis;
- research objects;
- intervention measures/exposure factors and control measures/combined treatment;
- evaluation indicators (main evaluation indicators and secondary evaluation indicators) and evaluation methods;
- methods for monitoring, registering and processing adverse events;
- research flow chart;
- observation period, follow-up time, and measures to ensure compliance of the study subject;
- criteria for completing or suspending research;

- quality assurance and quality control;
- data management plan;
- statistical analysis plan;
- measures to protect the rights and interests of the research object;
- references.

7.4 Research handbook

Acupuncture-moxibustion clinical research should formulate a researcher's work handbook and research object handbook. The researcher's handbook is a compilation of research and training programs, as well as relevant clinical and nonclinical data in clinical research. The research object handbook is to introduce and explain to the research object about the basic situation of participating in clinical research, the content of participation, and the obligations and rights of the research object.

7.5 Handbook for researchers

The researcher's handbook shall contain at least the following:

- version number and application period;
- research background;
- purpose and contents;
- research task division and contact information;
- filling instructions and standard operating procedures (SOPs) for various types of record files, such as: ① study case report form (Case Report Form, CRF) SOP (including indicators and terminology explanation, etc.), ② instructions SOP for filling in the subject's diary card and scale;
- operation specifications (SOPs), such as: ① SOP for operation(including video, image, document and other information of acupuncture-moxibustion operation and instrument operation), ② SOP for quality control, ③ SOP for specimen management (including specimen detection, transportation, etc.);
- training and assessment arrangements for insvestigators and list of multimedia training materials;
- attachment, such as: ① training materials (multimedia), ② references.

7.6 Handbook for research subjects

The handbook for research subjects contains at least the following:

- research background;
- introduction of research contents, benefit and risk of research subjects;
- the rights and obligations of the research object;
- attachment: ① informed consent, ② research diary, ③ popular science knowledge related to the research.

8 Qualifications and duties of related personnel

8.1 Composition of research group

Acupuncture-moxibustion clinical research related personnel generally include principle linvestigator, research secretary, research assistant, clinical researcher, manipulator of acupuncture-moxibustion, outcome assessor, statistical analysis personnel, quality management personnel, data management personnel, and financial staff and research management personnel.

8.2 Basic requirement of researchers

Researchers in acupuncture and moxibustion clinical research should have basic scientific research literacy, rigorous attitude, high sense of responsibility, and the spirit of seeking and get systematic training of rresearch methods. Corresponding qualifications should be obtained.

8.3 Professional qualification and permission

All types of personnel participating in the research should have corresponding professional and technical titles and qualifications, obtain the consent of the unit they work in, sign a due diligence letter of scientific research integrity, and ensure that there is sufficient time to complete the research task within the time limit specified in the program, receive special training in the research program and pass the assessment, and ensure that they are carried out in accordance with the program.

8.4 Principle investigator

Principle linvestigatorresearcher (PI) is the primary person responsible for acupuncture-moxibustion clinical research, who is responsible for the research purpose, the determination of the research content, and the formulation of the research design and research plan. PI is responsible for the budget and execution of research funding and related rewards. Institutions and researchers undertaking clinical research shall be responsible for the examination and approval of their qualifications and conditions. After obtaining the approval of the research sponsor and ethics committee, PI is responsible for the implementation of the research plan and quality assurance and responsible for drafting and publishing the research report. PI may select qualified personnel to serve as the research secretary. Research secretary conducts relevant text and liaison work in accordance with the requirements of PI. PI may hire research assistants as required. The research assistant is entrusted by PI to manage the related work. A multicenter, larger clinical study of acupuncture-moxibustion may establish a project office led by PI to assist in project management.

8.5 Clinical researchers

Clinical researchers shall be responsible for the on-site implementation of acupuncture-moxibustion clinical research. They shall carry out the study in strict accordance with the study plan, ensure the quality of the study, and deal with all kinds of adverse events and complications in a timely manner. For serious adverse events and serious complications, should be reported to the department. The researchers shall be responsible for the true, accurate, complete, timely, and lawful entry of study data into medical records and case reports.

8.6 Manipulator of acupuncture-moxibustion

Manipulator of acupuncture-moxibustion is clinical operators selected according to research requirement. They shall be trained and qualified, registered and filed by the research office, to assure they could be familiar with procedures of acupuncture-moxibustion operation, and they should accept the consistency inspection of operation effect organized by PI. Manipulators of acupuncture-moxibustion should be permanent, and any new manipulator should be retrained and filed.

8.7 Outcome assessor

The outcome assessor shall be a person who does not participate in the acupuncture-moxibustion operation and grouping who should also has relevant professional qualifications. Outcome assessor should adhere to the principles of fairness, standardization, science and rigor, and should not take the initiative to understand the grouping of clinical studies to ensure the authenticity and accuracy.

8.8 Data management personnel

Data management personnels include data administrators, programmers, medical coders, and entry personnel, etc.They are selected and recruited by research sponsors who can be third-party professional group. The data management personnel shall be responsible for data management and guarantee the quality of data in accordance with the corresponding operating procedures and operating specifications.

