Improve Management of Mental Well-being and Empathy in Chinese Medical Students: A Randomized Controlled Study

Rong Rong  
Sun Yat-sen University First Affiliated Hospital

Wei Chen  
Sun Yat-sen University First Affiliated Hospital

Zihao Dai  
Sun Yat-sen University First Affiliated Hospital

Jingli Gu  
Sun Yat-sen University First Affiliated Hospital

Weiyong Chen  
Sun Yat-sen University First Affiliated Hospital

Yanbin Zhou  
Sun Yat-sen University First Affiliated Hospital

Haipeng Xiao  
Sun Yat-sen University First Affiliated Hospital

Ming Kuang (orgetaladdress@sysu.edu.cn)  
Sun Yat-sen University First Affiliated Hospital  
https://orcid.org/0000-0002-7397-5779

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Abstract

Background: The Chinese medical students suffer from high prevalent mental health-related issues and low empathy. Effective strategies to improve the situations are lacking. This study aims to investigate the efficacy of the well-designed interventional courses to enhance the mental health and empathy of the senior Chinese medical students.

Methods: A total of 146 3rd and 4th year medical students were randomized to intervention group (n=74) and control group (n=72). A pilot study including 5 pre-clinical students and 5 interns was first carried out to determine the themes and contents of the interventional courses. The designed courses were delivered in the intervention group once a month for three times, while the control group had no specific intervention. Five self-assessment questionnaires including the General Self-Efficacy (GSE), Medical Outcomes Study Short Form 8 (SF-8), Patient Health Questionnaire-9 (PHQ-9), Maslach Burnout Inventory (MBI), and Jefferson Scale of Empathy-Health Care Provider Student version (JSE-HPS) that separately evaluated the level of self-efficacy (SE), quality of life (QoL), depression, burnout, and empathy were completed by the students before and one month after the courses. Qualitative data were collected via e-mails two year after the intervention.

Results: Compared to the control group, the interventional group showed significantly higher scores of the empathy (111.0 [IQR 102.0, 118.0] vs 106.0 [IQR 93.0, 111.5]; P = .01) and QoL (32.0 [IQR 28.0, 35.0] vs 29.5 [IQR 26.0, 34.0]; P = .04). The rate of depression was significantly decreased in the interventional group compared to that in the control group (13.5% vs 29.2%; Chi-square test, P = .02). However, no significant differences of self-efficacy (25.6 ± 4.8 vs 24.3 ± 6.3; P = .16) and burnout (27.0% vs 34.7%; Chi-square test, P = .31) were observed between the two groups.

Conclusions: The well-designed interventional courses had a positive impact on the mental well-being and empathy in senior Chinese medical students, which may help provide novel information for incorporation into the medical school curriculum.

Background

Many stress factors including long-hour study, frequent examinations and deteriorating patient-physician communication make medical students vulnerable to mental health problems [1-4]. Accumulative literature have shown that a significant proportion of medical students had different degrees of mental health problems [5, 6]. In addition, the prevalence of depression was significantly higher among medical students (22-36%) than the pre-college students and general population (2-16%) [7-10]. It was also well documented that medical students were more susceptible to burnout associated with a noticeable lack of self-efficacy (SE), which affected their academic performance, clinical empathy and overall quality of life (QoL) [11]. In China, these mental health-related issues were further exacerbated by the deteriorating patient-doctor relation as reflected by the intensive violent incidents perpetrated by the patients in the hospitals [12, 13]. Frequent medico-legal disputes have
brought a heavy psychological burden and stress to the medical students in China [14, 15] and have negatively impacted the students’ passion and confidence in pursuing their future medical careers [13, 16]. The lack of communication skills affected by the empathy was an important factor contributing to a tense patient-physician relation in China [17, 18]. In addition, the reduced empathy further compromised the students’ clinical ability and performance [14, 19].

