Review Article

Analysis of the Registration Information on Interventions of Acupuncture and Moxibustion Trials in the International Clinical Trials Registry Platform

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Purpose. To analyze and compare the clinical registration information about acupuncture and moxibustion for intervention characteristics.

Methods. Clinical trials from the International Clinical Trials Registry Platform of the World Health Organization in acupuncture and moxibustion were comprehensively collected from 2013 to 2015; data were independently screened and extracted by two retrievers, and relevant data involving either basic descriptions or intervention characteristics were analyzed. Results. 425 acupuncture and moxibustion registered clinical trials were included; 88.00% (374/425) were designed as controlled studies, among which 38.59% (164/425) had sham acupuncture as the control group. The most common diseases were pain-related at approximately 19.29% (82/425) of trials. Reports on the intervention information in these acupuncture and moxibustion clinical studies were not sufficiently presented; these reports included the reporting of names of points (39.8%), the method of needle stimulation (32.5%), needle type (29.6%), needle retention time (34.1%), the number of treatment sessions (22.4%), and the frequency and duration of treatment sessions (38.1%). Conclusion. The registration information for the clinical trials of acupuncture and moxibustion was quite low according to this investigational study. Steps should be taken to improve the quality of acupuncture and moxibustion registration information.

1. Introduction

Acupuncture and moxibustion have been practiced in China for more than 3000 years and are considered to be complementary and alternative therapy [1]. Benefits from these therapies include relative safety, effectiveness, feasibility, and economic wellbeing. Since 1979, the World Health Organization (WHO) has promulgated 43 diseases with indications applicable to acupuncture and moxibustion [2]. Therefore, these traditional Chinese therapies have become publicly acceptable in clinical practice in the West [3].

Since the 20th century, acupuncture and moxibustion clinical trials have progressed into a bustling and booming era not only in the quantity of studies but also in quality; in addition, the diseases included in clinical trials have expanded over these decades [4, 5]. Many problems and concerns manifested during this time period; for example, there was a shortage of well-designed and strictly implemented clinical studies [6]. Evidence from these clinical studies could not be cited and generalized to improve acupuncture and moxibustion practice. The barrier has been diminishing with solid evidence.
In November 2004 in Mexico City, the WHO was regarded as the lead organization in establishing the International Clinical Trials Registry Platform (ICTRP) [7]. This milestone event was a consensus decision during the Ministerial Summit on Health Research [8]. It was in May 2007 when the ICTRP officially broke ground [9], and the importance of trial registration has been gradually accepted [10–12]. To date, 16 data providers, including the United States and China, have been authorized as the first registration institutions of the WHO ICTRP [13]. In May 2007, the WHO Trial Registration Data Set (TRDS) was announced, setting a minimum of 20 items for trial registration [14]. International clinical trial registration has been implemented to a large extent to improve the quality of clinical trials, as well as form a transparent presentation of trial progress and execution [15].

This study aims to collect and analyze the 20 items of the WHO TRDS and other registry information from the 16 clinical trial register centers of the WHO ICTRP; provide an overview of the registered acupuncture-moxibustion clinical trials for manipulation specifications and reporting performance; and propose the necessity to establish the Acupuncture-Moxibustion Clinical Trial Registry (AMCTR) center.

2. Materials and Methods

2.1. Inclusion/Exclusion Criteria. All acupuncture and moxibustion clinical trials registered in the WHO ICTRP were eligible for inclusion. No criteria for disease were applied, nor were criteria applied for participant age, sex, and ethnicity; the studied interventions were acupuncture and moxibustion, including Filiform needle, percussopuncturator, Auricular Acupuncture, or transcutaneous electrical acupuncture stimulation, indicated as the major medical treatment. The control group for any comparison was placebo, no intervention, or another intervention. There was no definition for endpoint outcomes. Exclusion criteria included incomplete registry information, no information indicating that acupuncture or moxibustion had been used to intervene in the disease studied or that acupuncture or moxibustion were only used as a secondary concomitant therapy. Acupuncture, needling, acupressure, moxibustion, auriculotherapy, and acupoint were used as keyword search terms, regardless of the initial registry language.

2.2. Database Sources. Data from the WHO ICTRP (http://apps.who.int/trialsearch/Default.aspx) registry records between 2013 and 2015 were used. This registry platform included Australia, New Zealand, China, Korea, United States, India, Cuba, Germany, Iran, United Kingdom (UK), Japan, Pan African Region, Sri Lanka, Netherlands, Belgium, and the European Union (EU) Region. The specific names of the registries are as follows: Australian New Zealand Clinical Trials Registry (ANZCTR, Australia, and New Zealand), Chinese Clinical Trial Register (ChiCTR, China), Clinical Research Information Service (CRIS, Republic of Korea), Clinical Trials.gov (United States), Clinical Trials Registry, India (CTRI, India), Cuban Public Registry of Clinical Trials (RPCEC, Cuba), German Clinical Trials Register (DRKS, German), Iranian Registry of Clinical Trials (IRCT, Iran), ISRCTN.org (British), Japan Primary Registries Network (JPRN, Japan), Pan African Clinical Trial Registry (PAC-TR, Africa), Sri Lanka Clinical Trials Registry (SLCTR, Sri Lanka), the Netherlands National Trial Register (NTR, Netherlands), Brazilian Clinical Trials Registry (ReBec, Brazil), EU Clinical Trials Register (EU-CTR, EU), and Thai Clinical Trials Registry (TCTR, Thailand).

2.3. Data Extraction. Using a predefined data extraction form that collected information for this study, two evaluators independently extracted data (Wenjie Chen and Yingxin Tan); disagreements in the data extraction were resolved by another evaluator (Yali Liu) after further consultation. The content of the data extraction forms was categorized into the following sections.