8.9 Statistical analysis personnel

Statistical analysis personnel shall be professional biostatisticians, clinical epidemiologists, or personnel trained in systematic statistical methods, and shall be selected by PI. Statistical analysis personnel plays an important role in the design of clinical research, the formulation of clinical research statistical plans, statistical analysis of data, and the selection of data charts in clinical research reports.

8.10 Financial staff

The financial personnel of clinical research shall be the financial and accounting personnel of the clinical research undertaking unit, whose responsibility is to assist the PI to ensure the fund budget of clinical research, assist the fund implementation in accordance with the requirements of the research assignment and the regulations and systems of the research fund management of the state or relevant departments, and assist in the fund report and audit work when the project is concluded.

8.11 Research management personnel

The research management personnel shall be staffed by the relevant scientific research management departments of the clinical research undertaking unit. Their duties are to assist the research leaders in organizing and coordinating, directing and supervising the implementation of clinical research in accordance with relevant regulations, and supervising the reasonable compliance of research funding use and release and exchange of research results, and assist and supervise the communication and coordination between the clinical research team and the relevant departments of the undertaking unit.

8.12 Monitor

Units undertaking clinical research should have independent monitors. They should have a high sense of responsibility, and strictly follow the audit plan and operating procedures to conduct an audit of all the included research subjects, and focus on the authenticity, standardization and compliance of the implementation of the acupuncture-moxibustion clinical research; written report should be submitted to PI and actively accepts inspections.

8.13 Auditor

Auditor can be appointed or designated by the research sponsoring organization, and is responsible for conducting a systematic inspection of the qualifications, training, and implementation of clinical research personnel to evaluate whether the research conforms to the design plan, standard operating procedures, and relevant regulations. Carry out research on whether the data is recorded in a timely, authentic, accurate and complete manner, and be responsible for evaluating the work of the inspectors.

8.14 Inspector

The research sponsoring organization may organize inspectors to conduct comprehensive or focused inspection, evaluation, and guidance of the entire clinical research work. A written document shall be formed after each inspection and submitted to the research sponsoring department and PI.

9 Quality management

9.1 Purpose of quality control

The purpose of quality management of acupuncture and moxibustion clinical research is to improve the quality of acupuncture and moxibustion clinical research by formulating and implementing quality control plans and reporting plans for the implementation, data generation, recording and management of the research operation covering the process, and to verify the relevant operational techniques and activities in the research process according to quality requirements.

9.2 Training

Training is a key link in the clinical quality assurance of acupuncture-moxibustion clinical research. For clinical intervention operation, on-site training should be organized for all researchers and manipulators of acupuncture-moxibustion. Detailed operation training materials should be developed to ensure operation consistency, including video, images and other forms.

9.3 Content of quality control

Clinical research of acupuncture and moxibustion can set up a four-level quality control system of internal quality control, monitoring, auditing and inspection, and the level should be selected according to the research scale. The main contents of quality management include the examination of ethical data in the research process, the audit of the implementation of the inclusion criteria, the selection and development of the integrity, consistency, timeliness and accuracy evaluation tools of operations and records. It also includes reviewing the qualifications of acupuncture operators and index evaluators, assessing the operators' compliance with the program, checking the authenticity of the study objects, clarifying the preservation form of research files, and ensuring the traceability of research data. For real-world acupuncture clinical research, corresponding data collection forms, processes and quality control measures should be established according to different data sources, key fields of data extraction should be defined, data extraction templates should be established, data link rules should be established, and data cleaning rules should be formed to ensure the integrity, accuracy and timeliness of clinical data.

10 Data management and statistical analysis

10.1 Data management method

Acupuncture-moxibustion clinical research should choose the appropriate data management method according to the research purpose and design scheme to ensure the reliability, integrity and accuracy of data.

10.2 Data authenticity

Data management shall be carried out throughout the clinical research. In order to ensure the authenticity of the data cleaning process and the traceability of the data, all documents in the data cleaning process shall be archived.

10.3 Objectivity of data management

In order to ensure better implementation of blinding in acupuncture clinical research, especially large multi-center studies, it is recommended to adopt reasonable randomization scheme and third-party data management to make clinical research results objective and fair.

10.4 Usage of computer system

When the computer system is used in acupuncture and moxibustion clinical research, the safety, stability and reliability of the system itself and the operating environment should be ensured. System operating personnel should be trained and qualified accordingly. The computer system should have at least basic functions such as permission management, trace checking, and data backup. In order to study the data exchange and in-depth utilization, the database design should follow the relevant international, domestic and industrial data and terminology standards.

10.5 Statistical analysis plan

The statistical analysis plan, including specific analysis indicators and statistical analysis methods, should be developed in advance in the research program design stage in a formal document style. Appropriate and standardized statistical analysis methods should be selected according to the research purpose and data characteristics. If the plan changes, reasons should be given.

