Check for updates

The Royal Society of Medicine

Journal of the Royal Society of Medicine; 2025, Vol. 118(6) 191–198
DOI: 10.1177/01410768251345754

History of clinical trials for the treatment of tuberculosis in China. Part 2: the advent and expansion of randomised controlled trials

Xuan Yu[1,2,3,4], Yaolong Chen[1] and Scott H. Podolsky[2]

[1]Research Unit of Evidence-Based Evaluation and Guidelines, Chinese Academy of Medical Sciences (2021RU017), Lanzhou University School of Basic Medical Sciences, Lanzhou 730000, China
[2]Department of Global Health and Social Medicine, Harvard Medical School, Boston, MA 02115, USA
[3]Vincent V.C. Woo Chinese Medicine Clinical Research Institute, Hong Kong Baptist University, Hong Kong SAR, China
[4]Chinese EQUATOR Centre, Hong Kong Baptist University, Hong Kong SAR China

Corresponding authors: Yaolong Chen. Email: chenyaolong@lzu.edu.cn; Scott Podolsky. Email: scott_podolsky@hms.harvard.edu; Xuan Yu. Email: xuan_yu@hkbu.edu.hk

As detailed in Part 1, researchers from the 1940s-1950s engaged significantly with tuberculosis trials, including translating Western studies, and conducting observational studies and non-randomized controlled trials. In Part 2, we relate that the first randomized controlled trial (RCT) for tuberculosis in China would be published in 1963, and by the late 1970s, in the context of trials conducted in Hong Kong, large-scale, multicenter studies would be conducted and published in mainland China. By the 1990s, reflecting the rise of RCTs more generally in mainland China, RCTs integrating traditional Chinese and Western medicine in tuberculosis treatment would likewise begin to emerge. Throughout this history, clinical studies of tuberculosis would often serve as the leading edge of attempts to judge therapeutic efficacy through the RCTs in mainland China.

Large-Scale analysis and the start of randomized controlled trials (1960s)

In the early 1960s, a substantial body of case–control tuberculosis studies emerged. Examples included investigations into the impact of drug resistance on pulmonary resection therapy[1] and an analysis of the factors influencing the outcomes of chemotherapy in 441 non-hospitalised pulmonary tuberculosis patients.[2] In 1963, Xueshou Xu et al. at the Department of Pulmonary Medicine, Anhui Medical University Affiliated Hospital, conducted a retrospective study involving 1000 cases of pulmonary tuberculosis, particularly examining the effectiveness of tuberculosis drug treatment under different conditions of work and rest for non-hospitalised patients.[3] The clinical results ultimately suggested that if patients could rest, isoniazid alone was sufficient. However, if they needed to continue working, combination therapy was preferable. Xu et al. did not provide any methodological discussion in the document, and the results were solely presented as percentages.

Some scholars questioned Xu et al.'s research methodology, exhibiting developing concerns regarding methodological rigour. Chengzhi Xiao[4] argued that while the study used comparative analysis to determine the relative differences in effectiveness between groups, the groups lacked comparability in terms of the complex factors potentially impacting the patients. He also pointed to methodological flaws in the statistics, inconsistencies in the data, and discrepancies between the conclusions and the results of statistical analysis. Xiao mentioned:

> *In the document, the rates of improvement and deterioration used as efficacy assessment were relative indicators, and the comparison of relative indicators required a scientific determination. Relying on common sense or superficial numerical appearances often leads to errors. Authors may consider as differences some variations that might have been caused by chance, especially when they lack statistical significance.*[4]

Zhichun Wang[5] from Jia Xing Sanatorium likewise expressed doubts about the statistical methods used by the authors, finding that the results did not substantiate the conclusions made by Xu et al. As Wang asserted:

> *In fact, when assessing the relationship between efficacy and drug types, one should also consider whether*

© The Author(s) 2025
Article reuse guidelines: sagepub.com/journals-permissions

factors such as lesion severity were evenly distributed in various drug categories, and these factors were not standardized in the text.[5]

