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The history of controlled clinical trials in China. Part 1: from the advent of clinical trials through the conduct of single-centre or small-sample RCTs

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From the mid-20th century, randomised controlled trials (RCTs) rose to become the gold standard for evaluating therapeutic efficacy throughout much of the world, despite occasional criticism.[1,2] Especially towards the end of the 20th century, the development of 'evidence-based medicine' elevated RCTs to the top of the evidence hierarchy.[3,4] Initially prevalent in Western countries such as the United Kingdom and the United States, RCTs gradually extended their influence into diverse domains, encompassing social sciences, economics, technology and policy interventions.[5] The methodology of RCTs did not materialise overnight but evolved over time, incorporating elements such as control groups (including through alternate allocation, prior to the advent of randomisation), methods to mitigate multiple forms of bias, statistical innovations to enable the demonstration of efficacy, and considerations of ethics.[5,6]

Over the past 75 years, the principles and methods of RCTs have been disseminated worldwide. However, the circumstances concerning how and when RCTs were initially conducted and disseminated in mainland China, as well as their impact on clinical decision-making, remain largely unexplored. Examining this in detail – amid such contexts as China's unique political, social and cultural history throughout the 20th century, the complicated and evolving relationship between China and the West (including the former British colony of Hong Kong), the complicated relationship between Traditional Chinese Medicine (TCM) and Western medicine over the course of the 20th century, and the development of China's own pharmaceutical industries, hospitals, medical journals and medical schools – would represent a field of study in itself. We thus offer here what we hope is a useful starting-point.

More recent reviews related to the advent and history of clinical trials in mainland China – often grounded in extensive empirical work – have been extraordinarily valuable to our own work here.[7–10,a] Building on this, an examination of the existing historiography, combined with newly available (and extensive) full-text searching of Chinese medical journals, affords an overview of the advent of clinical trials and research ethics in China.

In Part 1, we begin with a brief account concerning the pre-RCT era, and then trace the scattered RCTs in the 1960s that were followed by more robust expansion from the late 1970s (after the Cultural Revolution) onward, amidst enduring introspection concerning the conduct of clinical trials. In Part 2, we will turn to the large-scale multicentre RCTS that, starting from the early 1990s, began to be conducted in mainland China.

Clinical trials in China prior to the advent of RCTs

Existing historiography points to scattered pre-1949 attempts at clinical trials in China. Most famously, in the 11th century (Song Dynasty in 1061), the Atlas of Materia Medica (Ben Cao Tu Jing), the earliest documented Chinese government-organised pharmacopeia, documented a controlled trial to evaluate the efficacy of ginseng.[11] It was mentioned that in order to evaluate the effect of genuine Shangdang ginseng, two individuals were asked to run together. One was given ginseng, while the other ran without it. After running for approximately three to five li (equivalent to 1500 to 2500 m), the one without the ginseng

developed severe shortness of breath, while the one who took the ginseng breathed evenly and smoothly. It is not known where the idea of a controlled experiment using individuals originated in Ancient China, but it may have reached China through the Silk Road from Persia.[12]

In the early 20th century, amid larger efforts to reduce plague mortality in Hong Kong, as well as tensions between TCM and Western medicine, Henry Blake, the Governor of Hong Kong from 1898 to 1904, made a rough comparison of patients with plague receiving TCM with others receiving Western medicine. During a defined period of observation, 25 patients were treated with TCM, with 21 deaths. This was deemed largely equivalent to cases of 'Chinese' patients treated during the same time period (with careful attention given to making such a comparison across the same time period, in an attempt to render the groups comparable) at a Western hospital established in Hong Kong, with an 86.2% mortality rate. Although Blake was aware that the numbers in the trial were too small to afford a sound basis for scientific comparison, he considered it noteworthy that there was a miniscule difference in mortality rate between the two realms of treatment.[13,14,b]

The advent of RCTs in Mainland China (1950s–1960s)

In the sparse existing historiography, there is still no consensus regarding when an RCT was first developed and published in China. Some researchers have stated that controlled trials involving TCM were reported in the late 1950s or early 1960s, though specific articles were not cited by them.[15] Others have noted (again, without directly citing the relevant articles) that the first Western medicine RCT developed and published in China was attributed to Delong Su (likely related to schistosomiasis or what was then considered 'paracholera'[c]) in the early 1960s.[16–19] We have not yet found a published RCT to support this claim,[d] though Delong Su would clearly be regarded as one of the pioneers in clinical epidemiology in China,[20] and in 1962 published on the concepts, methods and significance of RCTs in an article titled 'Clinical trial design (临床实验设计)' in the *National Medical Journal of China*.[21,e]