For real world study, should control bias and apply proper data mining methods based on the characteristics of real world data.

For international multi-center clinical studies, the overall research data should be summarized and analyzed, and also focus on the effectiveness and safety among different regional populations.

11 Clinical research report

11.1 Authenticity of research report

After the clinical research of all acupuncture-moxibustion is completed, a clinical research report should be written, regardless of whether the research results are positive or negative, and whether the clinical research is completed as planned or whether the research purpose is achieved. It should clearly report the authenticity of the results and the reliability of the conclusions.

11.2 Submission

All acupuncture-moxibustion clinical research reports shall be provided to the research sponsor, relevant management departments, clinical institutions participating in the research, ethics committee, etc.. Acupuncture-moxibustion clinical research report is an important basis for project conclusione, results identification, promotion and application, and research paper publication.

11.3 Publicity

All registered acupuncture-moxibustion clinical research is encouraged, and the summary of the research results and conclusions will be published in the registration department at an appropriate time; after the acupuncture-moxibustion clinical research funded by the government department is finished, the original database should be compiled and submitted to the designated department according to relevant regulations for verification, data sharing and reuse. After the completion of research, the original database should be submitted to designated department in accordance with relevant regulations for verification, data sharing and reuse.

11.4 Publication

Publication of research results and conclusions is encouraged. When research paperis published, it should strictly abide by relevant laws, regulations and academic ethics regulations. When publishing acupuncture-moxibustion clinical research papers, the registration number delegated by registration platform should be indicated.

11.5 Research report

Research report should be consistent with the study protocol published at the time of study registration and protocol publication, including the following contents:

- title: reflect the type of study design, the study object and the main intervention measures;
- introduction: research background, research necessity, research purpose and clinical problems to be solved;

- basic research information：PI，research code，project funding source，research duration，research units，research group members，and registration information；

- ethics approval：information on ethics approval institutions，ethics approval time，and ethics approval number；

- study design：study type，study object（inclusion criteria，exclusion criteria，suspension criteria），control group setting method，sample content estimation basis，intervention measures，evaluation indicators，data management，quality control，statistical processing，etc.；

- research results：baseline data，demographic data，main indicators，secondary indicators，safety analysis；

- research conclusions：according to the research results，while comprehensively analyzing similar studies，the research conclusions should be presented cautiously and objectively，and the research objectives and clinical guiding significance should be answered. At the same time，the existing deficiencies in the research and further research plans should be expounded appropriately.

Adjust the corresponding report content according to the type of clinical research.

11.6 Report style and requirement

When writing an acupuncture-moxibustion clinical research report，the following specifications should be consulted according to different research types.

- Standards for Reporting Interventions in Clinical Trials of Acupuncture：STRICTA；Extending the CONSORT Statement to Moxibustion：STRICTA（2010）.

- Consolidated Standard of Reporting Trials：CONSORT statement.

- Quality of Reporting of Meta-analyses：QUOROM statement.

- Preferred Reporting Items for Systematic Reviews and Meta-Analyses：PRISMA statement.

- Transparent reporting of evaluations with nonrandomized designs：TREND statement.

- Strengthening the Reporting of Observational Studies in Epidemiology：STROBE statement.

- Meta-analysis of observational studies in epidemiology：MOOSE statement.

- Standards for the Reporting of Diagnostic accuracy studies：STARD statement.

- Strengthening the Reporting of Genetic Associations：STREGA statement.

- Reporting specifications for observational studies based on real-world data：the RECORD statement，STaRT-RWE .

- Reporting specifications for case series studies：the Reference STROBE statement.

- Reporting norms for case reports：CARE.

When assessing the quality of evidence for clinical research in acupuncture-moxibustion，the following evaluation tools should be referred to according to the different types of studies.

- Quality evaluation criteria for randomized controlled clinical trials：Cochrane RoB，modified Jadad scale，CASP，CONSORT.

- Quality evaluation criteria for systematic evaluation and meta-analysis：AMSTAR 2，GRADE.

- Quality evaluation criteria for studies with non-randomized designs：MINORS entries，Reisch evaluation tool.

- Quality evaluation criteria for observational epidemiological studies：NOS scale，CASP inventory，JBI criteria，AHRQ，Combie.

- Quality evaluation criteria for diagnostic accuracy studies：QUADAS tool，CASP inventory.

- Quality evaluation criteria for observational studies based on real-world data：reference ArRoWs，MINORS，ROBINS-1.

- Quality assessment criteria for case series studies：NICE，JBI，IHE.

- Quality assessment criteria for case reports：JBI.

Bibliography

［1］ *Quality Management Standards for Drug Clinical Trials*（*GCP*）［J］.Chinese Journal of Medicinal Guide，1999（1）：5-9.

［2］ 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.

［3］ Zhang Ying，Wang Junhui，Hu Yeyin，et al. *Determination of sample size for pre-test in clinical research of traditional Chinese medicine*［J］. Journal of Traditional Chinese Medicine，2021，62（4）：307-311.