But 1963 also represented the publication year of the first randomised controlled trial (RCT) of tuberculosis treatment in mainland China that we have identified. Since the development of effective tuberculosis drugs, particularly the application of isoniazid, there had been a revolutionary change in the treatment of tuberculosis. The three most commonly used treatment regimens were isoniazid only, isoniazid combined with streptomycin (SM), and isoniazid combined with para-aminosalicylic acid (PAS). To clarify the efficacy of these three commonly used treatment regimens and to assess the impact of different disease conditions on their effectiveness, Shi Wang et al.[6] from the First Tuberculosis Hospital of Shanghai conducted a relatively large RCT. The report outlined the allocation method, whereby a physician who was 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 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 streptomycin (SM), followed in order of efficacy by isoniazid plus para-aminosalicylate (PAS). In the discussion, the authors noted:

There is much literature on different drug treatment methods, generally believed to be most effective with isoniazid combined with streptomycin, followed by isoniazid combined with PAS, and least effective with isoniazid alone. However, this view is often based on reports of a single treatment group. There are many factors affecting drug efficacy, and it is only through rigorous simultaneous large-scale comparative methods that we can make clear distinctions and draw conclusions. However, such comparative data are relatively scarce, so there are still different opinions among experts.[6]

Wang et al. also discussed the results of RCTs conducted in other settings, such as the British Medical Research Council (MRC),[7] the Veterans Affairs system in the United States,[8] East African/British MRC[9] and British MRC/Madras,[10] and compared them with the results of their own trial. They emphasised that due to differences in drug dosages, duration of treatment, disease conditions and other factors between Chinese trials and trials in other settings, it was difficult to directly compare the absolute values of treatment efficacy and arrive at definitive conclusions. Nevertheless, based on the issues clarified by existing data, they believed it was sufficient to propose treatment regimens tailored to different situations and disease conditions.

By the mid-1960s, several additional RCTs for evaluating the efficacy of tuberculosis chemotherapy drugs would be conducted and published in mainland China. Although these trials conducted in Shanghai and Beijing mentioned the use of random allocation, some trials lacked a methods section[11] or divided the participants into two groups without specifying the random allocation process used to compare the two groups' effectiveness.[12,13] In these early tuberculosis RCTs, there was also no mention of methods to reduce biases in their reports, and the sample sizes were around 100 cases each. Still, the methods used can at times be inferred from the text of the paper, as when in 1966, Jinyuan Zhang[11] conducted a RCT aiming to explore the optimal daily dosage and frequency of PAS administration. Zhang mentioned the method of using the same disease cases, forming pairs, and randomly assigning them to Groups A (PAS + Isoniazid divided into two oral doses daily) and B (PAS + Isoniazid divided into four oral doses daily) based on random sampling numbers. The objective was to achieve better efficacy with fewer side effects. While the British MRC trials emphasised the role of high doses (16 g/day–20 g/day),[14] the blood concentration measurements in Zhang's study indicated that Chinese patients could seemingly achieve the desired results with sodium para-aminosalicylate (PAS-Na) at lower doses to avoid causing more side effects and unnecessary waste. And it demonstrates to us the intention of Chinese researchers to both engage directly with the Western literature and to pursue RCTs of their own by this time, directly on the eve of the Cultural Revolution.

Large-scale, multi-centre randomised controlled trials of short-course regimens (from the late 1970s) and the relationship to Hong Kong

As with controlled clinical trials more generally,[15] tuberculosis trials and publications appear to have

been curtailed during the Cultural Revolution. For instance, the *Chinese Journal of Antituberculosis*, established in 1948, was discontinued in 1966 and resumed publication in 1979.[16] The *Chinese Journal of Tuberculosis and Respiratory Diseases*, founded in 1953, first ceased publication in 1959[a] and resumed publication in September 1978.[17] Yet, by the late 1970s, we begin to see the advent of large-scale tuberculosis RCTs, often in direct engagement with British MRC trials, including those conducted in Hong Kong.