Although many previous reports have raised extensive concerns regarding the mental health of medical students, effective interventional strategies were lacking [16]. Recent years, several randomized controlled studies, using mindfulness-based stress reduction (MBSR), have been proposed to reduce the mental distress and burnout, and improve their coping skills as well [20, 21]. In addition, many other various interventions including Yoga, psychological counseling and Williams LifeSkills training were also reported to introduce positive effect on the improvement of stress, depression and quality of life [2, 22-24]. While these studies provided important data for our understanding on the modulation of mental health, however, there were still some limitations in these work. The previous trials often focused on the short-term effects, nevertheless, the long-term effects of the designed interventions were unclear. More importantly, most of the interventions were designed without a detailed research of the targeted medical students. In this context, the intervention might not be precise, which could affect the intervention efficacy. Moreover, except the MBSR, many of these interventions were not delivered by the trained clinician, which might lead to the failure in emotion transmitting that impair the teaching efficiency and the learning experience in the medical education [25, 26]. Therefore, a problem-oriented educational intervention, precisely targeting the specific medical student population, with measurable short- and long-term efficacy should be explored and developed.

In China, the medical students usually spend five years in their undergraduate courses and begin getting into clinical work in their third year. Beside the heavy academic burden, this school-clinic transition always exacerbated the study load and the mental well-being [17, 27]. Moreover, the 3rd and 4th year students will directly face the professional patient-doctor communication. However, in our university, there were only some courses about the medical humanities for the first-year students, which mainly focused the theories of medical development and the modern patient-doctor relation. The communication skills training was lacking for the preclinical students. Higher frequencies of depression and burnout, and lower empathy and sense of personal achievement have been reported in the senior grade medical students compared to the junior grade students [17, 18, 28]. Nevertheless, the related randomized interventional studies carried out in these Chinese medical students were very limited and urgently needed.

In the current study, we aimed to performed a prospective randomized controlled study to evaluate the efficacy of the evidence-based and physician-guided interventional courses to improve the mental well-being and empathy of the 3rd and 4th year medical students in China. The impacts of the designed interventional courses on the medical students’ mental well-being (e.g., SE, QoL, depression, burnout) and clinical empathy were measured using the General Self-Efficacy (GSE) scale, Medical Outcomes Study
Short Form 8 (SF-8), Patient Health Questionnaire-9 (PHQ-9), Maslach Burnout Inventory (MBI), and Jefferson Scale of Empathy-Health Care Provider Student version (JSE-HPS), respectively.

**Materials And Methods**

**Participants**

This was a single-center, randomized controlled study carried out in Zhongshan School of Medicine, Sun Yat-sen University between March 2016 and June 2016. Enrollment criteria included: (1) Third and fourth-year medical students; (2) Major subject of clinical medicine; (3) Absence of previous history of mental illness. Finally, a total of 146 medical students were enrolled. All the enrolled participants have read and signed the written informed consent before commencing the study.

**Sample size**

The power and sample size were calculated with two-sided Chi-square test at a 5% significance level. We estimated that the study would have 80% power to detect 5 points differences with standard deviation of 10 in the primary end point of Empathy between two groups with a sample size of 64 students assigned to each group. In the current study, the sample size was 146, rendering 85% power to detect a 2.5 points difference with a standard deviation of 5 in the quality of life scale and 64% power to detect a 15.7% difference between both groups in the depression.

**Study design and randomization**

Eligible participants were randomly assigned to the intervention (n= 74) and control (n=72) group according to the results sealed in an opaque envelope delivered by the co-investigators. The randomization coding list was generated by a simple randomization allocation method PLAN procedure (SAS, version 9.4, USA). Each student was assigned a number, which was linked to the corresponding contact information kept by the third party supervisor. Neither the students nor their teachers were blind to the allocated group due to the interactive schedules between both groups. Each group received one session per month for three months.