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。

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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

针灸的临床研究证据关乎针灸在国际上的广泛应用、发展与政策的制定。长期以来,《临床试验管理规范》(Good Clinical Practice,GCP)[1]在保障药物临床研究证据质量和水平中发挥着重要作用,为研究者提供了行为准则,其中的基本要求对于针灸临床研究也是适用的。但由于针灸干预的特殊性以及针灸临床研究目的的差异性,以上 GCP 不能针对性满足针灸临床研究的需求,有必要制定符合针灸临床研究特点的临床研究管理规范。

本文件的宗旨在于规范针灸临床研究中组织管理、研究对象的权益保障、研究设计、临床研究方案、国际化实施等的要求,保障针灸临床研究的质量和证据的公认度。

针灸临床研究管理规范

1 范围

本文件规定了针灸临床研究过程中的关键技术和管理要求。

本文件适用于研究者、医疗工作者等开展针灸临床研究使用，也可为审批机构、管理机构提供管理要求参考。

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 0007—2022 针灸临床研究注册指南

3 术语和定义

下列术语和定义适用于本文件。

3.1

针灸临床研究 clinical study of acupuncture-moxibustion

以人为对象进行的任何意在发现或证实一种针灸疗法的临床疗效，和/或确定一种针灸疗法的任何不良反应、安全性和/或有效性的研究。

3.2

针灸操作者 manipulator of acupuncture-moxibustion

在针灸临床研究中针灸干预措施的实施人员。

3.3

效力 efficacy

干预措施在理想条件下能达到的最大期望作用。

注：效力强调理想条件下干预的自身作用，体现的是干预措施的净效应。

3.4

效果 effectiveness

干预措施在实际真实条件下能达到的作用大小。

注：效果是效力和医疗卫生服务条件、水平的综合结果。

3.5

真实世界研究 real world study；RWS

在常规医疗条件下，利用日常医疗实践过程中产生的信息，所开展的科研活动。

3.6

多区域临床试验 multi-regional clinical trials；MRCT

由多区域研究者在多个国家或地区的多个临床试验中心共同进行的临床试验，并且使用同一个方案。

4 组织管理

4.1 发起者

针灸临床研究可由政府机构、高等院校、科研院所、医疗机构和社会团体等组织机构发起。研究发起者应以科研立项书的形式，确定研究立项，提出针灸临床研究目的。研究发起机构还承担着组织选聘研究负责人、批准研究预算、提供研究经费、监督研究进展、评估和验收研究结果等职责。

4.2 研究过程

针灸临床研究过程一般包括：

a） 项目确定；
b） 研究队伍组建；
c） 研究设计、研究方案制定；
d） 伦理审查；
e） 临床研究注册；
f） 研究实施及质量控制；
g） 数据管理或数据治理；
h） 统计分析或数据挖掘；
i） 研究报告撰写与发表；
j） 数据汇交与共享；
k） 研究总结及资料管理。

4.3 多中心管理

多中心针灸临床研究，应根据研究目的与研究内容，选择具备相关资质的临床研究单位作为分中心。作为分中心的研究单位应提供相应的研究条件，采取必要措施保障研究质量，提供服务并按承诺完成研究任务。研究过程应由专人负责协调各中心，进行技术管理、质量监督、协调任务、组织培训。多地域临床试验应符合研究实施所在地的科学研究要求，并针对不同语言、文化对研究质量的影响制定相应的措施。

4.4 合同管理

临床研究协作活动应以具有法律效应的合同/协议书等文书形式，通过相关机构与研究负责人的签章确认来明确各方的研究任务、权利义务以及经费分配等。合同/协议书应进行存档。

4.5 经费管理

研究经费应实行专款专用，列入临床合作协议中的经费管理内容应符合研究实施所在地的相关政策法规和项目经费预算、执行的财务管理要求，并由财务人员对经费的使用进行日常管理与记录，课题结题前应通过规定的财务审计。

4.6 档案管理

针灸临床研究中所产生的所有资料（如影像、图像、录音、文本、电子文档等），均应进行整理编号并在独立文件柜存放，由专人保管和管理，并主动接受质量控制部门的检查。针灸临床研究的原始数据档案，应允许相关的监查员、稽查员、伦理委员会成员和管理部门视察直接查看。在研究结束后，所有资料应保存至少5年。

4.7 知识产权管理

对针灸临床研究中可能形成的相关专利、论文、科技成果等知识产权，均应在研究开始前对持有人、论文作者、共同作者、通讯作者、作者排名原则等各方权利与义务作出明确规定，并形成签字的文件。

5 研究对象的权益保障

5.1 伦理原则

针灸临床研究应符合世界医学大会《赫尔辛基宣言》[2]临床研究伦理以及医学伦理的基本原则，在公正与尊重人格的前提下，力求使研究对象最大程度受益和尽可能避免伤害。

5.2 独立的伦理委员会

针灸临床研究方案应通过伦理委员会审查和批准。伦理委员会应由 5 名以上委员组成，包括医学专业、药学专业、法律专业以及外单位人员，并且应包含不同性别的委员。对于针灸临床研究方案的审查，应有针灸相关的专业人士或独立的针灸顾问参加。