One of the challenges in the advancement of chemotherapy for tuberculosis was the inability of some tuberculosis patients to adhere to the full course of standardised treatment. Shortening the treatment duration while achieving the same efficacy as standardised treatment thus became a new focus of attention and research. In 1972, the East African/British MRC collaboration first reported on an RCT of short-course chemotherapy, revolutionising tuberculosis chemotherapy.[18] During the same period, the Hong Kong Government Chest Service had officially begun collaborating with the British MRC, starting in 1967[19] to conduct a series of important tuberculosis-related research projects and RCTs, including a series of studies of short-course therapy (first started in 1972) and publishing results starting in 1975.[19–27] In this context, China's National Tuberculosis Prevention and Control Conference in 1978 decided to include short-course chemotherapy for pulmonary tuberculosis as one of its own research topics. Thereafter, the National Coordinating Group of Investigations on Short-course Chemotherapy was established. As requested by the Ministry of Health, the Beijing Tuberculosis Research Institute (now Beijing Chest Hospital) was the leading institute, the Shanghai Tuberculosis Control Institute was the second leading institute, and collaborating with another 23 institutes, including ones in Guangzhou, Guangxi and Inner Mongolia, they initiated a randomised clinical controlled trial comparing the efficacy of two short-course regimens (6 months and 9 months) with standardised treatment in 566 cases. In 1982, the results from the first year and a half of the trial were published,[28] though the published results did not provide detailed explanations of the randomisation methods or how biases were reduced. This study cited the 1975 RCT conducted by Hong Kong/British MRC, and cited it in the determination of the primary endpoints – smear examination.[b]

With the initial collaborative research results suggesting that a shortened treatment regimen could achieve the same efficacy as the 1.5-year standardised treatment, the National Coordinating Group of Investigations on Short-course Chemotherapy conducted a second clinical trial, published in 1984.[29] In the methods section, clear selection criteria were established, and randomisation was conducted to assign participants to four groups. A total of 1029 participants completed the trial. The results of the second trial, with intermittent dosing after intensified treatment, were generally consistent with the results of an 8-month short-course regimen reported in Hong Kong in 1978.[21]

Starting from the early 1980s, as attention to RCTs in mainland China began to expand more generally,[15] Chinese researchers began to publish specifically on the methodology of tuberculosis clinical trials, especially the methods of RCTs. In 1980, Guanqing Kan, the director of the Beijing Tuberculosis Prevention and Control Institute, published an article in the *Chinese Journal of Antituberculosis*, discussing the scientific aspects of chemotherapy in tuberculosis. As Kan stated:

> *On the one hand, we must respect science*; *anything with sufficient objective scientific basis should be believed and accepted. On the other hand, when there isn't enough scientific basis, we should not blindly proceed. We have taken the wrong path on this issue. Some researchers often work based on subjective wishes, enthusiasm, and imagination, without considering or giving little thought to its scientific foundation. Some researchers, due to traditional habits, were reluctant to believe and accept new things with sufficient scientific basis. Both of these show significant obstacles to the modernization of tuberculosis prevention and control efforts and the full utilization of chemotherapy*.[30]

That same year, Kan translated the chapter written by Czech tuberculosis expert Kurt Toman, originally titled 'What are the principles and requirements of a controlled chemotherapy trial?' and published by the World Health Organization in 1979. Kan translated this chapter word by word in the *Chinese Journal of Antituberculosis*.[30] As Toman had proposed in 1979:

> *It is mainly in the last 25 years that determined efforts have been made to use scientific techniques in evaluating the treatment of tuberculosis on a larger scale. An important advance in this field has been the development of an assessment method known as the controlled trial, which has been found particularly suitable for studying the effect of chemotherapeutic substances. Since their introduction, many controlled trials have been carried out, and have made it possible to establish the efficacy, toxicity, and applicability of practically all the chemotherapeutic regimens currently used. However, there are still physicians who do not*

appreciate the value and scope of the method. And there are some authors who call their investigations controlled trials without observing the essential requirement.[31]

Meanwhile, researchers in mainland China appear to have continued to recognise the role of Hong Kong's scientific research in the field of tuberculosis chemotherapy, and to have appreciated the rigour of their studies.[32] In 1985, the aforementioned Guanqing Kan, still the director of the Beijing Tuberculosis Prevention and Control Institute, was invited to visit Hong Kong by the Hong Kong Tuberculosis, Heart, and Chest Diseases Association. During his visit, while observing tuberculosis prevention efforts in Hong Kong, he noted that Hong Kong's scientific research work was highly respected and that it had made significant contributions on the international stage. Kan remarked that Hong Kong's scientific research was conducted rigorously and meticulously, adhering strictly to the scientific method. He also noted that in their selection of cases for chemotherapy research, they adhered strictly to pre-allocated randomisation (prepared in advance by the London MRC) with sealed and sequenced patient assignments.[33]

