Assessment of clinical competency among TCM medical students using standardized patients of traditional Chinese medicine: A 5-year prospective randomized study

Jinhao Zeng [a,1], Shuang Liang [b,1], Xiaotong Zhang [b], Ran Yan [c], Chongli Chen [a], Lijuan Wen [c], Ting Xia [d], Wenyuan Li [e], Bingqing Lu [e], Qing Nian [a], Han Yang [a,*], Jing Guo [d,*]

[a] Department of Chinese Internal Medicine, Hospital of Chengdu University of Traditional Chinese Medicine, Chengdu, China
[b] Department of Student Affairs, Clinical Medical School of Chengdu University of TCM, Chengdu, China
[c] Clinical Skill Center, Clinical Medical School of Chengdu University of TCM, Chengdu, China
[d] Education Department, Clinical Medical School of Chengdu University of TCM, Chengdu, China
[e] Sichuan Evidence-Based Medicine Center of Traditional Chinese Medicine, Chengdu, China

ARTICLE INFO

ABSTRACT

Background: Some Western medicine schools in China established standardized patient (SP) programs for medical education. However, SP programs are rarely applied to the education of traditional Chinese medicine (TCM). In this study, we evaluated the effectiveness of using standardized patient traditional Chinese medicine (SP-TCM) to improve clinical competency among TCM medical students.

Methods: This study was a prospective, 2-group, parallel-training randomized trial over the course of 5 years. Data were collected from September 2016 to December 2020. Participants in each year were randomly allocated into the traditional-method training group or the SP-TCM training group (1:1) for a 3-month curriculum. Measurement of clinical competency among all trainees was based on a standardized examination composed of scores of medical record documentation, scores of TCM syndrome differentiation and therapeutic regimen, and checklist assessment from both SP-TCMs and TCM professionals. Feedback was collected using semi-constructive questionnaires from both groups.

Results: Compared with those assigned to traditional-method training, those assigned to SP-TCM training demonstrated significantly greater post-training improvement in medical record documentation and TCM syndrome differentiation and therapeutic regimen. Moreover, SP-TCM trainees outscored those assigned to traditional training in the assessment for encounter performance given by independent SP-TCMs and TCM professionals. The SP-TCM method gained higher satisfaction of training efficacy and test performance than the traditional method.

Conclusion: This SP-TCM program demonstrated great benefits for improving clinical competency among TCM medical students.

1. Introduction

* Corresponding authors at: Hospital of Chengdu University of Traditional Chinese Medicine, 39 Shi-er-qiao Road, Chengdu, Sichuan 610072, PR China (H. Yang); Clinical Medical School of Chengdu University of TCM, 1166 Liu-tai Avenue, Chengdu, Sichuan 610075, PR China (J. Guo).

* Corresponding authors at: Hospital of Chengdu University of Traditional Chinese Medicine, 39 Shi-er-qiao Road, Chengdu, Sichuan 610072, PR China (H. Yang); Clinical Medical School of Chengdu University of TCM, 1166 Liu-tai Avenue, Chengdu, Sichuan 610075, PR China (J. Guo).

E-mail addresses: 15882458490@163.com (H. Yang), guojing66@cdutcm.edu.cn (J. Guo).

[1] These authors contributed equally.

Standardized patients (SPs) are trained actors who constantly and realistically duplicate the clinical symptoms, physical signs, and medical history to portray real patients and serve as evaluators and instructors in medical education.[1,2] More than 95% of medical schools use SPs for undergraduate teaching, and 85% of schools use them as part of student assessment procedures.[3] Moreover, all clinical competency stations have adopted SPs for the current assessment in the United States Medical Licensing Examination.[4] The SP method shows good validity and reliability in cultivating and assessing medical students' clinical competency, physician-
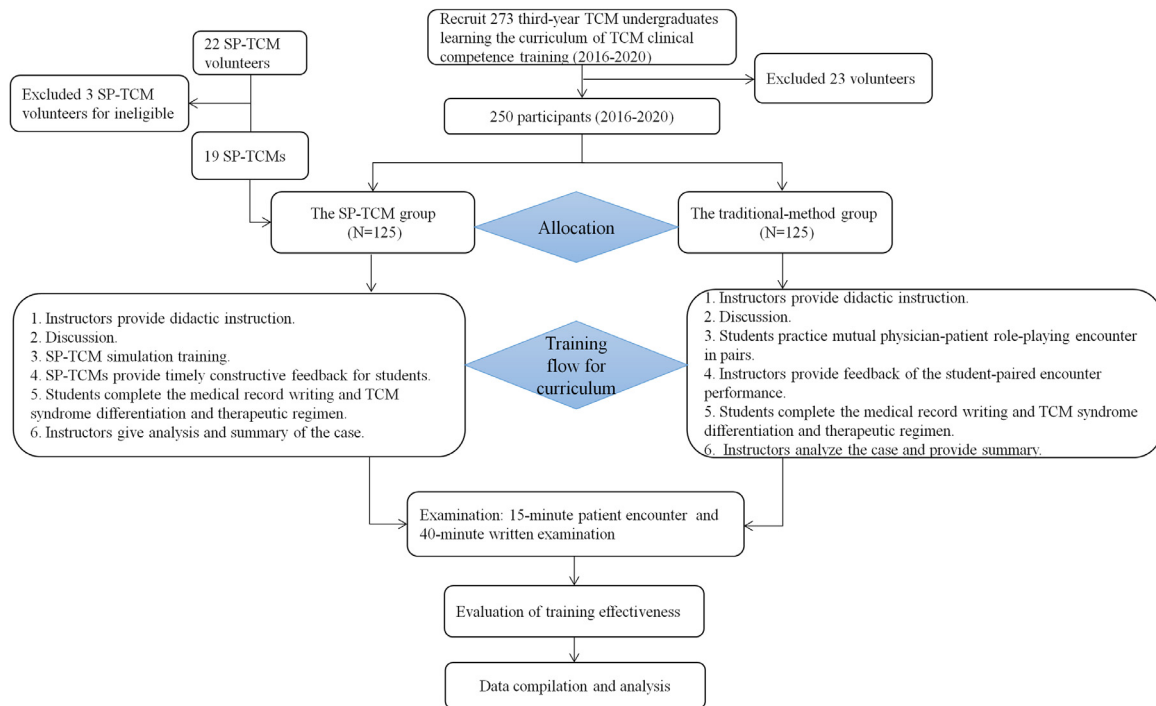
Fig. 1. The study's flow diagram.