5.3 研究实施与修订

针灸临床研究应在获得伦理委员会审批同意后实施。实施过程中如有方案修改，应依照伦理委员会的要求，及时提交修改的研究方案。发生严重不良事件时，应及时报告伦理委员会及项目主管部门。

5.4 知情同意

提供给研究对象签署的书面知情同意书，其内容在符合知情同意书一般要求的同时，应对可能得到的替代治疗及其程序或过程加以说明；研究对象可拒绝参加研究，或在任何时候退出研究，并且不会因此受到处罚或损失本来应当得到的治疗。

5.5 真实世界研究伦理

对于利用临床病历信息与相关数据库资料进行的真实世界研究，也应经伦理委员会审核批准，其中患者知情同意的内容和形式应符合医学伦理的要求。应特别关注对患者隐私、医疗信息知识产权的保护。

5.6 国际多中心临床试验伦理

对于国际多中心临床试验，应建立联合伦理审查机制，需经牵头单位伦理委员以及研究中心所在地伦理委员的审核批准。所在地的伦理委员应充分考虑各方面的影响因素，保证受试者符合伦理要求，避免出现不同国家或地区间的双重标准。

6 研究设计

6.1 内容

针灸临床研究设计主要包括医学设计、统计设计、伦理设计和管理设计等。根据针灸临床研究的特点，对于研究人员及研究对象的依从性和可能产生的各种偏倚等，应有专门的分析与控制措施。

6.2 目的

针灸临床研究的医学设计应明确研究目的与要解决的临床实际问题。应开展预试验，积累研究基

础，充分归纳已有证据，根据研究目的建立科学、可行的临床研究假说。

6.3 方法

针灸临床研究应采取阶梯递进的研究方法，依据针灸干预方案的成熟度，将针灸临床研究分为干预方案的临床发现阶段、优化完善阶段、验证阶段、临床推广应用与再评价阶段。

每一阶段的临床研究设计，均应根据本阶段干预措施、干预效果、干预对象、已有的其他标准化干预方法以及临床研究的环境因素等临床研究要素的具体情况，结合研究目的选择合适的临床研究设计，包括干预措施设计、对照设计、评价指标的选择。应根据影响针灸效应的穴位或刺激部位、刺激方法以及人体状态等因素，审慎选择合理、恰当的干预措施。对针灸干预措施的描述，应明确表述腧穴定位方法、操作技术及器具规范。宜尽量采用国际、国家或行业的相关标准。对照组的干预措施也应提供具体方法、选择依据以及出处等。对于拟作为“假针灸”“安慰针灸”的对照方法，可经过小样本的临床预试验，来确认其预设的对照作用。应采用国际或国内公认的疗效评价指标。

6.4 统计设计

统计设计应首选可以确切反映临床效果、重要性强、可量化测量、专业领域公认的评价指标。应对评估者盲法的实施制定详细计划；应根据针灸临床研究阶段，选择合适的数据获取及管理方法；应做好统计分析计划，预先做好亚组分析的设计；应充分考虑针灸操作的实施情况、穴位或刺激部位动态、敏化特性、针灸效应与人体状态相关性等因素，对设计类型、样本含量以及评估指标的影响。

应明确样本量估算的方法，预试验样本量的确定可从可行性、精确度、试验总和样本量和干预的标准效应量 4 个方面考虑[3]。对于国际多中心临床试验样本量估算，宜考虑各区域法规体系、符合统计学要求、疾病的流行病学特征以及样本选取的代表性等因素；应根据研究类型和问题选择合适的统计分析方法。针对真实世界研究，应明确数据采集条件或平台、数据采集标准，宜充分考虑减小和控制偏倚。

6.5 伦理设计

伦理设计应根据研究对象权益可以得到充分保障，同时临床研究可以有效开展的要求，深入分析研究对象的受益与潜在风险；应对晕针、针孔出血、皮肤起泡等制定相应处理措施，尤其应对危险部位针刺等可能出现的意外制定相应的处理预案。应针对不同阶段针灸临床研究的人群特点，起草相应的知情同意书。

应针对不同区域的人群特点，对知情同意书进行本土化，以保障受试者的权益。

6.6 管理设计

在临床研究管理设计中，应针对影响依从性的具体原因，制定可靠有效的管理措施，尽量减少病例脱落；对于研究者、操作者与指标评估者的管理、培训以及实际掌握水平制定详细的计划，应做好培训效果的一致性测评；应对针灸临床实施制定规范的操作规程，并有临床的质量监测措施，保障群体层次临床干预的预期效果。

针灸是一种医患互动的复杂干预过程，在管理设计中，应认真分析研究者与研究对象互动对针灸临床研究结果的影响，制定相应的管理措施，保障研究基线的可比性以及研究结果的可靠性。