Continuing such an invocation of the relevance of the Hong Kong/British MRC history for mainland China, in 1991, the *Chinese Journal of Antituberculosis* published the translation of an article written by Zhaolin Chen, the director of the Department of Chest Medicine at the Government Health Service of Hong Kong, titled 'The role of scientific research in tuberculosis chemotherapy efforts in Hong Kong'.[34] This translated article noted that prior to the early 1960s, Hong Kong had also faced challenges such as high treatment failure rates and drug resistance. Therefore, the Hong Kong government had invited Frederick Heaf and Wallace Fox from the UK to report on tuberculosis prevention and control measures in Hong Kong, and to provide recommendations for future development. This had made the Hong Kong government fully aware of the importance of clinical research in tuberculosis and had led to practice-changing collaborative clinical trials. The editors of the *Chinese Journal of Antituberculosis* also pointed out:

The research in the field of tuberculosis in Hong Kong was highly recognized in the academic community. Their research was based on local needs, with clear objectives and results that not only guided practice but were also widely applicable to real work situations. This research design and approach had a significant influence on China's tuberculosis workers.[34]

In 1996, Shiu Hung Lee, the President of the Hong Kong Tuberculosis, Heart and Chest Diseases Association, published an article in the *Chinese Journal of Antituberculosis*, aiming to summarise the development of tuberculosis prevention and control in Hong Kong and promote collaboration between mainland China and Hong Kong in tuberculosis prevention and control.[35] The article emphasised that over the past 50 years (1950s–1990s), tuberculosis prevention and control in Hong Kong had achieved significant success, with research on tuberculosis drug treatment conducted in collaboration with the British MRC playing a crucial role. By this time, as we have seen, RCTs had become more broadly implemented within mainland Chinese medicine.

Tuberculosis-related RCTs may have been dwarfed by the more general advent of RCTs by this time,[15] but they appear to have played a pioneering role in generating attention to such methodology. And they provide a useful window into the relationship between China and the West in the evaluation of therapeutic efficacy and the uptake of the RCT in particular.

Traditional Chinese Medicine in tuberculosis treatment

To this point, it appears that the advent of RCTs for Traditional Chinese Medicine (TCM) of tuberculosis in mainland China lagged behind their Western chemotherapeutic counterparts.[c] That said, TCM has a history of over a thousand years in treating tuberculosis. Among the various TCM methods for treating pulmonary tuberculosis, the use of 'Bai Ji' has been documented in mainland Chinese literature since the 1950s.[36] In 1959, Ben Zhang provided a review of the past decade's research on TCM and traditional Chinese herbs in tuberculosis in the *Chinese Journal of Antituberculosis*. Zhang mentioned that many clinical studies were conducted during the previous decade, primarily observational studies.[37] Nevertheless, Zhang did mention that seven tuberculosis inpatient institutions in Beijing jointly observed the results of acupuncture combined with tuberculosis drugs in 154 cases of 'infiltrative'[d] pulmonary tuberculosis patients for a duration of 3 months. Simultaneously, another 154 cases using only tuberculosis drugs were set up for comparative observation.

The conditions of the two groups were roughly similar, with the former showing higher efficacy than the latter.[e]

From there, controlled trial methodology did begin to appear in TCM tuberculosis studies. In 1975 (notably, amid the Cultural Revolution), the Department of Infectious Diseases of the 51st Hospital of the People's Liberation Army reported on a controlled study on the use of Bai Ji in treating pulmonary tuberculosis, conducted from 1972 to 1974. The study had three groups: Group A received only Bai Ji, Group B received Bai Ji plus isoniazid, and Group C received isoniazid, PAS-Na and SM. The results were published in the *New Medicine* journal and showed that the use of Bai Ji appeared to have superior efficacy in terms of lesion absorption, cavity closure and sputum conversion compared with the exclusive use of Western medicine. Moreover, there was no significant difference when Bai Ji was combined with Western medicine. The article presented the three groups without specifying the grouping methods. However, in the discussion, the study acknowledged that due to the lack of randomisation, unbiased significance testing could not be performed.[38]

Since the 1990s, by which point RCTs were being conducted more generally in mainland China, there have been several RCTs employing integrated Traditional Chinese and Western medicine in the treatment of tuberculosis.[39,40] More generally with respect to TCM, with the dissemination and advancement of evidence-based medicine in China, RCTs of TCM have been widely promoted to test their therapeutic effects. Simultaneously, the Chinese government has formulated a series of policies applicable to the development of TCM. For instance, in certain situations, Chinese classical formulas for pharmaceutical prescriptions may be exempted from clinical trials and still remain eligible for approval.[41,42] However, the implementation of this policy has generated diverse opinions and criticism, with some expressing concerns that the lack of clinical trials may impact the assessment of the safety and efficacy of these medicinal formulas.[43]