patient communication, and bedside etiquette.[5,6] Ratings grounded in medical students' interactions with SPs are predictive of their subsequent performance with real patients.[7]

SP was introduced into medical education in China by Paula Stillman[8] in 1991 and was formally used for instruction and assessment in 1994.[9] Some Western medicine schools in China established SP programs that have been considered very useful and valuable for medical education. Inexperienced medical students trained by traditional methods (such as lecture-based methods) are easily overwhelmed when they are exposed to live clinical settings. SPs, as an invaluable source of performance feedback,[10] would provide objective evaluation and timely correction of the performance of students. Despite the multiple advantages of SP-based medical education, there have always been concerns about the costs associated with their use in terms of the hourly wage paid to SPs for their training, performance, and time-consumption.[11,12]

TCM has its own disciplinary characteristics. For example, "dialectical thinking and syndrome differentiation" is the priority in TCM, which is quite different from Western medicine. The training and teaching pattern of SP should be tailored according to the characteristics of TCM. To our knowledge, SP programs are rarely implemented in TCM medical education environments, as most colleges or universities of TCM in China face a lack of professional SPs trained in TCM.

Chengdu University of TCM is one of China's top Chinese medicine institutions. We formally established an education program for standardized patients of traditional Chinese medicine (SP-TCM) in 2015 and trained the first cohort of SP-TCM students according to the clinical characteristics of TCM. Next, we introduced the SP-TCM to the clinical competence training curriculums of TCM and carried out an SP-TCM-based training pattern. It has been widely acknowledged that assessment is the most appropriate engine in which to drive the curriculum.[13] However, limited evidence exists regarding the efficacy of using the SP-TCM-based method compared with the traditional method in the clinical competence training curriculums of TCM. In this study, we not only understand

the importance of the evaluation of students' TCM clinical competency but also the importance of productive feedback from both SP-TCMs and students.

2. Methods

2.1. Participants

2.1.1. Participants recruitment

This was a prospective, 2-group, parallel-training randomized study that compared SP-TCM training with traditional training methods. After a pre-consent screening, 273 third year TCM undergraduates who were learning the curriculum of TCM clinical competence training at Chengdu University of TCM from September 2016 to December 2020 were recruited. Fig. 1 presents the flow of participants throughout the study. Informed consent was provided by all participants. The work was approved by Chengdu University of TCM (no. 1005510).

2.1.2. Inclusion and exclusion criteria

The inclusion criteria for participants were as follows: 1) Third-year undergraduates majoring in TCM at Chengdu University of Traditional Chinese Medicine. 2) Participation was entirely voluntary, and informed consent was obtained. 3) Participants were required to sign a confidentiality agreement. 4) Male or female ages 19–22 years. 5) Successful completion of the pre-test of foundational courses before the formal investigation. 6) In good physical and psychological health state.

Exclusion criteria included the following: 1) Participants who had received prior formal training as a standardized patient in a study project. 2) Participants who had participated in a similar intervention. 3) Participants who had a reasonable understanding of the process of this study project. 4) Participants who failed to observe the confidentiality agreement on the curriculum content during the study period. 5) Participants who failed to follow the schedule of study or withdrew from the study.

Table 1
The curriculum cases used in the training.

Curriculum cases					
Common cold	Cough	Wheezing	Dyspnea	Phlegm-fluids retention	Perspiration syndrome
Palpitations	Cardiac pain	Stroke	Headache	Vertigo	Sleeplessness
Depressive syndrome	Gastric pain	Vomiting	Diarrhea	Dysentery	Constipation
Jaundice	Ji-ju syndrome	Tympanites	Xiao Ke	Edema	Stranguria
Urine retention	Low back pain	Bleeding syndrome	Bi-arthralgia Syndrome	Wei-flaccidity syndrome	Fever due to Internal Injures

2.1.3. Randomization and blinding

We used computer-generated randomization to assign enrolled participants into the traditional group and SP-TCM group (1:1 allocation). Randomization was conducted by an individual with no exposure to the participants. The training assignment was blinded and confidential to the participants and the remaining study staff. The data collected were concealed during the whole study and the data were not analyzed until the end of the test.

2.2. SP-TCM training and eligibility

Three months before the commencement of the curriculum, a batch of voluntary and healthy SP-TCMs without any medical background were recruited. Priority was given to those with acting talent and a strong sense of responsibility. 22 SP-TCM volunteers were selected after signing the informed consent. An experienced SP trainer adopted a multimodality educational intervention consisting of didactic sessions, skills practice, and self-study sessions using standardized training materials. In the early stage of training, the instructor and the SP trainer cooperated to appropriately lecture theoretical knowledge, including the SP-TCM required performance skills, four diagnostic methods of TCM, common TCM diseases and symptoms, interrogation techniques, physical examination, etc. The instructor interpreted the scripts, followed by an hour of clinical simulation training (covering a live group situational rehearsal and targeted one-on-one guidance.) in which the SP-TCM volunteers were asked to remember their roles. Moreover, SP-TCM volunteers were able to learn by themselves through scenario scripts and case videos, and the training instructors posted class video recordings on WeChat where SP-TCMs could asynchronously view playback. Finally, the eligibility of 22 SP-TCMs was assessed by a team of senior SP instructors with no exposure to the trained SP-TCMs.

2.3. Curriculum

2.3.1. Curriculum setting

This was a case-based and group-based curriculum, which lasted for 12 weeks covering 48 class hours. Two groups experienced the same amount of training time and selected identical training cases. Two experienced instructors organized the curriculum once a week. The SP-TCM group consisted of 16 SP-TCM actors assigned to routine training who took turns participating in the curriculum (the remaining 3 SP-TCMs were scheduled for a final examination). Cases used were common clinical diseases and reviewed by the program director to ensure that they were at the same level of complexity. The cases used in the training are shown in Table 1. Two groups of participants followed the same standardized format as a framework for rating and performance assessment, such as guidelines for case writing, checklist items, written examination questions of TCM syndrome differentiation, and therapeutic regimen.