7 临床研究方案

7.1 方案

针灸临床研究方案，是针灸临床研究培训、实施与质量控制、监督检查以及针灸临床研究信息公开的依据，应在研究负责人与研究发起机构共同商定研究目标与研究内容的基础上，由研究负责人组织起

草,经伦理委员会审批后实施。

临床研究中,若确有需要,可按规定程序对研究方案做修改。重大修改需经伦理委员会批准后方可实施,修改后的方案应在研究发起机构处备案。

7.2 透明化

针灸临床研究方案应在公开的临床研究注册平台进行登记注册,公布研究目的、研究设计和主要内容。建议已经注册登记的针灸临床研究方案在相关杂志公开发表,增加临床研究的透明化。针灸临床研究方案注册应符合 T/CAAM 0007—2022 的相关规定。

7.3 方案内容

针灸临床研究方案的基本内容如下,可根据研究规模、研究目的以及立项部门的要求等适当调整:

- 研究题目;
- 研究发起机构、研究负责人、研究承担单位、统计单位及其负责人、数据管理单位及其负责人、监查单位及其负责人、研究者的姓名及资质、研究场所;
- 研究摘要;
- 研究背景;
- 研究目的;
- 研究设计类型;
- 样本量及其计算依据;
- 研究对象;
- 干预措施/暴露因素与对照措施/合并治疗;
- 评价指标(主要评价指标和次要评价指标)和评价方法;
- 不良事件监测、登记与处理方法;
- 研究流程图;
- 观察周期、随访时间和保证研究对象依从性的措施;
- 完成、中止研究的标准;
- 质量保证与质量控制;
- 数据管理计划;
- 统计分析计划;
- 研究对象权益保障措施;
- 参考文献。

7.4 研究手册

针灸临床研究应制定研究者工作手册与研究对象手册。研究者工作手册是对研究方案、培训方案以及临床研究中有关的临床资料和非临床资料的汇编。研究对象手册是向研究对象介绍和说明所参与临床研究的基本情况、参与内容以及研究对象的义务与权益等。

7.5 研究者工作手册

研究者工作手册应至少包含以下内容:

- 版本编号、使用期限;
- 研究背景;
- 目标与内容;
- 研究任务分工及联系方式;

- 各类记录文件填写说明及操作规范(Standard Operation Procedure,SOP),如:①研究病历及病例报告表(Case Report Form,CRF)填写的 SOP(含指标及术语解释等),②研究对象日记卡以及量表等填写的说明与 SOP;
- 各类操作规范(SOP),如:①操作方法的 SOP(含针灸操作、仪器操作等视频、图像、文档等形式的资料),②质量控制的 SOP,③标本管理的 SOP(含标本检测、运输等);
- 各类研究人员的培训、考核安排以及多媒体培训教材清单;
- 附件,如:①培训教材(多媒体),②参考文献。

7.6 研究对象手册

研究对象手册应至少包含以下内容:

- 研究背景;
- 研究内容介绍、受试对象受益与风险;
- 研究对象的权利与义务;
- 附件,如:①知情同意书,②研究对象日记卡,③与研究相关的科普知识。

8 相关人员的资格与职责

8.1 人员组成

针灸临床研究及其相关人员一般包括研究负责人、研究秘书、研究助理、临床研究者、针灸操作者、指标评估者、数据管理人员、统计分析人员、财务人员、研究管理人员以及质量管理人员等。

8.2 基本要求

参与针灸临床研究的人员均应具备基本的科研素养、认真严谨的态度、高度的责任心、实事求是的精神,并经过系统的针灸临床研究方法培训,取得相应的资格认定。

8.3 执业资格和许可

参加研究的各类人员都应具有相应专业技术职称任职和执业资格,获得所在单位的同意,签署科研诚信尽责承诺书,保证有充裕的时间在方案规定的期限内完成研究任务,均需接受研究方案的专门培训并通过考核,保证按照方案执行。

8.4 研究负责人

研究负责人是针灸临床研究的首要责任人,负责研究目的、研究内容的确定以及研究设计与研究方案的制定;负责研究经费的预算与执行以及相关的奖励;负责选择承担临床研究的机构和研究者,负责其资格及条件的审定;在获得研究发起机构与伦理委员会批准后负责研究方案的实施和质量保障;负责研究报告的起草与发表。研究负责人可选择具备资质的人员担任研究秘书,研究秘书按照研究负责人的要求,进行相关的文字和联络工作。研究负责人可根据需要选聘研究助理,研究助理受研究负责人的委托管理相关方面的工作。多中心、较大型的针灸临床研究可成立由研究负责人领导的项目办公室,协助对项目实施管理。

8.5 临床研究者

临床研究者是针灸临床研究现场实施的责任人,应严格按照研究方案进行实施,保证研究质量,及时处理各种不良事件和并发症;对于严重不良事件和严重并发症,应上报规定部门。临床研究者应负责将研究数据真实、准确、完整、及时、合法地载入病历和病例报告表。