2.3.1. Basic Registry Information on the 16 Clinical Trial Registry Centers. This information included the name of the registry platform, nationality/region, website, language, the date in which the platform was established, the setup and disposition of the 16 first-rate study centers worldwide, and the 20 items in the World Health Organization (WHO) Trial Registration Data Set (TRDS).

The categories for the registry information were formulated by the 16 ICTRP clinical study centers; these included the registered title for the platform, update time, registry time, status of the registry number, information on the applicant, approval-related report from the institutional ethics board, information on the study-center that conducted the designated trials, funding and financial resources, study design (disease, study category/type, purpose, design, methodology, inclusion and exclusion criteria, interventions, outcomes, and endpoints), study time (initiation, duration, and close-out), designated study sites, human histology samples collected, subject recruitment and enrollment, study data management institution, and any commissioned/contracted data analysis companies/agents.

2.3.2. Basic Information Registered Clinical Trials in the Acupuncture and Moxibustion Fields. These fields involved registry time, the name of the clinical trials registry platform, study type, sample size, the object disease/symptoms, intervention(s), and endpoint outcomes.

2.3.3. Specific Information on Interventions in Registered Clinical Trials in the Acupuncture and Moxibustion Fields. Based on the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICRTA) [16], the data extraction form was used to investigate the manipulation procedures. The information collected included the number of needle insertions per subject per session, names (or location if no standard name) of points used, depth of insertion, response sought, needle stimulation, needle retention time, needle type, and the registry information on sham acupuncture.
Table 1: The characteristic information of platforms in ICTRP.

| Platform     | Countries/District | Internet site                  | Language       | The time of establishment |
|--------------|--------------------|--------------------------------|----------------|---------------------------|
| ANZCTR       | Australia/New Zealand | http://www.anzctr.org.au/ | English | 2003                      |
| ChiCTR       | China               | http://www.chictr.org.cn/    | English, Chinese | 2005                    |
| CRIS         | Kore                | http://cris.nih.go.kr/       | English, Korean | 2005                     |
| Clinical Trials.gov | United States | http://www.clinicaltrials.gov/ | English | 1988, 1997               |
| CTRI         | India               | http://www.ctri.nic.in/      | English        | 2005                     |
| RPCEC        | Cuba                | http://registroclinico.sld.cu/ | English, Spanish | 2008          |
| DRKS         | Germany             | http://www.germanctr.de/     | English, German | 2005                     |
| IRCT         | Iran                | http://www.irct.ir/          | English, Arabic | 2007                     |
| ISRCTN.org   | United Kingdom      | http://www.isrctn.org/       | English        | 2007                     |
| JPRN         | Japan               | http://rctportal.niph.go.jp/ | English, Japanese | 1988         |
| PAC-TR       | Africa              | http://www.pactr.org/        | English        | 2005                     |
| SLCTR        | Sri Lanka           | http://www.slctr.lk/         | English        | 2005                     |
| NTR          | Netherlands         | http://www.trialregister.nl/ | English    | 2005                     |
| ReBec        | Brazil              | http://www.ensaiosclnicos.gov.br/ | English, Portuguese | 2004         |
| EU-CTR       | Europe              | https://www.clinicaltrialsregister.eu/ | English | 2004                     |
| TCTR         | Thailand            | http://www.clinicaltrials.in.th/ | English, Thai |                         |

2.4. Data Analysis. Microsoft Excel (Version 2007) was used to analyze the coded data items for any statistically significant differences. Categorical data is presented as number (n) and percent (%).

3. Results

3.1. Basic Information of the Registered Clinical Trial Centers of ICTRP. To date, 16 registries have been designated by the WHO ICTRP as first-rate clinical trial registry centers which cover all six continents. These are summarized in Table 1.

3.2. Categorization of the Registry Information Designated by the ICTRP Clinical Trial Registry Centers. There are 20 items in the TRDS stipulated by the WHO ICTRP that are reported by the first sixteen registry platforms, as shown in Table 2. Moreover, specific registry information from these centers supplements the fundamental TRDS. In Table 3, some supplemental data are included, except for the 20 items in the WHO TRDS; in this study, a total of 45 registry items are included. It is notable to mention that the ANZCTR had defined more than 30 items for its registry information; other centers have sets of items that vary from 15 to 25.

3.3. Basic Registry Information for Acupuncture and Moxibustion Clinical Trials. We reviewed 425 acupuncture and moxibustion clinical trials that had completed registration between 2013 and 2015. Among them, 124 (29.18%) were registered in 2013, 123 (28.94%) were registered in 2014, and 178 (41.89%) were registered in 2015. The studies that were registered in the WHO ICTRP were mainly interventional studies (89.18%, 379/425); only 3.53% (14/425) were observational studies; 88.00% (374/425) were controlled studies and 164 (38.59%) were compared with sham acupuncture; 187 and 50 studies recruited participants from China (including Hong Kong and Taiwan) and the United States, respectively. The largest sample size was 1000 subjects (Table 4). Clinical Trials.gov, ChiCTR, and CRIS had the most clinical studies (Table 5). Pain symptoms were the main indication for treatment with acupuncture or moxibustion, comprising 82 (19.29%) of the studies; the other diseases and symptoms were neoplasm (7.29%, 31/425), stroke (4.00%, 17/425), arthritis (3.53%, 15/425), depression (3.06%, 13/425), and insomnia (2.59%, 11/428) (Table 6).