2.3.2. Training flow for curriculum

Traditional TCM training was carried out in the traditional method group (TM group) as follows: 1) Instructors provided didactic instruction that reviewed foundational content concerning the disease, as well as key points for history-taking and physical examination. 2) Discussion. 3) Students practiced mutual physician-patient role-playing encounters in pairs. 4) Instructors provided feedback on student-paired encounter performance. 5) Students completed the medical record writing and TCM syndrome differentiation and therapeutic regimen. 6) Instructors analyzed the case, particularly in terms of TCM diagnosis, TCM therapeutic principles and methods, TCM formula, Western medicine diagnosis and differential diagnosis, and provide a summary of the case.

The SP-TCM group implemented the SP-TCM training pattern as follows: 1) Instructors provided didactic instruction that reviews foundational content concerning the disease, as well as key points for history-taking, and physical examination. 2) Discussion. 3) SP-TCM simulation training: Patient information, such as personal data, disease course, pertinent history, and physical findings was presented upon the script of clinical cases. Some TCM-specific symptoms and signs were given orally through image presentation or specific instruments (e.g., TCM tongue manifestation by imaging; TCM pulse-taking by pulse diagnosis instrument). 4) SP-TCMs provide timely constructive feedback for students (e.g., pointing out insufficiency, providing advice, and correct demonstration), initiate discussion and exchange ideas, and then they repeat the clinical encounter to improve performance. 5) Students completed the medical record writing, TCM syndrome differentiation, and therapeutic regimen. 6) Instructors conducted professional analysis and provided a case summary.

2.4. Examination design

Two groups of participants would take an objective, standardized examination employing uniform cases when the curriculum was over. The test was developed as a 15-minute patient encounter in which participants were required to complete a medical interview and physical examination upon SP-TCM interaction. Meanwhile, both SP-TCMs and TCM professionals evaluate the performance of students using prior developed checklists and written comments. Following the patient encounter, a 40-minute written examination (medical recording, TCM syndrome differentiation and therapeutic regimen) was given.

2.5. Test confidentiality and objectivity

An hour was provided for each student to complete the whole examination process, which was arranged on the same day. Brand-new cases were extracted from the case database for testing. Precautions were taken to ensure that there would be no communication among the testing students. To eliminate evaluation bias, another batch of SP-TCMs and TCM professionals, who were not involved in the study, participated in the examination. To maintain the high fidelity and consistency of performance required for SP-TCMs, eligibility of SP-TCMs was determined again 10 days before the final examination. All the test processes were supervised and video-recorded by independent experts and staff from the Clinical Skill Center, Hospital of Chengdu University of Traditional Chinese Medicine.

2.6. Evaluation of training effectiveness

2.6.1. Documentation of medical records

The items and their value in medical records on a 100-point scale are categorized as follows: General data (3 points) and chief complaint (5 points), present history (30 points), past history (10 points), personal history (10 points), family history (6 points), physical examination (20 points), and four examinations of TCM (16 points). Each item in the written medical record was scored according to explicit criteria.

2.6.2. Scoring of TCM syndrome differentiation and therapeutic regimen

The content of TCM syndrome differentiation and therapeutic regimen comprised the following items: diagnosis of TCM (6 points), diagnostic evidence of TCM (6 points), diagnosis in terms of Western medicine (6 points), diagnostic evidence of the practice of Western medicine (14 points), syndrome type of TCM (10 points), analysis of TCM syndrome differentiation (24 points), method of TCM treatment (8 points), formula (8 points), medicinal administration, method of administration, and corresponding dosages (14 points), and medical advice (4 points). Each item in the written examination of TCM syndrome differentiation and therapeutic regimen was scored based on pre-determined criteria.

2.6.3. Real-time assessment from TCM professionals

The performance of participant interactions with SP-TCMs was rated by TCM professionals using pre-developed checklists, which mainly emphasized the measurement of basic clinical skills of TCM and TCM thinking ability. Multiple items on the checklist were presented as follows: introduction (4 points), chief complaint (8 points), present history (30 points), past history (12 points), personal history (12 points), family history (8 points), physical examination and four examinations of TCM (16 points), and concluding remarks (10 points).

2.6.4. Real-time assessment from SP-TCMs

After each SP-TCM interaction, SP-TCMs immediately rated the performance of the participant using the Arizona Clinical Interviewing Rating Scale (ACIR), a 20-item scale that assesses the interpersonal, communication, and interviewing skills of a physician (scored from 1 to 5 points, where 5 points is the highest score).[14]

2.6.5. Feedback questionnaire from medical students

Participants enrolled in the study were given a post-training and a post-examination survey. An anonymous questionnaire was handed out to collect feedback. Items in the post-training questionnaire included "Satisfied with the teaching effectiveness of the course", "Improved your interest in learning TCM", "Improved TCM thinking ability", "Enhanced the quality of medical records", and "Improved physician-patient interpersonal and communication skills" (There is a five-gradient scale for the questionnaire items that are designed to obtain feedback from participants, including 'strongly agree', 'agree', 'neutral', 'disagree', and 'strongly disagree'). Items in the post-examination questionnaire involved: "Did your test performance surpass the fidelity rate of your usual performance?", "Do you think the "patient" in the examination acted like a real patient?", and "The time length for the patient encounter in examination is?".

2.6.6. Feedback questionnaire from SP-TCMs

To investigate their attitude, cognition, and behavior toward SP-TCM simulation training, pre and post-study questionnaire surveys on SP-TCMs who were enrolled in the curriculum were carried out. The SP-TCMs completed and submitted the anonymous questionnaires 1 week before and after the study. Categorical items in the

questionnaire included: "Satisfied with your portrayal as a patient and fulfilled high fidelity", "Had any hints in the simulation", "Familiar with the procedures of TCM's four examination methods", and "Understanding about the principle of TCM syndrome differentiation".

