

# Design and Application of the Case Report Form for the Clinical Observation on Acupuncture and Moxibustion

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## ABSTRACT

This paper aims to design a case report form for the clinical observation on acupuncture and moxibustion (hereinafter referred to as "CRF") to standardize the collection of clinical data of acupuncture and moxibustion, serve the clinical research on acupuncture and moxibustion, and provide support for the integration of clinical scientific research on acupuncture and moxibustion. The methods adopted are based on the standards of the Chinese Association of Acupuncture-Moxibustion, such as *Real world acupuncture clinical research information collection*, and *Real world acupuncture clinical research basic information classification and code* (drafts for review), and the characteristics of the acupuncture and moxibustion clinical diagnosis and treatment, a dedicated CRF for clinical acupuncture and moxibustion was developed. Through the research on the preliminary clinical application, the practicability of the CRF was evaluated and its design was optimized. Finally, the design of the CRF for the clinical observation on acupuncture and moxibustion was completed and passed the clinical application verification and optimization. Through the research, it can be found that the CRF designed in the research can be used in the clinical research on acupuncture and moxibustion, and will be continuously optimized in practical applications to better serve clinical research.

**Keywords:** Case report form (CRF), Acupuncture and moxibustion, Clinical observation, Design.

## 1. INTRODUCTION

Acupuncture and moxibustion is a crucial part of traditional medicine, featuring convenience, affordability, wide indications, safety, and rare toxic side effects. However, to make acupuncture and moxibustion really effective, there must be efficacy supported by high-quality evidence. Therefore, clinical research on acupuncture and moxibustion has received more and more attention [1]. Not only rigorous scientific research design and standardized quality management are needed for clinical research on acupuncture and moxibustion, but also high-quality data are required to explain the problem [2]. Standardized and complete data are a prerequisite for clinical data analysis and a strong guarantee for the authenticity and credibility of clinical research results [3]. Through recording the actual conditions, treatment measures, etc. of patients, the clinical electronic medical records of

acupuncture and moxibustion can provide sufficient data for clinical research. However, the current electronic medical records of acupuncture and moxibustion cannot meet the needs of clinical research. Therefore, it is urgent to build an integrated data collection system for acupuncture and moxibustion clinical research to highlight the characteristics of clinical diagnosis and treatment of acupuncture and moxibustion, solve the problem of standardization of acupuncture and moxibustion clinical data collection, and realize the integration of acupuncture and moxibustion clinical research. Case Report Form [4], CRF for short, is a way to record clinical information in clinical trials. It is designed in accordance with the test protocol and used to record the data of each subject during the test. At present, there is no dedicated CRF for clinical acupuncture and moxibustion. On the basis of reflecting the clinical treatment characteristics of acupuncture and moxibustion, a dedicated CRF for clinical acupuncture

and moxibustion should be designed for the study on the standardization of the acupuncture and moxibustion clinical data collection. The design of the CRF directly affects a series of handling processes such as the database construction in the later period, data entry, and analysis [5]. Therefore, the standardized design of the CRF is essential. The design and application of the CRF under the project are summarized as follows.

## **2. CRF DESIGN PRINCIPLES AND BASIS**

The compliance with the theory of traditional Chinese medicine, the conformance to the rules of acupuncture and moxibustion, the embodiment of the characteristics of acupuncture and moxibustion clinical diagnosis and treatment, and the meeting of the requirements of the integration of clinical scientific research on acupuncture and moxibustion and the structure of acupuncture and moxibustion clinical data are the principles in designing the clinical CRF for acupuncture and moxibustion. The design basis is the standards of the Chinese Association of Acupuncture-Moxibustion, such as Real world acupuncture clinical research information collection, and Real world acupuncture clinical research basic information classification and code (drafts for review), among which the information collection standard stipulates the basic content and requirements of the real world acupuncture and moxibustion clinical research information collection, which are applicable to the standardized collection of the real world acupuncture and moxibustion clinical research information and the building of the acupuncture and moxibustion clinical database; the basic information classification and code standard stipulates the name, classification and code of the acupuncture and moxibustion clinical research basic information, which is applicable to traditional Chinese medicine, scientific research, teaching, Chinese medicine information technology application, and domestic and foreign academic exchanges, and other fields.

## **3. CRF COMPOSITION**

CRF includes the following basic content [6]: (1) Cover: It displays the name of the research project, and the basic information of the patient and the researcher for quick search. The content includes the title of the CRF, the name of the patient, the clinical observation unit and department, the preparer, the date of filling, the unit responsible for the project, and the unit responsible for clinical research. (2) Instructions for filling: In order to standardize the filling, and facilitate the later data sorting, it is necessary to give instructions for filling out the form. For example, the abbreviations with strong professionalism should be avoided; the time should be recorded in the form of MM/DD/YYYY, etc. (3) Clinical observation flow chart: The research process

should be listed in a list to ensure the correct research process and prevent omissions. (4) Inclusion/exclusion criteria: The inclusion and exclusion should be determined according to the specific disease observed to ensure that each observation case conforms to the requirements of the plan.