Conclusion

Tuberculosis has long served at the leading edge of attempts to judge therapeutic efficacy, especially, in the post-World War II era, through the RCT. Much as it served as a focus of such studies in the United States and Great Britain, tuberculosis appears to have served as a focus of such early efforts in mainland China. Yet, the history of clinical trials for the treatment of tuberculosis also serves as a window into the evolution of trial methodology more generally in mainland China, into China's engagement with Western medicine (and Western medical literature), and into the dynamic between Western medicine and TCM. We hope, through our examination of the existing clinical literature, to have made a useful start for this important and revealing subcategory of the history of clinical trials in China. And we recognise that this history opens up many sites for further inquiry and contextualisation.

Declarations

Competing Interests: None declared.

Funding: None declared.

Ethics approval: Not applicable.

Guarantor: XY, SHP, and YC.

Contributorship: Conceptualization: XY, SHP, and YC. Translating Chinese documents into English: XY. Writing – original draft: XY and SHP. Writing – review and editing: XY, SHP, and YC.

Acknowledgements: The authors would like to express their deepest gratitude to Iain Chalmers, Jinling Tang, Ted Kaptchuk, Qi Tan, Ming Liu, Mike Clarke and Karen Robinson for their insights and feedback on the manuscript.

Provenance: Invited article from the James Lind Library.

Notes

a. From 1959 to 1966, the journal experienced several interruptions. There are currently no articles included on the journal's website between 1960 and 1978.
b. Of note, the 1975 RCT was reference 3 of the original article. Within the main text of the article, citations were made to (2,4), rather than (2–4), but this was in a section which clearly seemed to be referencing citation 3 along with citations 2 and 4. It thus appears that (2–4) was meant here. Regardless, the 1975 RCT conducted by Hong Kong/British MRC was clearly referenced by the mainland China investigators.
c. A meta-analysis of the clinical evaluation of TCM in the treatment of tuberculosis,[44] published in 2022, systematically searched and screened relevant studies (up to 30 January 2022). After excluding studies with incomplete, duplicated, or erroneous data, as well as those lacking sufficient diagnostic and efficacy evaluation indicators, a total of 10 RCTs were included, with the earliest RCT published in 2014.[45,46]
d. 'Infiltrative' – in Chinese as '浸润型'.

e. The reference mentions that this information is from a conference paper abstract, and relevant abstracts for this conference cannot be currently retrieved. However, in 1959, the *Chinese Journal of Antituberculosis* published an article summarising the conference and also mentioned this study. The article did not specify whether it was a RCT; it only mentioned the presence of a control group and that the results in the study group were better than in the control group.[47]