8.6 针灸操作者

针灸操作者是研究者根据需要选聘的临床操作人员。针灸操作者应经过培训并考核合格，应在项目办公室登记备案，熟悉针灸操作的各种规程和程序，熟练掌握针灸操作的相关细节和参数，并接受研究负责人组织的操作效果一致性检查。针灸操作者宜相对固定，操作接任者应重新培训与备案。

8.7 指标评估者

指标评估者应由不参与针灸操作和试验分组，但具有相关专业资质的人员担任。指标评估者应坚持公正、规范、科学、严谨的原则，不能主动了解临床研究的分组，以保证测量结果的真实准确。

8.8 数据管理人员

数据管理人员分为数据管理员、程序员、医学编码人员和录入员等。其由研究发起单位选聘，可由第三方的专业团队担任。数据管理人员应按照相应的操作流程与操作规范，负责数据管理工作，保障数据的质量。

8.9 统计分析人员

统计分析人员应由专业生物统计学人员、临床流行病学专家或经过系统统计方法培训的人员担任，由研究负责人选聘。统计分析人员在临床研究设计、临床研究统计计划制定、数据统计分析中起重要作用。

8.10 财务人员

临床研究的财务人员由临床研究承担单位的财会人员担任，其职责是协助研究负责人确保临床研究的经费预算，按照国家或有关部门研究经费管理的规定和制度协助经费执行，协助做好课题结题验收时的经费报告与审计工作。

8.11 研究管理人员

研究管理人员应由临床研究承担单位相关科研管理部门的人员担任，其职责是协助研究负责人进行组织协调，指导与督促临床研究按照相关规定实施，监督研究经费的合理合规使用以及研究成果的发布与交流，并协助和督促做好临床研究组与承担单位相关部门的联系和协调工作。

8.12 监查员

临床研究承担单位应设立独立的监查员。监查员应具有高度责任感，严格按照监查计划和操作规程，对所有纳入研究对象进行监查，重点监查针灸方案执行的真实性、规范性和依从性；每次监查后应向研究负责人递交书面报告并及时反馈研究中出现的问题；主动接受稽查和视察。

8.13 稽查员

稽查员可由研究发起机构委派或指定，负责对临床研究人员的资质、培训情况以及临床研究实施情况进行系统性检查，以评价研究是否按照设计方案、标准操作规程以及相关法规要求进行，研究数据是否记录得及时、真实、准确、完整，负责对监查员的工作进行评估。

8.14 视察员

研究发起机构可组织视察员对整个临床研究工作进行全面或重点的检查、评估和指导。在每次视察后应形成书面文件，提交研究发起部门和研究负责人。

9 质量管理

9.1 质量管理目的

针灸临床研究质量管理的目的是通过制定覆盖过程实施、数据管理的质量控制计划，报告计划，并依据质量要求对研究过程中相关操作技术和活动开展查证，以提高针灸临床研究的质量。

9.2 培训

针灸操作培训是针灸临床质量保障的关键环节。对于临床干预方案，应组织所有研究者、针灸操作者进行培训并在培训后实施考核。应制定详细的操作培训教材，利用视频、图像等多种形式，讲解操作要点，以保障操作一致性。

9.3 质量管理内容

针灸临床研究最高可设置内部质控、监查、稽查、视察四级质量控制体系，应按照研究规模选择级数。质量管理的主要内容包含研究过程的伦理资料检查，入组标准执行情况的审核，操作与记录的完整性、一致性、及时性以及准确性评估工具的选择与制定；也包含审核针灸操作者、指标评估者的资质，评估操作者对方案的依从性，核对研究对象的真实性，明确研究档案的保存形式，保障研究数据的溯源等内容。真实世界针灸临床研究，应根据不同的数据来源，建立相应的数据收集表单、流程、质控措施，明确数据提取关键字段、建立数据提取模板、建立数据链接规则、形成数据清理规则，保障临床数据的完整性、准确性和及时性。

10 数据管理与统计分析

10.1 数据管理方法

针灸临床研究应根据研究目的和设计方案选择适合的数据管理方法，以确保数据的可靠、完整和准确。

10.2 数据的真实性

数据管理工作应贯穿临床研究始终，为保证数据清理过程的真实性和数据的溯源性，数据清理过程中的文档均应保存。

10.3 数据的客观性

为保证针灸临床研究中更好地实施盲法，尤其是大型多中心的研究，建议采用合理的随机化方案和第三方数据管理，使临床研究结果客观公正。

10.4 计算机系统的使用

在针灸临床研究中使用计算机系统时，应确保系统本身和所运行环境的安全、稳定和可靠；操作系统的人员应进行培训并具备相应的资质。计算机系统本身应至少具备权限管理、痕迹稽查、数据备份等基本功能。为了研究数据汇交和深入利用，数据库设计时应遵循国际、国内和行业的有关数据和术语标准。

