

OBJECTIVES

To explore and analyze the application and characteristics of patient-reported outcomes (PROs) in published randomized clinical trials of traditional Chinese medicine (TCM) globally.

METHODS

This cross-sectional study was conducted based on the randomized clinical trials of TCM published between 1 January 2010 and 31 December 2022 on the International Clinical Trials Registry Platform, which containing the trial registration provided by 20 registries worldwide. Randomized clinical trials involving TCM interventions was included. For each trial, we extracted data on study design, primary sponsors, target diseases, PROs and patient-reported outcome measures (PROMs).

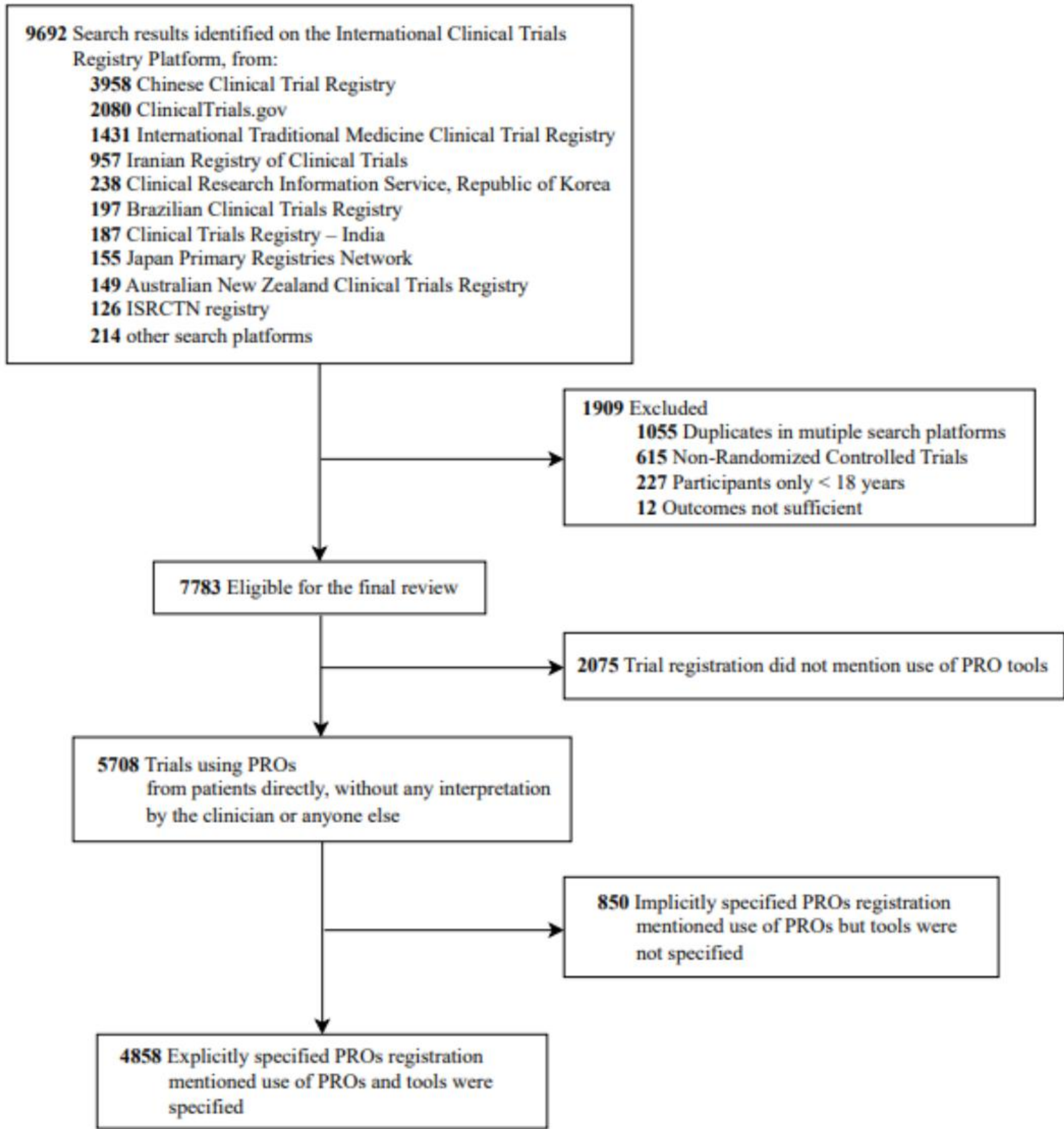


Figure 1. Flow Diagram of Trials Identification and Screening

RESULTS

There was an upward trend in the use of PROs in clinical trials of TCM from 2010 to 2022. Among 7783 eligible trials, 4858 trials listed explicit PROMs used and 850 trials referenced PROs but did not specify the names of tools. Globally, musculoskeletal diseases, symptoms, and neurological diseases were the most common conditions evaluated by PROMs. The most frequently used PROMs were Visual Analogue Scale, 36-item Short-Form Survey, and Pittsburgh Sleep Quality Index. At the regional level, PRO-related trials were conducted in the Western Pacific region (3904, 68.4%) at most and the Africa region (8, 0.1%) at least. At the country level, China, Iran, the USA, South Korea, and Brazil conducted the most numbers of PRO-related clinical trials. The top five disease types in these countries were musculoskeletal, symptoms, neurological, genitourinary, and digestive diseases. The most popular disease-specific PRO tools varied from country to country.

CONCLUSIONS

It is evident the utilization of PROs in clinical trials of TCM has grown during 2010 to 2022. However, the application of standard PROMs of TCM remained to be improved. There was an uneven distribution of PRO application across different regions. To address these issues, future researches are recommended to enhance the quality, prevalence, and standardization of PROs and PROMs in clinical research of TCM.

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