3.4. Characteristics of the Acupuncture and Moxibustion Trials in the WHO ICTRP. As summarized in Table 7, there were no sufficiently specific descriptions of acupuncture and moxibustion manipulation or the procedures in these reports of the clinical trials registered between 2013 and 2015. These trials mainly covered Acu-point [39.8% (169/425)], the method for acupuncture stimulation [32.4% (138/425)], the instrumental needle type [29.6% (126/425)], needling keep-in time [34.1% (145/425)], unit number for acupuncture therapy [22.4% (95/425)], therapeutic frequency, and the timing of each acupuncture scheme/regimen [38.1% (162/425)]. Among the countries of recruitment in these platforms, China represented 1.6% (3/187), 34.8% (65/187), 10.7% (20/187), 8.0% (15/187), 39.6% (74/187), 29.4% (55/187), 17.1% (32/187), 16.0% (30/187), and 32.1% (60/187), respectively. Fewer trials reported other details of the acupuncture intervention. For example, only 11.8% (50/425) of the trials reported anchoring depth, 8.9% (38/425) reported if a somatic response was triggered (such as specific self-sensual response from a receiver), and 4.9% (21/425) reported the number of needles. The manipulation in these registered
### Table 2: The WHO Trial Registration Data Set (TRDS).

| 20 items                                      | ANZCTR | ChiCTR | CRIS | ClinicalTrials.gov | CTRI | RPCEC | DRKS | IRCT | ISRCTN.org | JPRN | PAC-TR | SLCTR | NTR | ReBec | EU-CTR | TCTR |
|-----------------------------------------------|--------|--------|------|---------------------|------|-------|------|------|-------------|------|--------|-------|-----|-------|--------|------|
| Primary register and trial IDb                | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Date of registration in primary registry      | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Secondary IDb                                 | Y      | Y      | Y    | Y                   | Y    | Y     | N    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Source(s) of monetary or material support    | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Primary sponsor                               | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Secondary sponsor(s)                          | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Contact for public queries                    | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Contact for scientific queries                | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Public title                                  | Y      | Y      | Y    | Y                   | Y    | N     | N    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Scientific title                              | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Countries of recruitment                      | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Health condition(s) or problem(s) studied     | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Intervention(s)                               | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Key inclusion and exclusion criteria          | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Study type                                    | Y      | Y      | Y    | Y                   | Y    | Y     | N    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Date of first enrollment                      | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Target sample size                            | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Recruitment status                            | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Primary outcome(s)                            | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| Key secondary outcomes                        | Y      | Y      | Y    | Y                   | Y    | Y     | Y    | Y    | Y           | Y    | Y      | Y     | Y   | Y     | Y      | Y    |
| The other trial registration items | ANZCTR | ChiCTR | CRIS | Clinical Trials.gov | CTRI | DRKS | IRCT | ISRCTN.org | JPRN | PAC-TR | NTR | ReBec | TCCTR |
|-----------------------------------|--------|--------|------|---------------------|------|------|------|-------------|------|--------|-----|--------|------|
| Last updated date                 | N      | Y      | N    | Y                   | Y    | N    | N    | N           | Y    | N      | Y   | Y      | Y    |
| Estimated primary completion date | Y      | N      | Y    | Y                   | N    | N    | N    | N           | Y    | Y      | Y   | Y      | Y    |
| Estimated completion date         | Y      | Y      | Y    | Y                   | Y    | N    | Y    | N           | Y    | Y      | N   | Y      | N    |
| Actual date last participant enrolled | Y    | N      | Y    | N                   | N    | Y    | N    | Y           | Y    | Y      | N   | N      | N    |
| Current outcome measures          | N      | Y      | N    | N                   | Y    | N    | Y    | N           | Y    | N      | N   | N      | N    |
| Outcome time point                | Y      | Y      | Y    | N                   | N    | N    | N    | Y           | N    | Y      | N   | Y      | N    |
| Reason abandoned                  | N      | N      | N    | N                   | N    | N    | N    | Y           | N    | N      | N   | N      | N    |
| Public acronym                    | N      | N      | N    | N                   | N    | N    | N    | N           | N    | N      | N   | N      | N    |
| Trial acronym                     | Y      | N      | Y    | N                   | N    | Y    | Y    | Y           | N    | Y      | N   | N      | N    |