Xuezhang Zhou et al. from the Jiaxing Institute for the Prevention and Treatment of Schistosomiasis, however, *do* appear to have conducted several clinical trials with components of randomisation concerning the treatment of schistosomiasis during this period. During the summer and fall of both 1962 and 1963, they divided 66 patients with moderate to severe acute schistosomiasis into one of two groups through a 'random sampling method'.[f] The patients were treated with the anti-parasitic furapromidium versus a combination of an adrenocortical hormone (prednisone) and antimony potassium tartrate.[g] The trial result was published in abstract form in 1965 in the *National Medical Journal of China*.[22] In parallel, between 1961 and 1963, Zhou et al. conducted a controlled trial involving 250 cases of children with acute schistosomiasis. To compare the efficacy of furapromidium with that of prednisone combined with antimony potassium tartrate, 200 cases were treated with furapromidium alone, while another 50 cases were randomly divided into two groups. One group received furapromidium (25 cases), and the other group received prednisone combined with antimony potassium tartrate (25 cases). The results, published in 1965 in the *Chinese Journal of Internal Medicine*, demonstrated that furapromidium had a significantly greater antipyretic effect than prednisone combined with antimony potassium tartrate.[23]

At the same time, tuberculosis researchers, often engaged with Western literature (e.g., from the United States and Great Britain), served to pioneer the use of RCTs in mainland China.[24] In 1963, Shi Wang et al.[25] from the First Tuberculosis Hospital of Shanghai published a relatively large RCT to clarify the efficacy of three commonly used treatment regimens (isoniazid only, isoniazid combined with streptomycin (SM), and isoniazid combined with para-aminosalicylic acid (PAS)). Their report outlined their allocation method, whereby a physician unaware of the patient's conditions used randomisation. Patients were arranged in order of hospital admission numbers, with every three patients forming a small group. The group assignments were then determined according to the sequence of Fisher random number tables. The primary outcomes measured changes in sputum bacteria, and cavity resolution and lesion evolution (as seen on X-ray). The total number of participants in the trial was 151, with 135 patients included in the actual analysis (16 patients were excluded, including 11 with primary drug-resistant bacteria, 3 who left the trial against medical advice and 2 who were determined not to have tuberculosis). The results showed that sputum conversion to negative was optimal when using isoniazid plus SM, followed in order of efficacy by isoniazid plus PAS.

Single-centre or small-sample RCTs (post-cultural revolution to the mid-1990s)

During the Cultural Revolution (1966–1976), we find a gap concerning RCTs, in an era in which many

medical research institutions stopped scientific activities or were disbanded.[26] Most clinical trials were forcibly terminated,[19] and medical journals suffered severe devastation (with the number of officially published journals decreasing from 790 in 1965 to 20 in 1969).[27] Thereafter, the late 1970s and early 1980s appear as a critical inflection point for the increasing recognition in China of the utility of RCTs. At the end of 1979, Kerr White, who, as Deputy Director for Health Sciences at the Rockefeller Foundation, initiated the International Clinical Epidemiology Network (INCLEN), wrote to the Chinese Ministry of Health, inviting Delong Su to give a two-week international clinical epidemiology workshop at the University of Cambridge in the United Kingdom in September 1980.[28,29] Moreover, three senior clinical medicine professors from China were invited to participate and enhance their knowledge. One of the participating professors, Decheng Luo from the West China University of Medical Sciences, reported that he 'deeply recognized that if every clinician involved in research could grasp clinical epidemiology, it would undoubtedly accelerate the improvement of the quality of clinical practice, research, and teaching'.[28]

At the same time, other researchers have stated that the early phase of TCM RCTs in particular in China began in the early 1980s,[9,10] with the first 'rigorously-designed' RCT in the field of TCM published in 1982.[30] This study, conducted from August 1980 to August 1981 and published in the *Chinese Journal of Cardiology*, was titled 'The therapeutic effect of purified coronary heart II tablets on 112 cases of angina pectoris by double blind method' and led by Keji Chen from the Xiyuan Hospital attached to the Academy of TCM, with co-authors from Fuwai Hospital of the Chinese Academy of Medical Sciences, Beijing Tongren Hospital and Beijing Tongrentang pharmaceutical company. However, the report lacked detailed explanations of the randomisation and blinding methods beyond mentioning that 'Clinical observations were carried out in two phases using a double-blind method', and that '112 selected cases were randomly divided into Groups A and B, and were treated by a double-blind method with crossover'.