**Data collection**

In this trial, we used five validated questionnaires to evaluate the SE, QoL, depression, burnout and empathy. All participants were asked to complete the self-assessment scales and fill in their individual randomized number on the questionnaires before and one month after the whole intervention courses. The indicated scales were introduced as follows:

1. General Self-Efficacy Scale

Self-efficacy (SE) was measured by the General Self-Efficacy Scale (GSE Scale). The GSE scale was designed to measure a broad and stable sense of personal competence to effectively deal with a variety
of stressful situations [29]. The scale was composed of 10 itemized questions that were answered on a 6-point Likert-type scale ranging from strongly disagree (score 1) to strongly agree (score 6). A higher total score meant a higher level of SE.

2. Medical Outcomes Study Short Form 8

QoL was measured by the Medical Outcomes Study Short Form 8 (SF-8). SF-8 was a valid quality of life survey that covered the same eight domains of the SF-36 but in a shorter (eight question) form [30]. The domains covered by the SF-8 Likert-type scale included: physical function, limitations due to physical health problems, bodily pain, general health, energy/fatigue, social function, limitations due to emotional problems, psychological distress and mental well-being. The score of pain domain ranges from 1 to 6, while scores of the other domains range from 1 to 5. Higher scores represented better physical state and mental state.

3. Patient Health Questionnaire-9

Depression was measured by the Patient Health Questionnaire-9 (PHQ-9). PHQ-9 had 9 questions involving core symptoms of depression (anhedonia and depressed mood), suicidal tendency (suicidal thoughts), physical symptoms (trouble sleeping or concentrating, feeling tired, changes in appetite, feeling slowed down or restless) and the feeling of guilt or worthlessness over the past two weeks. Scores > 1 in the core symptoms of depression or suicidal tendency indicated the existence of depressive symptoms, in addition, medical students with a scoring > 9 points were also diagnosed with depression.

4. Maslach Burnout Inventory

Maslach Burnout Inventory (MBI) was a valid and widely used standard survey to measure burnout [31-33]. Burnout was comprised of three domains including emotional exhaustion (EE), depersonalization (DP), and personal accomplishment (PA). The MBI was a 7-point Likert scale including 22-items that evaluated all of the three domains (the score range of EE was 0-54, the score range of DP was 0-30 and the score range of PA was 0-48). Medical students who scored ≥ 27 in the EE domain or ≥ 10 in the DP domain were identified as having at least one manifestation of professional burnouts [34].

5. Jefferson Scale of Empathy-Health Care Provider Student version

We measured empathy by the Jefferson Scale of Empathy-Health Care Provider Student version (JSE-HPS) that included 20 items answered on a 7-point Likert scale. Student were required to score each item according to the level of agreement (from 1 = strongly disagree to 7 = strongly agree). Ten items were negatively worded with reverse score. The total JSE-HPS score ranges from 20 to 140, with higher score values indicating higher degree of empathy [35]. Itemized questions in each survey were initially translated into Chinese for data collection, then translated back into English by bilingual researchers at the First Affiliated Hospital of Sun Yat-sen University to ensure the accuracy of translation. All of the questionnaires including the General Self-Efficacy (GSE) scale [36, 37], the Medical Outcomes Study Short Form 8 (SF-8) scale [38], the Patient Health Questionnaire-9 (PHQ-9) scale [39-42], and the Jefferson
Scale of Empathy-Health Care Provider Student version scale [28] have been validated for a Chinese population.