| Brief summary                     | Y      | N      | Y    | Y                   | Y    | Y    | Y    | Y           | N    | Y      | N   | N      | N    |
| Detailed description              | Y      | N      | Y    | Y                   | Y    | N    | N    | N           | Y    | Y      | Y   | Y      | Y    |
| Additional inclusion criteria     | N      | N      | N    | N                   | N    | Y    | N    | Y           | N    | Y      | N   | N      | N    |
| Actual sample size                | Y      | Y      | N    | N                   | N    | N    | N    | N           | Y    | N      | N   | N      | N    |
| Gender                            | Y      | Y      | Y    | Y                   | Y    | Y    | Y    | Y           | Y    | N      | N   | Y      | Y    |
| Age                               | N      | N      | Y    | N                   | N    | N    | N    | Y           | N    | Y      | N   | N      | N    |
| Minimum age                       | Y      | Y      | N    | Y                   | N    | Y    | Y    | N           | Y    | Y      | N   | Y      | Y    |
| Maximum age                       | Y      | Y      | N    | Y                   | N    | Y    | Y    | N           | Y    | Y      | N   | Y      | Y    |
| Accept healthy volunteers         | Y      | N      | Y    | Y                   | N    | N    | N    | N           | N    | N      | N   | N      | N    |
| Condition category                | Y      | N      | N    | N                   | Y    | N    | Y    | N           | N    | N      | N   | N      | N    |
| Condition code                    | Y      | Y      | N    | N                   | N    | Y    | Y    | N           | N    | N      | N   | N      | N    |
| Removed location countries        | N      | N      | N    | Y                   | N    | Y    | N    | Y           | N    | N      | N   | N      | N    |
| Study design                      | N      | Y      | N    | N                   | N    | Y    | N    | Y           | N    | N      | N   | N      | N    |
| Allocation                        | Y      | N      | Y    | N                   | N    | Y    | N    | N           | Y    | Y      | N   | Y      | Y    |
| Blinding                          | Y      | Y      | Y    | Y                   | Y    | Y    | Y    | Y           | Y    | Y      | Y   | Y      | Y    |
| Who is blinded                    | Y      | Y      | Y    | Y                   | N    | N    | N    | N           | N    | N      | N   | N      | N    |
| Allocation concealment procedures | Y      | N      | N    | N                   | Y    | N    | N    | N           | Y    | Y      | N   | N      | N    |
| Sequence generation               | Y      | Y      | N    | N                   | N    | N    | N    | N           | Y    | N      | N   | N      | N    |
| Randomization                     | N      | N      | N    | Y                   | N    | Y    | N    | N           | Y    | N      | N   | N      | N    |
| Intervention model                | Y      | Y      | Y    | Y                   | N    | Y    | N    | N           | Y    | N      | N   | N      | N    |
| Intervention type                 | N      | Y      | N    | N                   | N    | N    | N    | N           | Y    | N      | N   | N      | N    |
| Purpose                           | Y      | Y      | Y    | Y                   | N    | N    | N    | N           | Y    | N      | N   | Y      | Y    |
| Assignment                        | Y      | N      | Y    | Y                   | N    | Y    | N    | N           | Y    | N      | N   | Y      | Y    |
| Phase                             | Y      | Y      | Y    | Y                   | Y    | Y    | Y    | Y           | Y    | N      | N   | Y      | Y    |
| Drug names                        | N      | N      | N    | N                   | N    | Y    | Y    | Y           | N    | N      | N   | N      | N    |
| Comparator/control treatment      | Y      | N      | N    | N                   | N    | N    | Y    | N           | Y    | Y      | N   | N      | N    |
| Other design features             | Y      | N      | N    | N                   | N    | N    | Y    | N           | N    | N      | N   | N      | N    |
| Study Arm (s)                     | Y      | Y      | Y    | Y                   | Y    | N    | N    | N           | Y    | Y      | N   | N      | N    |
| Number of Arms                    | N      | N      | Y    | N                   | N    | N    | N    | N           | Y    | N      | N   | N      | N    |
| Publications                      | Y      | N      | Y    | Y                   | Y    | N    | N    | N           | Y    | N      | N   | N      | N    |
| Information provided by           | N      | Y      | Y    | Y                   | N    | N    | Y    | N           | N    | N      | N   | N      | N    |
| Other related information         | Y      | N      | N    | N                   | N    | N    | Y    | N           | Y    | N      | N   | N      | N    |
| Ethics application status         | Y      | N      | Y    | N                   | N    | N    | Y    | N           | Y    | N      | N   | N      | N    |
| Ethic committee information       | Y      | Y      | N    | Y                   | Y    | N    | N    | Y           | N    | N      | N   | N      | N    |
| Data monitoring committee         | N      | N      | Y    | N                   | N    | N    | N    | N           | N    | N      | N   | N      | N    |
| Change history                    | N      | N      | Y    | N                   | N    | N    | N    | N           | N    | N      | N   | N      | N    |
Table 4: The number of clinical trials of acupuncture-moxibustion in WHO ICTRP.