Besides, according to the design principles, the clinical related information items of acupuncture and moxibustion are divided into four categories, namely basic information of the patient, diagnostic information, intervention information and evaluation information. The specific content is as follows.

### **3.1. Basic information**

The *Quality Standards for Data Filling in the Homepage of Chinese Medicine Hospitalized Medical Records (Provisional)* is adopted to standardize the basic information of patients under the clinical observations on acupuncture and moxibustion, and design the baseline data - demographic indicators (name, gender, age, marital status, height, weight, occupation, contact number, etc.) and features that may affect the outcome of the study (past medical history, history of allergies, history of acupuncture and moxibustion treatment).

### **3.2. Diagnostic information**

The content of acupuncture and moxibustion clinical diagnosis information is designed according to the *Basic Standards for Writing Chinese Medical Records* and the actual needs of the real world acupuncture and moxibustion clinical "differentiation of symptoms", including chief complaint, history of present illness, engraved syndrome, vital signs, four diagnoses of Chinese medicine, auxiliary examination, constitution diagnosis, syndrome differentiation according to meridian and collateral theory, diagnosis summary, etc. Among them, the four items of observation, auscultation, interrogation and palpation are designed as the four diagnoses of Chinese medicine according to the content of the *Diagnostics of Chinese Medicine*, a "12th Five-Year" Plan textbook published by China Press of Traditional Chinese Medicine; the information items for constitution diagnosis are designed based on the nine-constitution method of Professor Qi Wang, specifically including nine constitutions of gentleness, yang-deficiency, and blood stasis; fourteen regular channels information items are designed based on the syndrome differentiation according to meridian and collateral theory; in the diagnosis summary, the names of diseases and syndromes in Chinese medicine are based on the national standard: *Classification and codes of diseases and patterns of traditional Chinese medicine*, and the names of diseases in Western medicine are mainly based on the 64 kinds of acupuncture and

moxibustion indications and ICD-10 disease diagnosis names recognized by WHO.

### **3.3. Intervention information**

Clinical research on acupuncture and moxibustion should follow the traditional theories of Chinese medicine, reflect the characteristics of clinical practice of Chinese medicine, and explore the efficacy of dialectical treatment based on meridian circulation, different acupuncture methods or moxibustion methods, and so on [7]. Therefore, the intervention information should reflect the clinical characteristics of acupuncture and moxibustion. The intervention information specifically refers to information related to featured treatments commonly used in the clinical practice of acupuncture and moxibustion. It is mainly designed based on the *Acupuncture & Moxibustion Techniques*, a "12th Five-Year" Plan textbook published by China Press of Traditional Chinese Medicine, and includes acupuncture treatment therapy, moxibustion therapy, cupping therapy, scraping therapy, and special acupuncture point therapy. Among them, acupuncture therapy includes filiform needle, needle with electrical current, three-edged needle, dermal needle, intradermal needle, fire needle, auricular needle, elongated needle, needle knife, etc.; Moxibustion therapy includes moxibustion therapy (moxibustion with moxa stick, moxibustion with moxa cone), non-moxa moxibustion therapy (medicine moxibustion, photoelectric moxibustion), and other moxibustion therapies (warm needle moxibustion, moxibustion with moxibustioner), and so on; cupping therapy includes fire cupping, water cupping, suction cupping, needle cupping, and other cupping methods; special acupuncture point therapy includes acupuncture point injection, acupuncture point embedding, acupuncture point application, acupuncture infrared radiation, etc. In each therapy, basic information items such as acupuncture points or parts of treatment, operation methods, duration, frequency, and course of treatment are designed, while special information items include the technique, depth, angle, and direction of filiform needle acupuncture; the waveform and intensity of electroacupuncture; the amount of bloodletting of three-edged needle; the technique strength, speed and direction of scraping therapy; and the drugs and dosage injected into acupuncture points, and so on.

There is no doubt that there are various types of acupuncture and moxibustion therapy and those applied in different regions or hospitals may vary. Therefore, when the CRF is applied, the intervention information items adapted to it should also be designed as appropriate according to the design principles and requirements.