The editor's note on this study serves as a useful indicator of contemporary thinking regarding the utility of rigorous comparisons, and the perceived limitations of contemporary studies. Indeed, such a tension between aspirations to rigour and expressions of critique would represent a recurring theme in the Chinese medical literature across TCM and Western medicine alike. As the editors commented:

> *This article was a well-designed study, highlighting the importance of rigorous comparisons in clinical data. They emphasized the need for credible comparisons to distinguish between true and false, better and worse, while acknowledging the challenges in achieving convincing comparisons in clinical practice.*[30]

Nevertheless, they noted that the double-blind controlled method used in this study still had some limitations. The observation of 112 cases was considered an insufficient sample size, and they recommended multicentre and repeated validation. From that point, RCTs of TCM continued to expand. Tang et al., extrapolating from an examination of 28 selected TCM journals, reported that from the early 1980s through the late 1990s, RCTs of TCM doubled in number every two to three years, yielding an estimated total of 7500 RCTs by 1996, compared with an estimated 2500 RCTs of 'conventional medicine'.[9]

The 1980s likewise represented a significant turning point for the formal discussion of clinical epidemiology and clinical research methodology (Design, Measurement, Evaluation, or DME) from Western countries, and public reflection on the need for investigational rigour and attempts to support such rigour.[28,31] In 1985, Honghao Zhou from the National Training Center for Clinical Pharmacology at Hunan Medical School published an article titled 'How to evaluate drug clinical trial reports'. In this article, Zhou proposed that the standards for evaluating a drug's clinical trial report should be its reliability and practicality. In Zhou's explanation, reliability referred to whether the trial results genuinely reflect the true state of affairs, which depended on the scientific nature of the experimental design and the rigor of patient observation and follow-up. Practicality pertained to whether the research results would have clinical applicability. The reliability of clinical trial results, according to Zhou, would depend first on whether controls were used and whether the participants were allocated according to the principles of randomisation.[32]

In 1986, Mengxuan Hu from Sun Yat-sen University highlighted the importance of effective clinical trial design in analysing and evaluating the therapeutic efficacy of a drug or treatment in clinical research.[33] Hu pointed out that promoting RCTs in China faced certain (though unspecified) 'difficulties',[h] and that well-designed trials were not yet prevalent. Hu also provided an evaluation of a study published in the *Chinese Journal of Neurology* in 1985, conducted by Hechun Luo et al. from the Institute of Mental Health at Beijing Medical College, titled 'Analysis of the therapeutic efficacy

of double-blind controlled electroacupuncture and amitriptyline in the treatment of depression'.[34] Hu noted several reasonable aspects of the trial's design, such as the inclusion of a control group, the use of random allocation principles (with drug dispensing randomised by the pharmacy), the application of double-blind methodology (where patients and doctors were unaware of whether the capsules contained amitriptyline or a placebo), and attention to observer bias and comparability. Additionally, appropriate statistical methods were employed. However, Hu also pointed out some limitations of the trial, such as the lack of specific details about the method of random grouping and the unequal distribution of cases among the groups.

In April 1989, under the direct leadership of the Chinese Ministry of Health, the first National Epidemiology/DME Academic Conference was held in Chengdu, initiated by West China Medical University and Shanghai Medical University. During this conference, the 'China Clinical Epidemiology Network (CHINACLEN)' was formally established, with participation from a total of 44 medical schools and related institutions.[31] Guowei Lin, from Huashan Hospital, affiliated with Shanghai Medical University, has emphasised that:

> *the establishment of CHINACLEN marked a significant milestone in the development of clinical epidemiology in China. This signified the organized and guided development of clinical epidemiology in China, and it was resolved that a national academic conference would be held every two years, along with an annual executive committee meeting.*[31,i]

David Sackett, one of the principal initiators of the International Clinical Epidemiology Network, not only participated in the first National Epidemiology/DME Academic Conference in Chengdu, but would also have a profound impact on the development of clinical epidemiology and evidence-based medicine in China.[35]

Amid such advances, critiques persisted. Zhufan Xie and Ning Li, from the Institute of Integration of Traditional Chinese and Western Medicine at the First Hospital of Beijing Medical University, conducted a methodological evaluation of therapeutic studies published in the *Chinese Journal of Integrative Traditional & Western Medicine* (*CJIM*) from 1982 to 1994.[15] They found that during this period, a total of 787 studies evaluating the efficacy of remedies were published, of which 310 were RCTs. Although the annual growth distribution of RCTs was not uniform, the percentage of RCTs increased from 11% in 1982 to 62% in 1994, covering 135 diseases and conditions, with RCTs for coronary heart disease being the most common. Xie and Li considered blinding to be an important factor in RCTs, but reported that no double-blind trials were documented in *CJIM* in 1982–1983. In 1984, the use of double-blinding was first reported in the examined RCTs, and only 23 RCTs over the 12 years studied used a double-blind design. They also mentioned several flaws in the RCTs they had identified, including overemphasis on significance testing, inadequate randomisation, biased allocation, and publication bias, where almost all the clinical articles published in *CJIM* showed positive results of efficacy evaluation.