| Category             | Characteristic                          | Number of 𝑛 = 425 (%) |
|----------------------|-----------------------------------------|-----------------------|
| Register time (year) |                                        |                       |
| 2013                 |                                        | 124                   |
| 2014                 |                                        | 123                   |
| 2015                 |                                        | 178                   |
| Study type           | Intervention study                      | 379                   |
|                      | Observation study                       | 14                    |
|                      | Others                                  | 32                    |
| Study design         | With control group                      | 374                   |
|                      | Sham acupuncture in control group       | 164                   |
|                      | Acupuncture versus nonacupuncture (e.g., pharmacologic treatment, physiotherapy) | 163                   |
|                      | The other treatment program              | 97                    |
| Countries of recruitment |                                    |                       |
| China                |                                        | 187*                  |
| United States        |                                        | 50                    |
| Korea                |                                        | 47                    |
| Other Countries      |                                        | 120                   |
| Unclear              |                                        | 21                    |
| Sample size          | Maximum/minimum                         | 1000/4                |
* Including Hongkong and Taiwan.

Table 5: The number of clinical trials of acupuncture-moxibustion in 16 countries in WHO ICTRP.

| Platform          | Countries/district      | Internet site                          | The number of clinical trials in acupuncture | The number of clinical trials in moxibustion | The others | Total number |
|-------------------|-------------------------|----------------------------------------|----------------------------------------------|---------------------------------------------|------------|--------------|
| Clinical Trials.gov | United States          | http://www.clinicaltrials.gov/         | 178 (176 + 2* )                               | 3 (1 + 2*)                                  | 22         | 201          |
| ChiCTR            | China                   | http://www.chictr.org.cn/              | 99                                           | 3                                           | 4          | 106          |
| CRIS              | Kore                    | http://cris.nih.go.kr/                 | 28 (27 + 1* )                                 | 2 (1 + 1*)                                  | 1          | 30           |
| IRCT              | Iran                    | http://www.irct.ir/                    | 13                                           | 0                                           | 8          | 21           |
| ANZCTR            | Australia/New Zealand   | http://www.anzctr.org.au/              | 8                                            | 0                                           | 4          | 12           |
| ISRCTN.org        | United Kingdom          | http://www.isrctn.org/                 | 16                                           | 0                                           | 1          | 17           |
| JPRN              | Japan                   | http://rctportal.niph.go.jp/           | 16 (14 + 2* )                                 | 4 (1 + 2*)                                  | 0          | 18           |
| DRKS              | Germany                 | http://www.germanctr.de/               | 4                                            | 0                                           | 1          | 5            |
| ReBec             | Brazil                  | http://www.ensaisoclinicos.gov.br/     | 5                                            | 0                                           | 1          | 6            |
| TCTR              | Thailand                | http://www.clinicaltrials.in.th/       | 6                                            | 0                                           | 0          | 6            |
| NTR               | Netherlands             | http://www.trialregister.nl/           | 1                                            | 0                                           | 0          | 1            |
| PAC-TR            | Africa                  | http://www.pactr.org/                  | 1                                            | 0                                           | 0          | 1            |
| CTRI              | India                   | http://www.ctri.nic.in/                | 1                                            | 0                                           | 0          | 1            |
| **Total**         |                         |                                        |                                              |                                             |            | 425          |
* Report both acupuncture and moxibustion in titles.

Among the 425 trials, 164 (38.59%) trials used sham acupuncture as a control, but specific information, such as the application materials (0.61%, 1/164), needle stimulation (14.02%, 23/164), depth of insertion (11.59%, 19/164), and needle retention time (0.61%, 1/164), was reported at a low rate; 61 (32.70%) trials did not report any details about the sham acupuncture (Table 9).
4. Discussion

4.1. Current Status of the Registration Information in the WHO ICTRP. In this overview, we have compared the registry items of the 16 clinical centers that were designated according to the recommendations of the WHO ICTRT. Generally, the minimum 20 items in the WHO TRDS were followed; however, information outside of these 20 items varied widely between different countries. The main information reported was a brief summary, purpose, trial completion time (registry update date, time to trial termination), methodologic details (inclusion criteria, age of the subjects, study phase, and design including groups/distribution/blinding of subjects and blinded groups/interventions/drug names), and other information (dropouts, ethical issues, data monitoring committee, and updates on important information).

4.2. Deficiencies in the Characteristics of Clinical Trials of Acupuncture and Moxibustion Registered in the ICTRP. Acupuncture and moxibustion are a core part of traditional Chinese medicine and are also very important in complementary and alternative medicine. Compared with surgery and other modern medical interventions, acupuncture and moxibustion are characterized by obvious differences. To standardize clinical study reporting on acupuncture and moxibustion, STRICTA and STRICTOM (Standards for Reporting Interventions in Clinical Trials of Moxibustion) have been issued as an extended section in the CONSORT statement [17–19]. Six criteria have been set as STRICTA items: acupuncture rationale, details of needling, treatment regimen, other components of treatment, practitioner background, and control or comparator interventions [17]. In this study, a data extraction form was designed based on the STRICTA to collect and analyze the registration information. As the results indicated, necessary information, such as instrumental needle type, name of points used, depth of insertion, method of needle stimulation, needle retention time, response sought, and treatment sessions, was incompletely reported (less than 40% according to our analysis). However, this information needs to be described in detail because it is an important component of integrative therapy, directly influencing the authenticity and reliability of studies.

Controlled studies are fundamental to assessing effects in clinical trials. The purpose of controlled studies is to minimize confounding factors and provide a reliable, cogent conclusion. Because of their unique manipulation process, acupuncture and moxibustion have encountered difficulties in developing and validating placebo needles as appropriate controls [20]. Researchers designate sham acupuncture as a control group, such as sham treatment with invasive skin or needling at inappropriate points or at nonacupuncture points, needling with blunt needles, sham laser, and sham electroacupuncture [16, 21–24]. However, the rationale for these simulation designs and their anticipated placebo-effect is closely related to conscientious pseudo-manipulation and, consequently, rigid implementation. Detailed reports are needed about sham acupuncture materials, sham-acupoint, or locations without standard names, manipulation methods, and procedures (stimulation methods, depth of insertion). Moreover, the rationale for sham-needling or its purported placebo-effect should also be explained; otherwise, the reader of the study cannot comprehend or be persuaded to trust the sham-needling maneuvers to enhance the accuracy of measuring intervention effectiveness. Among the 164 trials reporting the use of sham acupuncture, some necessary information such as materials, stimulation methods, depth of insertion, and duration are not available because of the low incidence of reporting.

The reporting rate of the characteristics of acupuncture and moxibustion in the WHO ICTRP for both Chinese and clinical trials and those from other countries was low. The reasons may be as follows: (1) all 16 clinical trials registry centers were founded based on the mode or convention of Western-medicine-oriented registry format design, which may not have sufficiently considered the characteristics/specifications of acupuncture and moxibustion; (2) clinical trials reported and delineated acupuncture interventions in a meticulous manner, and completing registration information was done with little detail; (3) the inclusion and exclusion criteria for the clinical trials, such as the PICO, have not been included.

| Condition focused on in the studies | Acupuncture | Moxibustion | The others | Total number |
|------------------------------------|-------------|-------------|------------|--------------|
| Pain                               | 75          | 1           | 6          | 82           |
| Cancer                             | 28          | 0           | 3          | 31           |
| Stroke                             | 17 (16 + 1<sup>∗</sup>) | 1<sup>∗</sup> | 0          | 17           |
| Arthritis                          | 11          | 0           | 4          | 15           |
| Depression                         | 11          | 0           | 2          | 13           |
| Insomnia                           | 11          | 0           | 0          | 11           |
| Polycystic ovarian syndrome        | 9           | 0           | 1          | 10           |
| Obesity                            | 7           | 0           | 2          | 9            |
| Hypertension                       | 6           | 0           | 1          | 7            |
| The others                         | 208 (202 + 6<sup>∗</sup>) | 11 (5 + 6<sup>∗</sup>) | 24 | 237 |
| **Total**                          | **376**     | **6**       | **43**     | **425<sup>∗</sup>** |

<sup>∗</sup>Report both acupuncture and moxibustion in titles. <sup>∗</sup>Seven trials with 2 diseases in titles (2 with pain + cancer, 2 with cancer + insomnia, 2 with stroke + depression, 2 with depression + insomnia).