References

1. Fu Y, Li M and Chen Y. The impact of drug-resistant bacteria on surgical treatment of tuberculosis. *Chin J Antitubercul* 1963; 5: 299–302. [傅堯箕,李敏学,陈玉平 (1963). 耐药菌对肺结核切除疗法的影响. 中国防痨杂志 5: 299–302.]
2. Li S and Xiao C. Factors influencing and effectiveness of chemotherapy in non-hospitalized pulmonary tuberculosis patients. *Chin J Antitubercul* 1963; 2: 76–83. [李树森,肖成志 (1963). 不住院肺结核病人化学疗法的影响因素及效果分析. 中国防痨杂志 2: 76–83.]
3. Xu X, Tan Q, Cheng N, Zhu C, Guan S, Zhang X, et al. Discussion on chemotherapy treatment for 1,000 non-hospitalized tuberculosis cases. *Chin J Antitubercul* 1963; 2: 84–87. [许学受,谈清霖,程南,等 (1963). 1000例肺结核病例不住院化学治疗的探讨. 中国防痨杂志 2: 84–87.]
4. Xiao C. Comments on the article 'Discussion on chemotherapy treatment for 1,000 non-hospitalized tuberculosis cases'. *Chin J Antitubercul* 1965; 1: 54–55. [肖成志 (1965). 对《1,000例肺结核病例不住院化学治疗的探讨》一文的意见. 中国防痨杂志 1: 54–55.]
5. Wang Z. Discussion on the article 'Discussion on chemotherapy treatment for 1,000 non-hospitalized tuberculosis cases'. *Chin J Antitubercul* 1965; 1: 53. [王致春 (1965). 对《1,000例肺结核病例不住院化学治疗的探讨》一文的探讨. 中国防痨杂志 1: 53.]
6. Wang S, Chu Y, Zhang Z, Jin Z, Jiang Y and Yang D. Comparison of the efficacy of different treatment regimens for initial therapy of tuberculosis. *Chin J Antituberculs* 1963; 4: 227–233. [汪士,諸云程,張振朝,等 (1963). 肺結核病初次治疗不同用药方法的疗效比較. 中国防痨杂志 4: 227–233.]
7. Medical Research Council. Various combinations of isoniazid with streptomycin or with PAS in the treatment of pulmonary tuberculosis. *Br Med J* 1955; 1: 435–445.
8. Phillips S. Comparison of isoniazid alone with isoniazid – PAS in the original chemotherapy of noncavitary pulmonary tuberculosis. Results from the Veterans Administration-Armed Forces co-operative study on the chemotherapy of tuberculosis. *Am Rev Respir Dis* 1959; 80: 641–647.
9. East African Hospitals/British Medical Research Council. Comparative trial of isoniazid alone in low and high dosage and isoniazid plus PAS in the treatment of acute pulmonary tuberculosis in East Africans. *Tubercle* 1960; 41: 83–102.
10. Tuberculosis Chemotherapy Centre, Madras. A concurrent comparison of isoniazid plus PAS with three regimens of isoniazid alone in the domiciliary treatment of pulmonary tuberculosis in South India. *Bull World Health Organization* 1960; 23: 535–585.
11. Zhang J. Dosage and administration of PAS in the treatment of tuberculosis. *Chin J Antitubercul* 1966; 1: 31–33. [张錦垣 (1966). 对氨基水楊酸治疗肺結核的用量和用法. 中国防痨杂志 1: 31–33.]
12. Shen Z. Efficacy analysis of isoniazid 'single oral dose method' in outpatient initial treatment of 145 cases of tuberculosis. *Chin J Antitubercul* 3: 141–143. [沈冶六 (1965). 異菸肼'一次口服法'門初治肺結核145例疗效分析. 中国防痨杂志 3: 141–143.]
13. Tong J, Wang C, Xu F and Chen M. Comparison of daily vs. intermittent streptomycin administration in the treatment of initial cases of tuberculosis. *Chin J Antitubercul* 1966; 1: 29–30. [童驥,王承美,徐富良,等 (1966). 鏈霉素每日应用和間歇应用治疗肺結核初治病例的疗效比較. 中国防痨杂志 1: 29–30.]
14. Medical Research Council. Isoniazid in combination with streptomycin or with PAS in the treatment of pulmonary tuberculosis. *Br Med J* 1953; 2: 1005–1014.
15. Yu X, Chen Y and Podolsky S. 2025. The History of Controlled Clinical Trials in China. JLL Bulletin: Commentaries on the history of treatment evaluation. See www.jameslindlibrary.org/articles/the-history-ofcontrolled-clinical-trials-in-china/ (last checked 7 May 2025).
16. Huang D. Celebrating the re-launch of the '*Chinese Journal of Antituberculosis*'. *Chin J Antitubercul* 1979; 00: 1–2. [黄鼎臣 (1979). 祝'中国防痨通讯'复刊. 中国防痨通讯 00: 1–2.]
17. Li L and Tang S. Remembering the past and looking to the future: an essay on the 70th anniversary of the *Chinese Journal of Tuberculosis and Respiratory Diseases*. *Chin J Tubercul Respir Dis* 2024; 47: 1–2. [李亮,唐神结 (2024). 谨记历史 着眼未来——《中华结核和呼吸杂志》创刊70周年随笔. 中华结核和呼吸杂志 47: 1–2.]
18. East African/British Medical Research Councils. Controlled clinical trial of short-course (6-month) regimens of chemotherapy for treatment of pulmonary tuberculosis. *Lancet* 1972; 1: 1079–1085.
19. Hong Kong Tuberculosis Treatment Services/British Medical Research Council. Controlled trial of 6- and 9-month regimens of daily and intermittent streptomycin plus isoniazid plus pyrazinamide for pulmonary tuberculosis in Hong Kong. *Tubercle* 1975; 56: 81–96.
20. Hong Kong Chest Service/British Medical Research Council. Controlled trial of 6-month and 9-month regimens of daily and intermittent streptomycin plus isoniazid plus pyrazinamide for pulmonary tuberculosis in Hong Kong. The results up to 30 months. *Am Rev Respir Dis* 1977; 115: 727–735.
21. Hong Kong Chest Service/British Medical Research Council. Controlled trial of 6-month and 8-month regimens in the treatment of pulmonary tuberculosis. *Am Rev Respir Dis* 1978; 118: 219–228.