Compared with the early 1980s, the quality of clinical trials of TCM did seem to have improved gradually by the late 1980s and 1990s, as reflected in the literature of various journals. Nevertheless, critics still considered these to fall short of what by the 1990s were considered rigorous trial standards.[36] Tang et al., in their 1999 evaluation of TCM trials conducted from the 1980s through 1997,[9] reported that while the methodological quality of the RCTs examined had improved over time, there were still several problems, such as inappropriate descriptions of the randomisation method, a lack of blinding (used in only 15% of trials), small sample sizes, the use of another Chinese medicine treatment as a control whose effectiveness had often not been established through RCTs, a lack of exploration of medium- and long-term outcomes, publication bias, and a lack of baseline characteristics. They concluded:

> *The quality of trials of traditional Chinese medicine must be improved urgently. Large and well designed randomized controlled trials on long term major outcomes should be funded. Subsequently, such studies may serve as models for future trials in the area… The best evidence should be systematically reviewed, summarized, and disseminated, which in turn would lead to evidence-based decision making in traditional Chinese medicine.*[9]

Such concerns seemed to apply to studies of Western medicine as well. Qian Wang and Boheng Zhang[37] conducted an investigation into the trends in research types and statistical methods used in studies published in 1985 and 1995 in five major Chinese medical journals. The authors observed an increase in the use of statistical methods in original research over the years, from 40.2% in 1985 to 60.1% in 1995. Nevertheless, despite finding that the use of 'appropriate' methods also improved over time, from 22%

in 1985 to 46% in 1995, more than half of the studies apparently still did not utilise 'appropriate' statistical methods.

From ancient China through the mid-1990s, controlled clinical trials in China were thus conducted not only with Western medicines but within TCM, amidst ongoing reflection and discussion concerning the proper evaluation of therapeutic remedies. In Part 2, we will describe the large-scale multicentre RCTs that would emerge from the 1990s onward, the development of evidence-based medicine in China, the evaluation of artemisinin against the backdrop of this larger overall history, and the ethical and epistemic critiques concerning RCTs that remain to this day.

Declarations

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Notes

a. They likewise serve as important primary source documents in their own right, as they have often been framed in terms of self-reflection and critique, arguing for improved methodological rigour and ethical oversight.
b. Note that Lei[14] states that Blake 'decided in 1903 to conduct a controlled experiment to compare patients treated with Western medicine and those treated with Chinese medicine' (p. 32). The actual 'experiment' (Blake,[13] pp. 11–12) appears to have been a retrospective comparison between patients treated at home with TCM, and those in the hospital with Western medicine, admittedly during the same time period in the same city.
c. 'Paracholera' in Chinese is '副霍乱'.
d. Using full-text searching of the China National Knowledge Infrastructure (CNKI), we conducted a search for '苏德隆' (Su Delong) and '随机对照' (randomised control) on 9 January 2024, and examined the book named *Collected Papers of Professor Delong Su*.[38]
e. Note that all translations from the Chinese medical literature in this article have been rendered by Xuan Yu.
f. 'Random sampling method' in Chinese is '随机抽样方法'.
g. 'Furapromidium versus a combination of adrenocortical hormones (prednisone) and antimony potassium tartrate' in Chinese is '呋喃丙胺及泼尼松合并酒石酸锑钾'.
h. Hu mentioned it in Chinese as '临床试验尤其是随机对照试验在我国推广尚有一定的困难'.
i. In 1993, during the 3rd National Conference on Clinical Epidemiology/DME held in Guangzhou, the Clinical Epidemiology Association of Chinese Medical Association was formally established. This marked the official integration of China's clinical epidemiological academic activities under the unified leadership of the Chinese Medical Association. In 2013, the Clinical Epidemiology Association of Chinese Medical Association was renamed as the Clinical Epidemiology and Evidence-Based Medicine Association of Chinese Medical Association. In August 2023, the 21st academic conference was convened in Lanzhou, Gansu Province. From 15 to 18 August 2024, the 22nd academic conference was convened in Sichuan, Chengdu Province.

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