Table 6: The condition focus on in the trails in ICTRP.
Table 7: The characteristic information of clinical trials of acupuncture-moxibustion in WHO ICTRP.

| Platform                  | Number of needle insertions per subject per session (mean and range where relevant) $n$ (%) | Names (or location if no standard name) $n$ (%) | Depth of insertion, based on a specified unit of measurement, or on a particular tissue level $n$ (%) | Response sought (e.g., de qi or muscle twitch response) $n$ (%) | Needle stimulation (e.g., manual, electrical) $n$ (%) | Needle retention time $n$ (%) | Needle type (diameter, length, and manufacturer or material) $n$ (%) | Number of treatment sessions $n$ (%) | Frequency and duration of treatment sessions $n$ (%) | Total number |
|---------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------|----------------------------------|-----------------|---------------------------------------------------|----------------|-----------------------------------------------|--------------|
| ANZCTR                    | 0                                                                                               | 5 (41.7)                                      | 0                                                                                               | 2 (16.7)                                         | 7 (58.3)                          | 7 (58.3)                     | 9 (75.0)                                         | 4 (33.3)       | 7 (58.3)                                      | 12           |
| ChiCTR                    | 2 (1.9)                                                                                         | 18 (170)                                      | 2 (1.9)                                                                                         | 4 (3.8)                                          | 35 (33.0)                         | 12 (11.3)                   | 5 (4.7)                                          | 6 (5.7)        | 9 (8.5)                                       | 106          |
| CRIS                      | 5 (16.7)                                                                                       | 23 (76.7)                                      | 6 (20.0)                                                                                       | 5 (16.7)                                         | 8 (26.7)                          | 16 (53.3)                   | 17 (56.7)                                        | 13 (43.3)      | 25 (83.3)                                     | 30           |
| ClinicalTrials.gov        | 12 (6.0)                                                                                       | 93 (46.3)                                      | 37 (18.4)                                                                                      | 23 (11.4)                                        | 75 (37.3)                         | 85 (42.3)                   | 82 (40.8)                                        | 56 (27.9)      | 90 (44.8)                                     | 201          |
| CT-RI                     | 0                                                                                               | 0                                             | 0                                                                                               | 0                                                | 0                                | 0                            | 0                                               | 0              | 0                                             |              |
| DRKS                      | 0                                                                                               | 0                                             | 0                                                                                               | 0                                                | 1 (20.0)                         | 1 (20.0)                    | 2 (40.0)                                         | 2 (40.0)       | 2 (40.0)                                      | 5            |
| ICRCT                     | 1 (4.8)                                                                                       | 11 (52.3)                                      | 1 (4.8)                                                                                       | 0                                                | 1 (4.8)                          | 11 (52.3)                   | 3 (14.3)                                         | 2 (9.5)        | 8 (38.1)                                      | 21           |
| ISRCTN.org                | 0                                                                                               | 9 (52.9)                                      | 4 (23.5)                                                                                       | 3 (17.6)                                         | 2 (II/8)                         | 5 (29.4)                    | 4 (23.5)                                         | 5 (29.4)       | 11 (64.7)                                     | 17           |
| JPRN                      | 0                                                                                               | 3 (16.7)                                      | 0                                                                                               | 0                                                | 6 (33.3)                         | 1 (5.6)                     | 0                                               | 2 (II.1)       | 2 (11.1)                                      | 18           |
| PAC-TR                    | 0                                                                                               | 0                                             | 0                                                                                               | 0                                                | 0                                | 0                           | 1 (100.0)                                       | 1 (100.0)      | 1 (100.0)                                     | 1            |
| SLCTR                     | 0                                                                                               | 0                                             | 0                                                                                               | 0                                                | 0                                | 0                           | 0                                               | 0              | 0                                             |              |
| NTR                       | 0                                                                                               | 0                                             | 0                                                                                               | 0                                                | 0                                | 0                           | 0                                               | 0              | 0                                             |              |
| ReBec                     | 1 (16.7)                                                                                       | 4                                             | 0                                                                                               | 0                                                | 2 (33.3)                         | 4 (66.7)                    | 1 (16.7)                                         | 4 (66.7)       | 4 (66.7)                                      | 6            |
| EU-CTR                    | 0                                                                                               | 0                                             | 0                                                                                               | 0                                                | 0                                | 0                           | 0                                               | 0              | 0                                             |              |
| TCTR                      | 0                                                                                               | 3 (50.0)                                      | 0                                                                                               | 1 (16.7)                                         | 1 (16.7)                         | 2 (33.3)                    | 3 (50.0)                                         | 0              | 2 (33.3)                                      | 6            |
| **Countries of recruitment** | **China**                                                                                  | **65 (34.8)**                                 | **20 (10.7)**                                     | **15 (8.0)**                                     | **74 (39.6)**                     | **55 (29.4)** | **32 (17.1)**                                   | **30 (16.0)**  | **60 (32.1)**                                  | **187**       |
|                           | **United States**                                                                               | **14 (28.0)**                                 | **2 (4.0)**                                      | **1 (2.0)**                                      | **11 (22.0)**                     | **13 (26.0)** | **23 (46.0)**                                   | **17 (34.0)**  | **21 (42.0)**                                  | **50**        |
|                           | **Korea**                                                                                      | **36 (76.6)**                                 | **12 (25.5)**                                     | **8 (17.0)**                                     | **17 (36.2)**                     | **25 (53.2)** | **25 (53.2)**                                   | **18 (38.3)**  | **35 (76.6)**                                  | **47**        |
|                           | **Other countries**                                                                             | **43 (35.8)**                                 | **12 (10.0)**                                     | **10 (8.3)**                                     | **30 (25.0)**                     | **41 (34.2)** | **38 (31.7)**                                   | **26 (21.7)**  | **37 (30.8)**                                  | **120**       |
|                           | **Unclear**                                                                                    | **11 (52.4)**                                 | **4 (19.0)**                                      | **4 (19.0)**                                     | **6 (28.6)**                      | **11 (52.4)** | **8 (38.1)**                                    | **4 (19.0)**   | **9 (42.9)**                                   | **21**        |
| **Total**                 | **21 (4.9)**                                                                                   | **169 (39.8)**                                | **50 (11.8)**                                     | **38 (8.9)**                                     | **138 (32.5)**                    | **145 (34.1)** | **126 (29.6)**                                  | **95 (22.4)**  | **162 (38.1)**                                 | **425**       |