### **3.4. Evaluation information**

The evaluation information includes the effect (efficacy evaluation) after implementing the intervention and the record of whether adverse events occurred during this period. Efficacy evaluation indicators need to be determined according to specific diseases. For example, the evaluation indicators for Yaobi (lumbar discomfort) include the international common pain scale - VAS, lumbar spine mobility evaluation, and the lumbar spine JOA score table - a scale to evaluate the lumbar spine dysfunction developed by Japanese Orthopaedic Association. Adverse event records are made according to the recording and reporting requirements for adverse events and serious adverse events in the *Specification for the Quality Management of Clinical Trials of Drug* issued by China Food and Drug Administration, including the clinical manifestation, occurrence time, and end/relief time, severity, whether measures are taken, impact on the study, relationship with acupuncture and moxibustion therapy, related inspections, follow-up visit, and outcome of the adverse events/serious adverse events, and whether withdraw from the study due to the events, and other information items.

## **4. PRECAUTIONS FOR CRF FILING**

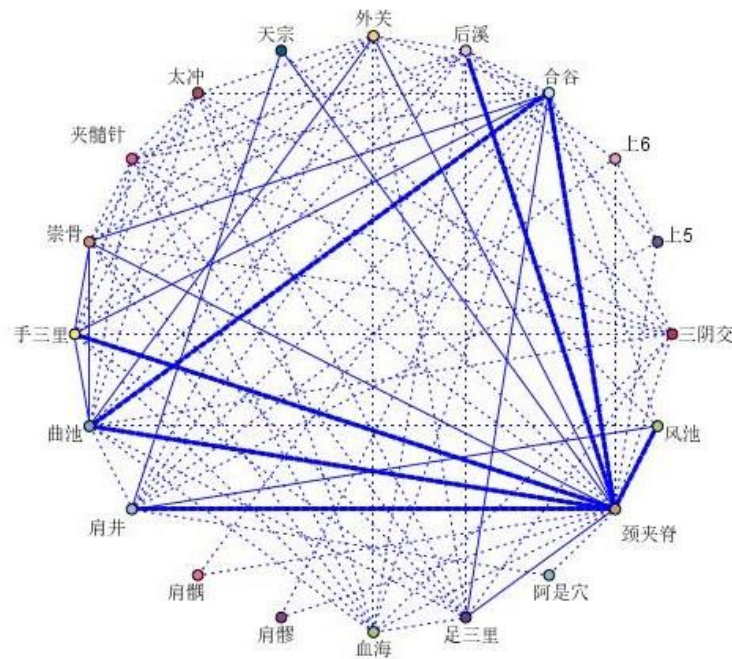
The purpose of the CRF design is to collect data completely and accurately to facilitate the data sorting and analysis in the later period. Therefore, some precautions in the CRF filling must be considered, for example: If "□" appears, corresponding figures must be filled in according to the filling requirements. If the "straight needling" in the filiform needle acupuncture is selected, fill the two figures of 0 and 1 in the boxes; For any option with "□" in the table, please tick an "×" in the "□" of the correct option to prevent the data from being changed; the case observation form should be filled in completely without any blanks. If an item was "not done", fill in "ND"; fill in "NK" for those that are "not known", and fill in "NA" for those that "cannot be provided" or "not applicable". If a mistake is made, please cross out the mistake and write the correct data in the blank space next to it and indicate the initials of the person who modifies it in pinyin and the data of modification. Please do not cover the incorrectly filled original data, for example 23 32, CJG2020/12/27, and so on.

## **5. STUDY ON THE CLINICAL APPLICATION OF CRF**

As a sub-project of the "Construction of Traditional Chinese Medicine Big Data Center and Health Cloud Platform", a key special project of the national key R&D program "Research on Modernization of Traditional Chinese Medicine", the "R&D and Implementation of the Information Sharing System for the Clinical

Scientific Research on Chinese Medicine" applied the CRF designed by the sub-project to the acupuncture and moxibustion clinical observation data collection study for the first time. The study took the department of acupuncture and moxibustion of a provincial hospital of Chinese medicine as the main body, and joined hands with the departments of acupuncture and moxibustion of other six Grade A hospitals to organize and develop the observation studies of the cases of "Yaobi", "Xiangbi" (neck discomfort) and "facial paralysis" and fill in and submit the CRF. Before the formal start of the research, the research team made a *Research Plan* and a *Work Manual* according to the project requirements, and organize relevant personnel for training, introducing project content and the CRF filling requirements of the three diseases of "Yaobi", "Xiangbi", and "facial paralysis" in detail, specially emphasizing the precautions for filling to avoid unnecessary omissions, improper filling, etc. At the same time, a WeChat group was established to maintain communication at any time when there is a problem in the collection of clinical cases and CRF filling. Finally, a total of 525 CRFs were filled in and submitted, including 219 copies for Yaobi,

210 copies for Xiangbi, and 96 copies for facial paralysis. The Institute of Standardization and Information Technology of Hubei University of Chinese Medicine extracted data from 525 CRFs, and encoded them for data conversion to form a Chinese medicine clinical case data form (CDF), namely CDF for illness history information, CDF for acupuncture and moxibustion diagnosis information, and CDF for acupuncture and moxibustion treatment information. After digitizing the information database, computer analysis and processing were carried out to verify the rationality and operability of CRF. For example, the Apriori algorithm in SPSS Modeler 18.0 was used to carry out the data association analysis of acupuncture point compatibility of patients with Xiangbi and different constitutions after being treated with filiform needles. As shown in Figure 1: For patients with blood stasis, the filiform needle acupuncture points with a relatively high degree of association were "Jingjiaji - Jianjing", "Jingjiaji - Houxi", "Jingjiaji - Hegu", "Jingjiaji - Shousanli", "Jingjiaji - Quchi", "Jingjiaji - Fengchi", and "Hegu- Quchi".