2.7. Statistical analysis

Statistical analysis was performed using SPSS 25.0 software (SPSS, Inc.). Variables were presented as the mean $\pm$ SD or as percentages. Measurement data were tested for normality with the Kolmogorov–Smirnov test, and the differences were analyzed using independent sample t tests when a normal distribution of the data was shown. Comparisons of proportions and correlation analyses were evaluated by the chi-square test. $P < 0.05$ was considered as significant.

3. Results

3.1. Demographic characteristics of the participants

According to the inclusion and exclusion criteria, 23 volunteers were excluded before randomization. A total of 250 participants were included in the final analyses, consisting of 40 participants in 2016, 60 in 2017, 50 in 2018, 60 in 2019, and 40 in 2020. Table 2 shows the demographic information. There were no significant differences in age or sex between the lecture-based group and SP-TCM group ($P > 0.05$). At baseline, no significant differences were found for academic performance in basic courses of traditional Chinese medicine (fundamental theory of TCM, Chinese materia medica, diagnostics of TCM, formulaology of TCM) and Western medicine (anatomy, physiology, pathology, medical biology, diagnostics of Western medicine) ($P > 0.05$).

3.2. Scores of medical record documentation

The scores of medical record documentation in the two groups are shown in Fig. 2A. After the 3-month curriculum, those assigned to SP-TCM training had higher medical record documentation scores than those assigned to TM training, and significant differences were found from 2017 to 2020 (2017, SP-TCM=77.87$\pm$7.86 vs. TM=72.43$\pm$9.92, $P = 0.022$; 2018, SP-TCM=80.20$\pm$8.48 vs. TM=74.68$\pm$8.51, $P = 0.026$; 2019, SP-TCM=80.23$\pm$8.20 vs. TM=74.40$\pm$8.91, $P = 0.011$; 2020, SP-TCM=74.75$\pm$6.66 vs. TM=69.40$\pm$8.11, $P = 0.028$). A similar trend was noted in 2016; however, no statistical differences emerged (2016, SP-TCM=77.40$\pm$8.20 vs. TM=72.60$\pm$7.25, $P = 0.057$).

3.3. Scores of TCM syndrome differentiation and therapeutic regimen
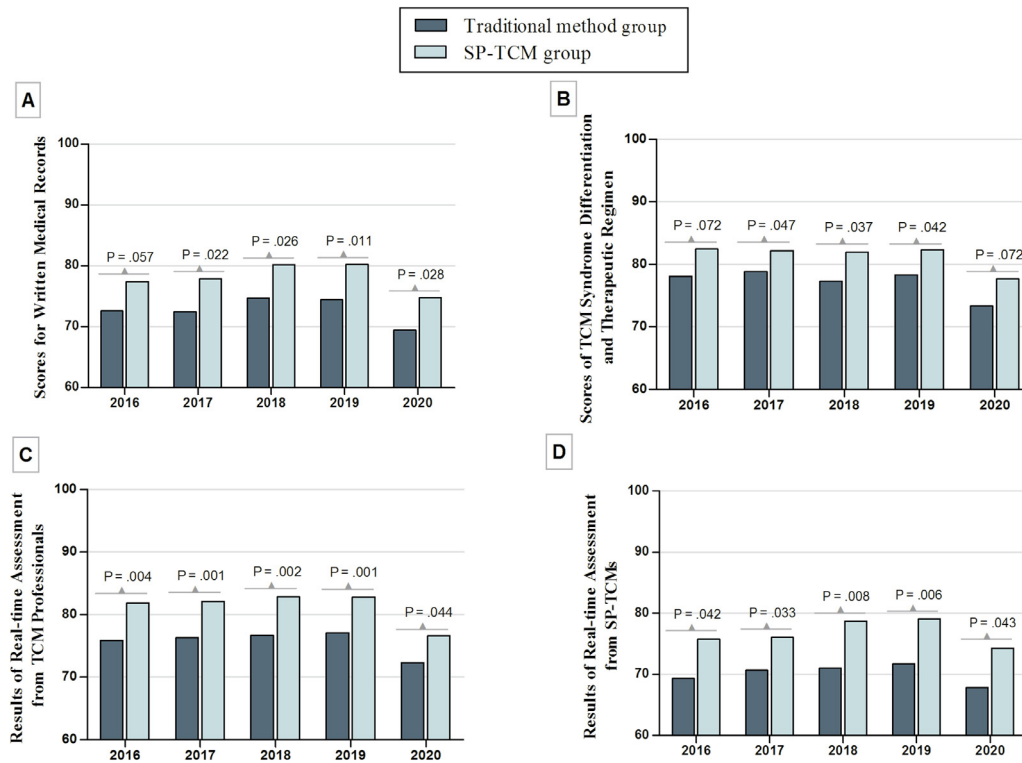
The TCM syndrome differentiation and therapeutic regimen scores in the two groups are presented in Fig. 2B. Differences were observed after the 3-month curriculum, with greater improvements achieved in the scores for participants in SP-TCM group when compared with those in the traditional method group, particularly in2017, 2018, and 2019 (2017, SP-TCM=82.20$\pm$7.45 vs. TM=78.80$\pm$5.37, $P = 0.047$; 2018, SP-TCM=81.96$\pm$7.76 vs. TM=77.32$\pm$7.52, $P = 0.037$; 2019, SP-TCM=82.30$\pm$7.42 vs. TM=78.33$\pm$7.34, $P = 0.042$).

3.4. Results of real-time assessment from TCM professionals and SP-TCMs

A comparison of the scores of TCM professionals' real-time assessment between the two groups is shown in Fig. 2C. In each academic year from 2016 to 2020, participants who received

Table 2
Participants' characteristics ($N = 250$).