22. Hong Kong Chest Service/British Medical Research Council. Controlled trial of 6-month and 8-month regimens in the treatment of pulmonary tuberculosis: the results up to 24 months. *Tubercle* 1979; 60: 201–210.
23. Hong Kong Chest Service/British Medical Research Council. Controlled trial of four thrice-weekly regimens and a daily regimen all given for 6 months for pulmonary tuberculosis. *Lancet* 1981; 1: 171–174.
24. Hong Kong Chest Service/British Medical Research Council. Controlled trial of 4 three-times weekly regimens and a daily regimen all given for 6 months for pulmonary tuberculosis. Second report: the results up to 24 months. *Tubercle* 1982; 63: 89–98.
25. Hong Kong Chest Service/British Medical Research Council. Five-year follow-up of a controlled trial of five 6-month regimens of chemotherapy for pulmonary tuberculosis. *Am Rev Respir Dis* 1987; 136: 1339–1342.
26. Hong Kong Chest Service/Tuberculosis Research Centre, Madras/British Medical Research Council. A controlled clinical comparison of 6 and 8 months of antituberculosis chemotherapy in the treatment of patients with silicotuberculosis in Hong Kong. *Am Rev Respir Dis* 1991; 143: 262–267.
27. Hong Kong Chest Service/British Medical Research Council. Controlled trial of 2, 4 and 6 months of pyrazinamide in 6-month, three-times-weekly regimens for smear-positive pulmonary tuberculosis, including an assessment of a combined preparation of isoniazid, rifampin and pyrazinamide. *Am Rev Respir Dis* 1991; 143: 700–706.
28. National Coordinating Group of Investigations on Short-course Chemotherapy. Study on short-course chemotherapy for tuberculosis. *Chin J Tubercul Respir Dis* 1982; 5: 78–81. [全国肺结核短化协作组 (1982). 肺结核短程化疗的研究. 中华结核和呼吸杂志 5: 78–81.]
29. National Coordinating Group of Investigations on Short-course Chemotherapy. Preliminary Report on the second batch of short-course chemotherapy research for tuberculosis. *Chin J Tubercul Respir Dis* 1984; 7: 198–202. [全国肺结核短化协作组 (1984). 第二批肺结核短程化疗研究初报. 中华结核和呼吸系疾病杂志 7: 198–202.]
30. Kan G. The role of chemotherapy in controlling tuberculosis epidemics. *Chin J Antitubercul* 1980; 1: 1–4. [阚冠卿 (1980). 化学疗法在控制结核病流行中的作用. 中国防痨通讯 1: 1–4.]
31. Toman K. *Tuberculosis Case-Finding and Chemotherapy*. Geneva: WHO, 1979.
32. Hong Kong Tuberculosis and Chest Service. 2024. Historical summary of TB and services in Hong Kong. See www.info.gov.hk/tb_chest/en/contents/c13.htm (last checked 7 May 2025).
33. Kan G. Tuberculosis control efforts in Hong Kong. *Chin J Antitubercul* 1986; 2: 1–3. [阚冠卿 (1986). 香港的防痨工作. 中国防痨通讯 2: 1–3.]
34. Chen Z, Guo Z and Jin S. The role of scientific research in tuberculosis chemotherapy efforts in Hong Kong. *Chin J Antitubercul* 1991; 3: 100–102. [陈兆麟,郭仲珂,金沙江 (1991). 科学研究在香港结核病化疗工作中的作用. 中国防痨杂志 3: 100–102.]
35. Lee S. Anti-tuberculosis work in Hong Kong, past and future. *Chin J Antitubercul* 1996; 2: 49–52. [李绍鸿 (1996). 香港防痨工作的过去和展望. 中国防痨杂志 2: 49–52.]