**Figure 1** Acupuncture point compatibility network diagram of patients with blood stasis

The association rules analysis was carried out to the acupuncture points after the setting that the support >15% and the confidence >80%. A total of 10 association rules were obtained, and the association rules were shown in Table 22.22. When the acupuncture point Jianjing appeared, the probability of the

appearance of Jingjiaji was 38.18%. The acupuncture and moxibustion prescriptions that support this association rule accounted for 38.18%.

**Table 1.** Association rules of acupuncture point compatibility of penitents with blood stasis

No.	Back	Front	Percentage of support %	Percentage of confidence %	Percentage of rule support %
1	Jingjiaji	Jianjing	38.18	100.00	38.18
2	Jingjiaji	Fengchi	38.18	90.48	34.55
3	Jingjiaji	Quchi	29.09	87.50	25.45
4	Jingjiaji	Hegu	27.27	93.33	25.45
5	Quchi	Hegu	27.27	80.00	21.82
6	Jingjiaji	Shousanli	23.64	100.00	23.64
7	Jingjiaji	Houxi	21.82	91.67	20.00
8	Jingjiaji	Quchi and Hegu	21.82	91.67	20.00
9	Shousanli	Quchi and Hegu and Jingjiaji	20.00	81.82	16.36
10	Jingjiaji	Shousanli and Hegu	18.18	100.00	18.18
11	Quchi	Shousanli and Hegu	18.18	90.00	16.36
12	Quchi	Shousanli and Hegu and Jingjiaji	18.18	90.00	16.36
13	Jingjiaji	Tianzong	16.36	100.00	16.36
14	Hegu	Shousanli and Quchi	16.36	100.00	16.36
15	Jingjiaji	Shousanli and Quchi	16.36	100.00	16.36
16	Jingjiaji	Shousanli and Quchi and Hegu	16.36	100.00	16.36
17	Hegu	Shousanli and Quchi and Jingjiaji	16.36	100.00	16.36

After analyzing these combinations, it is found that they are consistent with acupuncture and moxibustion theory and clinical practice, and the results can serve as a basis for clinical applications. Of course, through this application research, we have also found that there is room for improvement. For example, to embody the overall concept of "Tianren Ganying" (interaction between heaven and mankind) of Chinese medicine, information items of Wuyun Liuqi can be added; the theory of Chinese medicine believes that the spiritual sentiment and diet and daily life of a person are closely related to health, so they should also be recorded for analysis.

Through clinical applications and verification, it is proved that the design of the clinical CRF for acupuncture and moxibustion is scientific and reasonable, which has reached the basic goal of its design and application, and can be continuously optimized in practical application to better serve the clinical research.

## 6. CONCLUSIONS

The implementation of the Healthy China Initiative has provided a good development opportunity for acupuncture and moxibustion [1]. With the advancement of information technology and big data technology, Chinese medicine has gradually entered a standardized, modern and scientific application process, which also provide means and opportunities for the research and processing of information resources of

Chinese medicine.. Based on this, in order to make full use the clinical data resources of acupuncture and moxibustion, innovate the clinical research models and methods of acupuncture and moxibustion, under the guidance of the Chinese medicine clinical data structuring and knowledge association methodology, clinical case observation data of acupuncture and moxibustion in the real world are collected for standardized, structured and data-based processing, thereby deepening the knowledge representation level of acupuncture and moxibustion clinical data, achieving the attributed reconstruction and knowledge coding of acupuncture and moxibustion clinical knowledge, promoting the integrated application of acupuncture and moxibustion clinical application and data standards, and improving the application of data standards.

The clinical CRF for acupuncture and moxibustion provides a template for the standardized collection of acupuncture and moxibustion clinical data, and it also provides new ideas and new methods for the clinical research on acupuncture and moxibustion. Through verifying the clinical application of the CRF and further optimizing it, it can better serve the clinical research. The application of the acupuncture and moxibustion clinical CRF enables data to come from clinical application and serve clinical application, it will definitely promote the rapid development of the acupuncture and moxibustion clinical scientific research and lay a solid foundation for the objective of the integration of clinical research on acupuncture and moxibustion.

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