Demographics	Traditional method group ($n = 125$)	SP-TCM group ($n = 125$)
Age (year), mean ± SD	20.31 ± 0.69	20.17 ± 0.62
Gender, n (%)		
Female	66 (52.80)	69 (55.20)
Male	59 (47.20)	56 (44.80)
Basic courses of traditional Chinese medicine, mean ± SD, points		
Fundamental theory of TCM	70.35 ± 1.48	70.96 ± 1.29
Chinese materia medica	76.95 ± 1.39	76.17 ± 1.45
Diagnostics of TCM	73.13 ± 1.54	73.82 ± 1.43
Formulaology of TCM	61.08 ± 2.08	61.97 ± 2.06
Basic courses of Western medicine, mean ± SD, points		
Anatomy	70.54 ± 2.38	70.09 ± 2.26
Physiology	63.53 ± 2.78	63.08 ± 2.65
Pathology	75.00 ± 2.81	75.24 ± 2.65
Medical biology	74.51 ± 2.45	74.18 ± 2.43
Diagnostics of Western medicine	70.16 ± 2.60	70.46 ± 2.63

Fig. 2. The results of standardized examination between the two groups (2016–2020). (A) Scores for medical records, (B) Scores for TCM syndrome differentiation and therapeutic regimen, (C) Results of real-time assessment from TCM professionals, and (D) Results of real-time assessment from SP-TCMs.
Note: Two-way contrasts are depicted by the gray lines and P values.

SP-TCM training demonstrated significantly greater improvement in the performance rated by TCM professionals than those in the traditional method group (2016, SP-TCM=81.85±4.51 vs. TM=75.85±7.44, $P = 0.004$; 2017, SP-TCM=81.80±5.36 vs. TM=78.20±7.43, $P = 0.001$; 2018, SP-TCM=80.37±7.38 vs. TM=77.63±7.33, $P = 0.002$; 2019, SP-TCM=82.80±5.79 vs. TM=77.07±7.27, $P = 0.001$; 2020, SP-TCM=76.60±4.87 vs. TM=72.30±7.79, $P = 0.044$). Fig. 2D shows the scores of SP-TCMs' real-time assessment in the two groups. The statistical results of the participants in the SP-TCM training group from 2016 to 2020 demonstrated significantly higher scores compared with those in the traditional method group (2016, SP-TCM=75.75±10.83 vs. TM=69.35±8.22, $P = 0.042$; 2017, SP-TCM=76.10±10.02 vs. TM=70.67±9.21, $P = 0.033$; 2018, SP-TCM=78.72±9.15 vs. TM=71.00±10.46, $P = 0.008$; 2019, SP-TCM=79.10±9.31 vs. TM=71.77±10.69, $P = 0.006$; 2020, SP-TCM=80.10±9.24 vs. TM=73.65±10.26, $P = 0.043$). Although these scores decreased at baseline by an average of approximately 5 points in 2020, participants in the SP-TCM group still outscored those in the traditional method group.

3.5. Post-training and post-examination feedback from 250 participants

To determine how TCM students perceived their curriculum training (traditional training pattern or SP-TCM training pattern) and to further assess the learning efficacy among them, this study surveyed their attitude, cognition, and behavior feedback. Table 3 summarizes the student feedback on curriculum derived from a post-training survey via questionnaires. Overall, there was significantly higher training satisfaction among participants who were trained with the SP-TCMs than among those in the traditional method group ($P = 0.023$). More SP-TCM trainees than control

Table 3
Questionnaire feedback on curriculum from participants in two groups (N = 250).

Items	SP-TCM group (n,%)					Traditional method group (n,%)					x^2	P-value
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Strongly agree	Agree	Neutral	Disagree	Strongly disagree		
1. Satisfied with the training effectiveness of the course.	25 (20.00)	42 (33.60)	36 (28.80)	15 (12.00)	7 (5.60)	12 (9.60)	36 (28.80)	35 (28.00)	27 (21.60)	15 (12.00)	11.38	0.023
2. Improved your interest in learning TCM.	30 (24.00)	38 (30.40)	32 (25.60)	19 (15.20)	6 (4.80)	19 (15.20)	28 (22.40)	34 (27.20)	27 (21.60)	17 (13.60)	10.70	0.030
3. Consolidated fundamental theories previously learned.	30 (24.00)	35 (28.00)	34 (27.20)	18 (14.40)	8 (6.40)	18 (14.40)	29 (23.20)	35 (28.00)	28 (22.40)	15 (12.00)	7.88	0.096
4. Enhanced the quality of medical record.	34 (27.20)	36 (28.80)	31 (24.80)	18 (14.40)	6 (4.80)	19 (15.20)	26 (20.80)	39 (31.20)	26 (19.80)	15 (12.00)	12.08	0.017
5. Boosted your confidence in handling clinical work.	28 (22.40)	45 (36.00)	39 (31.20)	8 (6.40)	5 (4.00)	20 (16.00)	34 (27.20)	39 (31.20)	19 (15.20)	13 (10.40)	10.90	0.028
6. Accelerated proficiency in a collection of TCM medical history.	34 (27.20)	44 (35.20)	31 (24.80)	11 (8.80)	5 (4.00)	21 (16.80)	31 (24.80)	37 (29.60)	24 (19.20)	12 (9.60)	11.39	0.023
7. Encouraged decision-making and critical thinking.	32 (25.60)	35 (28.00)	31 (24.80)	20 (16.00)	7 (5.60)	20 (16.00)	31 (24.80)	37 (29.60)	23 (18.40)	14 (11.20)	6.08	0.193
8. Promoted autonomous learning ability.	21 (16.80)	39 (31.20)	41 (32.80)	19 (15.20)	5 (4.00)	15 (12.00)	30 (24.00)	43 (34.40)	25 (20.00)	12 (9.60)	5.92	0.205
9. Improved TCM thinking ability.	38 (30.40)	36 (28.80)	30 (24.00)	16 (12.80)	5 (4.00)	21 (16.80)	30 (24.00)	35 (28.00)	26 (20.80)	13 (10.40)	11.77	0.019
10. Improved physician-patient interpersonal and communication skills.	33 (26.40)	42 (33.60)	30 (24.00)	15 (12.00)	5 (4.00)	21 (16.80)	30 (24.00)	36 (28.80)	22 (17.60)	16 (12.80)	12.30	0.015
11. Improved basic clinical skills of TCM.	35 (28.00)	41 (32.80)	28 (22.40)	17 (13.60)	4 (3.20)	23 (18.40)	30 (24.00)	38 (30.40)	21 (16.80)	13 (10.40)	10.89	0.028

P-values are calculated using Chi-square test.

trainees gave positive feedback that their basic clinical skills of TCM ($P = 0.028$), TCM thinking ability ($P = 0.019$), interpersonal and communication skills ($P = 0.015$), quality of medical record ($P = 0.017$), and proficiency in the collection of TCM medical history markedly improved ($P = 0.023$). Regarding the items "Improved your interest in learning TCM" ($P = 0.03$) and "Boosted your confidence in handling clinical work" ($P = 0.028$), greater benefits were reported among SP-TCM participants than among TM controls.