*Including Hongkong and Taiwan.
Table 8: The information in acupuncture-moxibustion in detail about acupuncture manipulation/needle type.

| Platform     | Acupoint | Acupressure | Acupuncture | Auricular acupuncture | Auricular acupuncture | Battlefield acupuncture | Dry cupping | Dry needling | Electrical stimulation | Electroacupuncture | Heat therapy | Laser acupuncture | moxibustion | Pharmacological acupuncture |
|--------------|----------|-------------|-------------|-----------------------|----------------------|-------------------------|-------------|-------------|------------------------|-------------------|--------------|-----------------------|------------|------------------------|
| ANZCTR       | 0        | 0           | 3           | 0                     | 0                    | 0                       | 0           | 0           | 0                      | 3                | 1            | 3                     | 0          | 0                      |
| ChiCTR       | 5        | 2           | 64          | 0                     | 0                    | 0                       | 0           | 0           | 0                      | 30               | 0            | 2                     | 3          | 0                      |
| CRIS         | 0        | 0           | 22          | 0                     | 0                    | 0                       | 0           | 0           | 0                      | 5                | 0            | 1                     | 2          | 0                      |
| ClinicalTrials.gov | 0  | 7           | 102         | 2                     | 9                    | 3                       | 0           | 16          | 0                      | 43               | 2            | 11                    | 2          | 1                      |
| CTRI         | 0        | 1           | 0           | 0                     | 0                    | 0                       | 0           | 0           | 0                      | 0                | 0            | 0                     | 0          | 0                      |
| RPCEC        | 0        | 0           | 0           | 0                     | 0                    | 0                       | 0           | 0           | 0                      | 0                | 0            | 0                     | 0          | 0                      |
| DRKS         | 0        | 0           | 2           | 0                     | 2                    | 0                       | 0           | 0           | 0                      | 0                | 0            | 1                     | 0          | 0                      |
| IRCT         | 0        | 6           | 10          | 2                     | 0                    | 2                       | 0           | 0           | 1                      | 0                | 0            | 0                     | 0          | 0                      |
| ISRCTN.org   | 0        | 1           | 13          | 0                     | 1                    | 0                       | 0           | 0           | 0                      | 2                | 0            | 0                     | 0          | 0                      |
| JPRN         | 0        | 0           | 9           | 0                     | 0                    | 0                       | 0           | 0           | 6                      | 0                | 0            | 0                     | 3          | 0                      |
| PAC-TR       | 0        | 0           | 0           | 0                     | 0                    | 0                       | 0           | 0           | 0                      | 0                | 0            | 1                     | 0          | 0                      |
| SLCTR        | 0        | 0           | 0           | 0                     | 0                    | 0                       | 0           | 0           | 0                      | 0                | 0            | 0                     | 0          | 0                      |
| NTR          | 0        | 0           | 1           | 0                     | 0                    | 0                       | 0           | 0           | 0                      | 0                | 0            | 0                     | 0          | 0                      |
| ReRec        | 0        | 1           | 1           | 0                     | 1                    | 0                       | 0           | 0           | 3                      | 0                | 0            | 0                     | 0          | 0                      |
| EU-CTR       | 0        | 0           | 0           | 0                     | 0                    | 0                       | 0           | 0           | 0                      | 0                | 0            | 0                     | 0          | 0                      |
| TCTR         | 0        | 0           | 3           | 0                     | 0                    | 0                       | 0           | 2           | 0                      | 1                | 0            | 0                     | 0          | 0                      |
| Total        | 5        | 18          | 229         | 2                     | 15                   | 3                       | 2           | 20          | 0                      | 96               | 3            | 18                    | 13         | 1                      |
Table 9: The information about sham acupuncture in control group in register clinical trials of acupuncture-moxibustion.