10.5 统计分析计划

针灸临床研究应在研究方案设计阶段预先制定出统计分析计划,包括具体的分析指标及统计分析方法,并形成正式的文档。应根据研究目的和数据特点,选择适宜、规范的统计分析方法。若分析过程中发生变动,应说明理由。

对于真实世界研究,应考虑真实世界数据的特点,控制偏倚,还应注意数据挖掘方法的合理应用。

对于国际多中心临床研究,首先应整体研究数据进行总结和分析,其次应针对不同地域人群的有效性和安全性进行比较和趋势性分析。

11 临床研究报告

11.1 研究报告的真实性

针灸临床研究结束后,无论研究结果是阳性还是阴性,也无论临床研究是否按计划完成、是否达到研究目的,均应撰写临床研究报告。研究报告应明确报道研究结果的真实性与研究结论的可靠性。

11.2 提交

所有针灸临床研究报告均应提供给研究发起部门、相关管理部门、参与研究的临床机构、伦理委员会等。针灸临床研究报告是项目结题验收、成果鉴定、推广运用以及研究论文发表的重要依据。

11.3 公开

鼓励所有注册登记的针灸临床研究,在适当的时间将研究结果和结论的摘要在登记注册部门公布;针灸临床研究结束后,应根据相关规定将原始数据库汇交至指定的部门,以便核查、数据共享和再利用。

11.4 发表

鼓励公开发表研究结果和结论。在研究论文发表时,应严格遵守有关法律、法规以及学术道德规范。针灸临床研究论文发表时,应标明针灸临床研究临床试验注册编号或其他机构的临床试验注册编号。

11.5 研究报告

临床研究报告应与研究注册和方案发表时公布的研究方案保持一致,报告应包含以下内容:

- 题目:反映研究设计类型、研究对象和主要干预措施;
- 引言:研究背景、研究必要性、研究目的和拟解决的临床问题;
- 研究基本信息:研究负责人、研究编号、项目经费来源、研究实施周期、研究参与单位、研究参与人员、研究注册信息;
- 伦理审批:伦理审批机构信息、伦理审批时间和伦理审批号;
- 研究设计:研究设计类型、研究对象(纳入标准、排除标准、中止标准)、对照组设置方法、样本含量估算依据、干预措施、评价指标、数据管理、质量控制、统计学处理等;
- 研究结果:基线资料、人口学资料、主要指标、次要指标、安全性分析;
- 研究结论:根据研究结果,在全面分析同类研究的同时,审慎、客观地提出研究结论,回答研究目的以及临床的指导意义;同时对研究中存在的不足、进一步的研究计划等进行适当的阐述。

根据临床研究类型不同,适当调整报告的相应内容。

11.6 报告标准及要求

针灸临床研究报告撰写时,应根据不同的研究类型参照以下规范:

- 针灸临床干预措施报告标准:《针刺临床试验干预措施报告标准修订版:CONSORT 声明的扩展:STRICTA (2010)》;Extending the CONSORT Statement to Moxibustion;
- 随机对照临床试验的报告规范:CONSORT 声明;
- 随机对照临床试验的 meta 分析报告规范:QUOROM 声明;
- 系统评价和 meta 分析报告规范:PRISMA 声明;
- 非随机设计的研究的报告规范:TREND 声明;
- 流行病学观察性研究的报告规范:STROBE 声明;
- 流行病学观察性研究的 meta 分析报告规范:MOOSE 声明;
- 诊断准确性研究的报告规范:STARD 声明;
- 基因相关性研究的报告规范:STREGA 声明;
- 基于真实世界数据的观察性研究的报告规范:RECORD 声明、STaRT-RWE;
- 病例系列研究的报告规范:参考 STROBE 声明;
- 病例报告的报告规范:CARE 指南。

评估针灸临床研究证据质量时,应根据不同的研究类型参照以下评价工具:

- 随机对照临床试验的质量评价标准:Cochrane RoB、改良 Jadad 量表、CASP、CONSORT;
- 系统评价和 meta 分析的质量评价标准:AMSTAR2、GRADE;
- 非随机设计的研究的质量评价标准:MINORS 条目、Reisch 评价工具;
- 流行病学观察性研究的质量评价标准:NOS 量表、CASP 清单、JBI 标准、AHRQ、Combie;
- 诊断准确性研究的质量评价标准:QUADAS 工具、CASP 清单;
- 基于真实世界数据的观察性研究的质量评价标准:ArRoWs、MINORS、ROBINS-1;
- 病例系列研究的质量评价标准:NICE、JBI、IHE;
- 病例报告的质量评价标准:JBI。

参 考 文 献

[1] 临床试验管理规范(GCP)[J].中国医药导刊,1999(1):5-9.

[2] 杨丽然,邱仁宗.世界医学会《赫尔辛基宣言》:涉及人类受试者的医学研究的伦理原则[J].医学与哲学(人文社会医学版),2009,30(5):74-75.

[3] 张颖,王俊慧,胡烨胤,等.中医药临床研究中预试验样本量的确定[J].中医杂志,2021,62(4):307-311.