36. Jinzhou Zijing Mountain Tuberculosis Hospital. The efficacy of traditional Chinese medicine in the treatment of tuberculosis. *Liaoning J Trad Chin Med* 1958; 1: 20–24. [锦州市紫荆山结核医院 (1958). 中医药对肺结核的疗效. 辽宁中医杂志 1: 20–24.]
37. Zhang B. Research on traditional Chinese medicine and herbal medicine in tuberculosis over the past ten years. *Chin J Antitubercul* 1959; 5: 3–9. [张本 (1959). 十年来有关中医中药在结核病方面的研究. 中国防痨 5: 3–9.]
38. Fifty-first Hospital of the Chinese People's Liberation Army. Efficacy observation of Bai Ji Alone in the treatment of 60 cases of tuberculosis. *J New Med* 1975; 12: 564–565. [人民解放军第51医院 (1975). 单用白芨治疗肺结核60例疗效观察. 新医学 12: 564–565.]
39. Zhang Z, He L, Hou Y, Zhou G, Zheng S, Cao T, et al. Clinical observation of 60 cases of tuberculosis treated with tuberculins and chemotherapy. *Heilongjiang J Tradition Chin Med* 1992; 4: 24–25. [张政,何立生,候玉梅,等 (1992). 结核散并用化学疗法治疗肺结核60例临床观察. 黑龙江中医药 4: 24–25.]
40. Wei B, Guo Q, Xi Y, Yang X, Yang G and Zhang Y. Efficacy observation of anti-tuberculosis Yifei decoction in the treatment of 60 cases of tuberculosis. *Hebei J Tradition Chin Med* 1995; 6: 9–10. [魏兵军,郭庆儒,席永昌,等 (1995). 抗痨益肺冲剂治疗肺结核60例疗效观察. 河北中医 6: 9–10.]
41. National Medical Products Administration. Announcement by the National Medical Products Administration on the Simplified Registration and Approval Management Regulations for Classic Ancient Formulas of Traditional Chinese Medicine Compound Preparations (2018 No. 27). 2018.6.1. 2018. See www.nmpa.gov.cn/zhuanti/ypqxgg/ggzhcfg/20180601163901361.html (last checked 7 May 2025). [国家药品监督管理局关于发布古代经典名方中药复方制剂简化注册审批管理规定的公告 (2018年第27号) (2018). 2018.6.1.]
42. Luo H, Chen H, Liu C, Zhang S, Vong CT, Tan D, et al. The key issues and development strategy of Chinese Classical Formulas pharmaceutical preparations. *Chin Med* 2021; 16: 1–14.
43. Traditional Chinese medicine needs proper scrutiny. *Nature* 2017; 551: 541.
44. Guo Y, Kang Z, Fu L, Zhang W, Wang B, Hu P, et al. Meta-analysis of clinical evaluation of traditional Chinese medicine in the treatment of tuberculosis. *China Trop Med* 22: 434–439. [郭毅佳,康子卿,付雷,等 (2022). 中药治疗结核病临床评价的Meta分析. 中国热带医学 22: 434–439.]
45. Feng W, Liu Y, He F, Liu C, Ye Z, Fu Z, et al. A multicenter middle-term clinical effect observation of Yifei Tongluo prescription combined with

chemotherapy on the treatment of multi-drug resistant tuberculosis. *J Hunan Univ Chin Med* 2014; 34: 46–50. [封文军,刘艳科,何芳,等 (2014). 益肺通络方联合西药化疗对耐多药肺结核的多中心临床中期疗效观察. 湖南中医药大学学报 34: 46–50.]

46. Xi X, Li M, Wang X, Wu Z and Shang H. Efficacy and safety of Qijialifei capsule in adjuvant chemotherapy for retreatment pulmonary tuberculosis. *Chin J Antitubercul* 2014; 11: 948–952. [席秀娥,李明瑛,王霞,等 (2014). 芪甲利肺胶囊辅助治疗复治肺结核的疗效及安全性观察. 中国防痨杂志 11: 948–952.]
47. Ge Q and Dong T. The first academic symposium held by the tuberculosis committee of the Beijing Municipal Science and Technology Commission. *Chin J Antitubercul* 1959; 3: 43–44. [歌青,董天光 (1959). 北京市科学技术委员会结核病科委员会举办第一次学术报告会. 中国防痨 3: 43–44.]