| Platform                      | Acupuncture versus the other interventions without acupuncture (e.g., drugs and physiotherapy) | Acupuncture versus the other interventions (e.g., different acupuncture method) | Acupuncture versus sham acupuncture | Names of points | Material | Stimulation approach | Depth of insertion | Duration of treatment sessions | No related information |
|-------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------|----------------|----------|---------------------|------------------|-----------------------------|---------------------|
| ANZCTR                        | 3                                                                                | 3                                                                           | 6                                  | 0              | 0        | 0                   | 0                | 0                           | 6                   |
| ChiCTR                        | 41                                                                               | 16                                                                          | 49                                 | 20             | 0        | 8                   | 0                | 0                           | 21                  |
| CRIS                          | 12                                                                               | 9                                                                           | 9                                  | 2              | 0        | 0                   | 1                | 0                           | 6                   |
| Clinical Trials.gov          | 81                                                                               | 46                                                                          | 74                                 | 23             | 1        | 13                  | 15               | 0                           | 22                  |
| CTRI                          | 1                                                                                | 0                                                                           | 0                                  | 0              | 0        | 0                   | 0                | 0                           | 0                   |
| RPCEC                         | 0                                                                                | 0                                                                           | 0                                  | 0              | 0        | 0                   | 0                | 0                           | 0                   |
| DRKS                          | 1                                                                                | 3                                                                           | 1                                  | 0              | 0        | 0                   | 0                | 0                           | 1                   |
| IRCT                          | 11                                                                               | 2                                                                           | 8                                  | 7              | 0        | 0                   | 0                | 1                           | 0                   |
| ISRCTN.org                    | 4                                                                                | 6                                                                           | 7                                  | 5              | 0        | 0                   | 1                | 0                           | 1                   |
| JPRN                          | 3                                                                                | 8                                                                           | 7                                  | 2              | 0        | 2                   | 0                | 0                           | 3                   |
| PAC-TR                        | 1                                                                                | 0                                                                           | 0                                  | 0              | 0        | 0                   | 0                | 0                           | 0                   |
| SLCTR                         | 0                                                                                | 0                                                                           | 0                                  | 0              | 0        | 0                   | 0                | 0                           | 0                   |
| NTR                           | 0                                                                                | 0                                                                           | 1                                  | 0              | 0        | 0                   | 1                | 0                           | 0                   |
| ReBec                         | 3                                                                                | 1                                                                           | 2                                  | 0              | 0        | 0                   | 1                | 0                           | 1                   |
| EU-CTR                        | 0                                                                                | 0                                                                           | 0                                  | 0              | 0        | 0                   | 0                | 0                           | 0                   |
| TCTR                          | 2                                                                                | 4                                                                           | 0                                  | 0              | 0        | 0                   | 0                | 0                           | 0                   |
| **Countries of recruitment**  |                                    |                                                                              |                                    |                |          |                     |                  |                             |                     |
| China                         | 63                                                                               | 31                                                                          | 78                                 | 32             | 1        | 12                  | 2                | 0                           | 31                  |
| United States                 | 20                                                                               | 18                                                                          | 12                                 | 5              | 0        | 1                   | 3                | 0                           | 3                   |
| Korea                         | 22                                                                               | 9                                                                           | 16                                 | 5              | 0        | 2                   | 1                | 0                           | 8                   |
| Other countries               | 49                                                                               | 38                                                                          | 49                                 | 14             | 0        | 8                   | 8                | 1                           | 18                  |
| Unclear                       | 9                                                                                | 2                                                                           | 9                                  | 3              | 0        | 0                   | 5                | 0                           | 1                   |
| **Total**                     | 163                                                                              | 98                                                                          | 164                                | 59             | 1        | 23                  | 19               | 1                           | 61                  |
in the registration forms even though they might be well described in the trial protocols because of the limitation of the module in clinical register platform.

To summarize, some necessary information may have been missed in the registered clinical trials. This implies that steps of the registration process may not have been highly valued and, consequently, led to deficiencies in these reports.

4.3. Considerable Work Needs to Be Done to Improve Methodological and Reporting Quality of Acupuncture and Moxibustion Clinical Trials. As developments in clinical epidemiology and evidence-based medicine continue, some methods of interventional investigation to guide clinical practice have been modified updated into more incisive study designs. Clinical studies in acupuncture and moxibustion have been affected by the introduction of some clinical study methods, as demonstrated by the increased number of trials and the reporting quality; although there was steady progress, some remarkable redirected attention could be identified.

However, problems in practice and in studies inhibit substantial improvement and adaptation to modern medicine. Overall, rigidly controlled studies resulting in a highly credible publication comprised only a small number of the total [6]. Second, many trials have deficiencies and deviate from the clinical study methodology, even these that were labelled as systematic assessments and randomized controlled trials. Specific examples include lack of statistical calculation of sample size, incomplete analysis of baseline data, fragmented reporting on follow-up, or insufficiently scheduled visits, which can seriously undermine the reliability of clinical evidentiary studies [25]. Third, there are still large gaps between the clinical evidence and the clinical practice of acupuncture and moxibustion.

Therefore, a challenging and long-term goal to be undertaken is promoting the standardization of acupuncture and moxibustion clinical trial registries. The current principles and guidelines of institutions for clinical registration trials are skewed in favor of western medical drugs or surgical interventions, ignoring the special characteristics of acupuncture and moxibustion, which are founded on the Meridian-Collateral Theory.

The Acupuncture-Moxibustion Clinical Trials Registry (AMCTR), making the second-tier of the WHO ICTRP, has been established to regulate clinical trials of acupuncture and moxibustion [26]. This registry center will be obliged to improve the global mechanism, promote data collection, facilitate data sharing, regulate specific trial studies, and assure publicized honesty and integrity of acupuncture and moxibustion studies. It will also provide a registry service in Chinese regions, as well as for worldwide interest.

4.4. Limitations. Limitations include the following: (1) the study was only based on data collection from 2013 to 2015 from the WHO ICTRP register trials in acupuncture and moxibustion; (2) the main focus is on registering information from designated sources instead of acquiring specific study protocols; and (3) incomplete information from these registries could influence the results.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this article.

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