The questionnaire feedback on examination from participants is outlined in Table 4. According to the results of the questionnaires, 46 SP-TCM trainees considered their test performance to be near or even equal to typical performance. The fidelity rate of test performance relative to their normal level was self-evaluated as >99% by 36.8% of SP-TCM trainees, 71% to 99% by 36%, 40% to 70% by 27.2%, but none reported <40%. In contrast, TM trainees reported a decreased fidelity rate of test performance (28.2%, 32%, 34.4%, and 4.8%). Encounter time was considered adequate by 48.8% of SP-TCM trainees vs. 34.4% of TM trainees, too short by 30.4% vs. 40%, and no opinion by 20.8% vs. 25.6%, while none reported "too long". A similar trend was obtained in opinions about the time allocation for the written test. A majority of SP-TCM trainees reported that video recording did not (30.4%) or only slightly (30.4%) interfered with their performance in patient encounters. By comparison, those who were assigned to the TM group thought they were more likely to be interfered with by video recording (16% not at all, 31.2% slightly, 41.6% very much, and 11.2% had no opinion). Intriguingly, more TM trainees ($n = 46$, 36.8%) than SP-TCM trainees ($n = 28$, 22.4%) considered the portrayal of SP-TCMs to have high fidelity as real patients.

3.6. Pre-study and post-study feedback from 16 SP-TCMs

Three SP-TCM volunteers were excluded for ineligibility before the study, and a total of 16 SP-TCMs participated in the curriculum. The results of the questionnaire feedback are provided in Table 5. SP-TCMs demonstrated significantly higher satisfaction with their performance after five years of SP-TCM experience ($P = 0.024$). In parallel, SP-TCMs considered that they possessed higher proficiency now than before the study in providing live and flexible clinical settings ($P = 0.035$), presenting typical symptoms, and signs of TCM syndrome ($P = 0.011$). SP-TCMs felt that they provided more professional feedback now than before ($P = 0.043$). SP-TCMs became more familiar with the holistic concept of TCM ($P = 0.024$) as well as the procedures of TCMs four examination methods ($P = 0.026$). The understanding of the principle of TCM syndrome differentiation was also significantly deepened ($P = 0.047$).

4. Discussions

Thorough medical knowledge and confident clinical skills are deemed necessary for medical students seeking to achieve clinical competency.[15] Although numerous clinical practitioners of TCM have been trained through China's higher education of TCM, problems remain – particularly for novice students – such as the shortage of clinical teaching resources, deficiency of clinical skills, and communication and interpersonal skills. Concern about the gap between medical theory and clinical practice has been longstanding.

In the past few decades, several teaching approaches, such as case teaching, situational teaching and problem-based learning, have been attempted in TCM education. However, due to the lack of a core element in real clinical settings – namely the presence of patients – the efficacy of TCM pre-clinical training was not satisfactory. Previous studies have also confirmed that realistic educational simulation is especially effective for clinical subjects and

Table 4
Questionnaire feedback on examinations from participants in the two groups (N = 250).

Items	SP-TCM group (n,%)				Traditional method group (n,%)				x^2	P-value
	>99%	71–99%	40–70%	<40%	>99%	71–99%	40–70%	<40%		
1. Your test performance maintained the rate of your usual performance?	46 (36.80)	45 (36.00)	34 (27.20)	0 (0.00)	36 (28.80)	40 (32.00)	43 (34.40)	6 (4.80)	8.57	0.036
2. Do you think the "patient" in the examination acted like a real patient?	Very likely 34 (27.20)	Acceptable 38 (30.40)	Unlikely 44 (35.20)	No opinion 19 (15.20)	Very likely 46 (36.80)	Acceptable 38 (30.40)	Unlikely 29 (23.20)	No opinion 12 (9.60)	9.26	0.026
3. The time length for the patient encounter in examination is?	28 (22.40) Adequate	34 (27.20) Too long	44 (35.20) Too short	19 (15.20) No opinion	46 (36.80) Adequate	38 (30.40) Too long	29 (23.20) Too short	12 (9.60) No opinion	5.37	0.068
4. The time length for the written test in examination is?	61 (48.80) Adequate	0 (0.00) Too long	38 (30.40) Too short	26 (20.80) No opinion	43 (34.40) Adequate	0 (0.00) Too long	50 (40.00) Too short	32 (25.60) No opinion	11.11	0.011
5. Does the video recording in the examination interfere with your performance?	62 (49.60) Very much	1 (0.80) Slightly	1 (0.80) Not at all	27 (21.60) No opinion	38 (30.40) Very much	0 (0.00) Slightly	52 (41.60) Not at all	35 (28.00) No opinion	9.40	0.024

Data are presented as the (n,%). P-values are calculated using Chi-square test.

boosts learner-perceived competence and confidence, particularly when compared to didactic instruction.[16–18] Hence, we have recruited and trained in recent years a batch of SP-TCMs who vary in age, educational background, and life experience of social origin for non-medical work. In addition to being adept in basic clinical skills such as the recording of medical history and physical examination, SP-TCMs were required to be familiar with the characteristics of TCM syndromes, TCMs four examination methods, TCM nursing care, preparation, and administration of Chinese medicinal, etc. For instance, a case of constipation used in this study was "TCM Syndrome of Spleen-kidney Yang Deficiency". SP-TCMs need to portray the TCM trait of constipation accompanied by "Yang deficiency" symptoms that include weakness and laziness, crymodynia in the lower abdomen, frequent and clear urine, intolerance of cold and icy limbs, and cold pain in lumbar and knee. Tailored SP-TCM training is not only beneficial for students to master basic TCM clinical skills but can also cultivate their knowledge of TCM.

Based on ratings from SP-TCMs and TCM professionals, participants who received SP-TCM training evidenced significant improvement not only in basic clinical skills and knowledge of TCM but also in their interpersonal, communication, and interviewing skills. These results provide evidence that SP-TCM simulation training is very helpful for students to improve their systematic and complete comprehension of TCM history-taking. Additionally, greater improvement in the quality of medical records was found among SP-TCM trainees than among TM trainees. Evidence suggests that repetitive practice and interaction is positively associated with improved learner performance and that increases in learning outcomes are realized with more simulation practice.[19–21] The SP-TCM trainees demonstrated higher proficiency than TM trainees in terms of "basic clinical skills of TCM", "communication skills", and "TCM thinking ability". By comparison, those who were trained with the SP-TCMs showed greater interest in learning TCM while also reporting significantly higher training satisfaction. Advantages of SP training may have contributed to these findings. In addition to providing real clinical settings for deliberate practice, the SP-TCMs generated timely structured feedback and correction regarding the performance of students in doctor-patient interactions. This timely feedback and correction improved the clinical competency in a highly efficient and productive manner. The SP-TCM training method shifts medical students' concerns from "disease" to "patient". SP-TCM trainees outscored TM controls in "TCM syndrome differentiation and therapeutic regimen" in 2016, but no significant differences were achieved. We considered the limited sample size as one of the possible contributors. Another possibility is that the performance of the "TCM syndrome differentiation and therapeutic regimen" is closely associated with case analysis competence, which is heterogeneous in students. It is noteworthy that mean scores in both the SP-TCM and traditional method groups dropped in 2020, and the COVID-19 pandemic, which poses a significant challenge to medical education, is considered the most significant contributor to the decline.

In the early stage of the program, we found that there was little difference in the performance, simulation ability and feedback, evaluation, and guidance ability of SP-TCMs with different backgrounds. Pairwise analysis of pre and post-study feedback from SP-TCMs demonstrated changes in their perception of SP-TCM training. As the program proceeded, SP-TCMs became more proficient in performance skills and gained a deeper understanding of TCM characteristics. It is noteworthy that most SP-TCMs hope to spend more time observing real patient cases in hospitals to gain practical experience. The opportunity to gain pratical experience enables them to identify inconsistent practices and knowledge gaps to seek breakthroughs in SP-TCM teaching patterns and provide insightful suggestions.

Table 5
Questionnaire feedback from SP-TCMs ($N = 16$).

Items	Pre-study (n,%)					Post-study (n,%)					x^2	P-value
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Strongly agree	Agree	Neutral	Disagree	Strongly disagree		
1. Are you satisfied with your portrayal as a patient and that you maintained consistency.	1 (6.25)	3 (18.75)	8 (50.00)	3 (18.75)	1 (6.25)	9 (56.25)	3 (18.75)	2 (12.50)	2 (12.50)	0 (0.00)	11.20	0.024
2. Did you provide live and flexible clinical settings?	1 (6.25)	4 (25.00)	7 (43.75)	3 (18.75)	1 (6.25)	8 (50.00)	5 (31.25)	2 (12.50)	1 (6.25)	0 (0.00)	10.33	0.035
3. Were there any issues in your simulation?	1 (6.25)	2 (12.50)	5 (31.25)	4 (25.00)	4 (25.00)	1 (6.25)	1 (6.25)	3 (18.75)	5 (31.25)	6 (6.25)	1.34	0.854
4. Did you provide consistent and accurate portrayals to different students?	4 (25.00)	4 (25.00)	5 (31.25)	2 (12.50)	1 (6.25)	8 (50.00)	4 (25.00)	2 (12.50)	1 (6.25)	1 (6.25)	2.95	0.566
5. It is difficult to transform your role to SP-TCM?	1 (6.25)	2 (12.50)	7 (43.75)	5 (31.25)	1 (6.25)	1 (6.25)	1 (6.25)	4 (25.00)	7 (43.75)	3 (18.75)	2.49	0.647
6. Did you correctly present typical symptoms and signs of TCM syndrome?	1 (6.25)	2 (12.50)	7 (43.75)	4 (25.00)	2 (12.50)	7 (43.75)	6 (37.50)	2 (12.50)	1 (6.25)	0 (0.00)	13.08	0.011
7. Is the constructive feedback provided professional?	1 (6.25)	3 (18.75)	8 (50.00)	3 (18.75)	1 (6.25)	8 (50.00)	4 (25.00)	3 (18.75)	1 (6.25)	0 (0.00)	9.86	0.043
8. Is the assessment fair and just?	3 (18.75)	4 (25.00)	8 (50.00)	1 (6.25)	0 (0.00)	5 (31.25)	5 (31.25)	5 (31.25)	1 (6.25)	0 (0.00)	1.30	0.728
9. Did you need more time to observe real patient cases in hospitals to gain practical experience?	1 (6.25)	5 (31.25)	4 (25.00)	5 (31.25)	1 (6.25)	3 (18.75)	7 (43.75)	4 (25.00)	1 (6.25)	1 (6.25)	4.00	0.406
10. Are you familiar with the procedures of TCM four examination methods?	1 (6.25)	2 (12.50)	8 (50.00)	3 (18.75)	2 (12.50)	7 (43.75)	5 (31.25)	3 (18.75)	1 (6.25)	0 (0.00)	11.06	0.026
11. Do you have a good understanding about the principle of TCM syndrome differentiation?	1 (6.25)	2 (12.50)	7 (43.75)	3 (18.75)	3 (18.75)	6 (37.50)	5 (31.25)	3 (18.75)	2 (12.50)	0 (0.00)	9.66	0.047
12. Do you have a goodl understanding of the holistic concept of TCM?	1 (6.25)	3 (18.75)	7 (43.75)	3 (18.75)	2 (12.65)	7 (43.75)	6 (37.50)	2 (12.50)	1 (6.25)	0 (0.00)	11.28	0.024

P-values are calculated using Chi-square test.

There are several limitations to the current SP-TCM training pattern that should be noted. First, although the SP-TCMs demonstrated good internal consistency as the program proceeded, homogenization for different SP-TCMs in training and evaluation should be highlighted. Second, similar to some previous studies,[22,23] SP-TCMs are incapable of fully conveying certain symptoms during physical examination. For example, TCM-specific tongue manifestation (e.g., hypoglossal petechiae or ecchymosis) and pulse-taking symptoms were given orally or through image presentation or pulse diagnosis instruments. Finally, due the specialized knowledge and professional skills of TCM, professional TCM instructors had to serve as assistants involved in the training and evaluation of trainees. It was indisputable that the instructors played multiple roles in running the study and were overburdened in teaching. There were also concerns about the costs associated with SP-TCM-based use, both in terms of the hourly wage paid to SP-TCMs and the time-consuming labor of instructors required for training SP-TCMs.

In conclusion, this randomized trial demonstrated great benefits for improving the clinical competency of TCM among participants trained with SP-TCM. The goal of this study was to establish an easy-to-disseminate, scalable SP-TCM training model, thereby shortening the transition period from TCM "medical students" to clinical "doctors". Moreover, due to resource constraints of professional social origin SP-TCMs, we have already initiated a student-SP-TCM program and trained TCM medical students as SP-TCMs. The SP-TCM training method merits further dissemination in TCM universities' educational curriculum.

Acknowledgment

Author contributions

Conceptualization: J. Zeng, H. Yang, B. Li, X. Fu, Y. Zhang. Methodology: Conceptualization: J. Zeng, H. Yang, B. Li, X. Fu, Y. Zhang. Formal investigation: J. Zeng, S. Liang, X. Zhang. Data analysis: J. Zeng, S. Liang, X. Zhang, B. Li, X. Fu. Writing – original draft: J. Zeng, S. Liang, X. Zhang. Writing – review & editing: Y. Zhang, J. Guo, H. Yang. Funding acquisition: Y. Zhang, X. Fu, J. Guo. Supervision: Y. Zhang, J. Guo, H. Yang.

Conflict of interest

Authors declare no conflict of interest.

Funding

Ethical statement

Informed consent was provided by all participants. This work was approved by Chengdu University of TCM (no. 1005510).

Data availability

The data of this study will be made available upon request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imr.2021.100804.

References

1. Kurbatova EV, Dalton T, Ershova J, et al. Additional drug resistance of multidrug-resistant tuberculo in patients in 9 countries. *Emerg Infect Dis.* 2015;21(6):977–983.
2. Nestel D, Clark S, Tabak D, et al. Defining responsibilities of simulated patients in medical education. *Simul Healthc.* 2010;5(3):161–168.
3. Association of American Medical CollegesEmerging trends in the use of standardized patients. *Contemp Issues Med Educ.* 1998;1:1–2.
4. Casey PM, Goepfert AR, Espey EL, et al. To the point: reviews in medical education - the objective structured clinical examination. *Am J Obstet Gynecol.* 2009;200(1):25–34.
5. Chang D, Mann M, Sommer T, et al. Using standardized patients to assess hospitalist communication skill. *J Hosp Med.* 2017;12(7):562–566.
6. Shirazi M, Labaf A, Monjazebi F, et al. Assessing medical students' communication skills by the use of standardized patients: emphasizing standardized patients' quality assurance. *Acad Psychiatry.* 2014;38(3):354–360.
7. Tamblyn R, Abrahamowicz M, Schnarch B, et al. Can standardized patients predict real-patient satisfaction with the doctor-patient relationship? *Teach Learn Med.* 1994;6:36–44.
8. Stillman PL, Sawyer WD. A new program to enhance the teaching and assessment of clinical competencys in the People's Republic of China. *Acad Med.* 1992;67(8):495–499.
9. Yang HX, Xu Y, Liang NX, et al. Standardized patient methodology in mainland China: a nationwide survey. *BMC Med Educ.* 2019;19(1):214.
10. Turner TR, Scerbo MW, Gliva-McConvey GA, et al. Standardized patient encounters. *Simul Healthc.* 2016;11(3):164–172.
11. Gibbons SW, Adamo G, Padden D, et al. Clinical evaluation in advance practice nursing education: using standardized patients in health assessment. *J Nurs Educ.* 2002;41(5):215–221.
12. Lovell K, Mavis B, Turner J, et al. Medical students as standardized patients in a second year performance-based assessment experience. *Med Educ Online.* 1998;4:6.
13. Wass V, Van der Vleuten C, Shatzer J, et al. Assessment of clinical competence. *Lancet.* 2001;357(9260):945–949 Mar.
14. Stillman PL, Brown DR, Redfield DL, Sabers DL. Construct validation of the Arizona clinical interview rating scale. *Educ Psychol Meas.* 1977.
15. Wang WD, Yang PC, Chen CY, et al. Using senior residents as standardized patients for evaluating basic clinical competencys of medical students. *J Formos Med Assoc.* 2004;103(7):519–525 Jul.
16. Kaddoura M, Vandyke O, Smallwood C, et al. Perceived benefits and challenges of repeated exposure to high fidelity simulation experiences of first degree ac-celerated bachelor nursing students. *Nurse Educ Today.* 2016;36:298–303.
17. Shin S, Park JH, Kim JH. Effectiveness of patient simulation in nursing education: meta-analysis. *Nurse Educ Today.* 2015;35(1):176–182.
18. McKenzie C, Tilashalski K, Peterson DT, et al. Effectiveness of standardized patient simulations in teaching clinical communication skills to dental students. *J Dent Educ.* 2017;81(10):1179–1186.
19. Koo LW, Idzik SR, Hammersla MB, et al. Developing standardized patient clinical simulations to apply concepts of interdisciplinary collaboration. *J Nurs Educ.* 2013;52(12):705–708.
20. Weller JM, Nestel D, Marshall SD, et al. Simulation in clinical teaching and learning. *Med J Aust.* 2012;196(9):594.
21. Swartz MH, Colliver JA. Using standardized patients for assessing clinical performance: an overview. *Mt Sinai J Med.* 1996;63(3–4):241–249 May-Sep.
22. Li L, Lin C, Guan J. Using standardized patients to evaluate hospital-based intervention outcomes. *Int J Epidemiol.* 2013;43(3):897–903.
23. Chen YL, Hou MC, Lin SC, et al. Educational efficacy of objective structured clinical examination on clinical training of traditional Chinese medicine - a qualitative study. *Complement Ther Clin Pract.* 2015;21(3):147–153 Aug.