**Development of the Intervention courses**

To increase the efficacy of the intervention courses, we attempted to know about the psychological disturbances of the 3\textsuperscript{rd} and 4\textsuperscript{th} year medical students before the intervention development. We randomly recruited five pre-clinical medical students (3rd year) and five interns (4th year) to serve as a pilot study group for the preliminary data collection to determine the themes of the interventional courses. We met with the pilot group members and discussed their impressions of the current clinical work and the related mental troubles for three months. Students often mentioned the lack of motivation and achievement in the daily repetitive medical work, the pressure to cope with the doctor-patient relationship and the need to acquire action-oriented strategies or skills to help them face the workload and potential medical negligence. Thus, topics concluded from the pilot study were organized into modules entitled “Establishing the sense of Achievement”, “Means for Efficient Patient-Doctor Communication”, and “Strategies to Manage Medical Errors”. To develop the problem-oriented interventions, we introduced three experienced clinicians to narrate the theme-related stories based on their own real clinical experience. In the “Establishing the sense of Achievement” module, we hoped to deliver four positive aspects of medical practice to our students including the professionalism of physicians to save lives, the meaning of gratitude or good faith from the patient, the importance of any newly acquired clinical knowledge from the daily work and the reputation award from colleague. These stories should help the students establish a good feedback of cognition and behavior in their daily clinical study and work, thus reducing the burnout and enhancing the self-efficacy. In the “Means for Efficient Patient-Doctor Communication” module, we emphasized the importance of the art of patient-doctor conversation and the empathy ability. The lecturer shared some successful examples (No regret or complaint on the clinical decision from patients or their family members) involved with the ethical background such as the expensive treatment cost and poor economics of the patient’s family, the unexpected blood relation of the parent and children, etc. The communication skills and empathy reflected by these vivid stories should help our students optimize the clinical decision or advise with the respect for the patients, thus promoting the students’ empathy and also reducing the depressive symptoms due to the released pressure. In the “Strategies to Manage Medical Errors” module, the lecturer shared the medical errors that she had made and the strategies to prevent and solve similar problems in her future work. These stories were of importance to tell our students that everyone could make mistakes even she was a very experienced doctor. In addition, how to report the mistake to the superior doctor and communicate with the patient and their family members after medical errors were essential skills for the students. These stories should help the students establish confidence, thus reducing depression and enhance self-efficacy. As a result, the quality of life should be improved due to the reduced stress. Building on previous literature [43-45], we combine the form of facilitated discussion groups that incorporated some elements of mindfulness, shared experience, and small-group learning to give the intervention. The same general structure was followed in each course: (1) check-in and welcome, (2) environment preparing (eg, leisure, friendly atmosphere,
simple reflective exercise), (3) story narration, (4) skills and solutions learning, (5) facilitated group discussion, (6) summary and checkout.

**Courses administration**

The intervention course focused on three main subjects: (1) Establishing the sense of Achievement, (2) Means for Efficient Patient-Doctor Communication, (3) Strategies to Manage Medical Errors. Three experienced clinicians with at least 10 years of clinical service in our affiliated hospital were selected to serve as the lecturers. The lecturers were trained by a member of our team to ensure that they were familiar with the protocols and were able to narrate these stories fluently. The shared stories involved with various theme-related experience or skills about, for example, the positive aspects of medical practice such as letters of gratitude, awards or newly acquired experience, the strategies for efficient patient communication and ways to break bad news, and the dealing with medical errors.

The interventional courses were delivered in leisure, friendly atmosphere after the regular medical courses. The students were divided into three small groups (25 students/group) based on the order of their code number and each group was guided by a corresponding lecture. During the course, each lecture narrated a story and summarized the skills for 20-30 minutes, then the students were given 30 min for group discussion and sharing their own feelings. Thus, each intervention lasted about 60 minutes. Students in the control group has random conversation under similar leisure, friendly atmosphere, however, no specific topics, coping strategies and skills were guided and discussed.

**Follow up**

In order to evaluate the long-term impact of the intervention courses, we contacted all the interventional group students two years after the intervention (June, 2018) by e-mails. They were requested to reflect on the interventional courses by answering the following three questions: (1) Please write down the most impressive story you remember from the interventional courses? (2) Which aspect of the interventional course influence you the most? (3) How did you apply strategies from the interventional courses in your daily clinical practice? The qualitative data were collected and analyzed.

**Statistical Analysis**

Questionnaires with missing information in three or more items were excluded from subsequent analysis. If the scores of few scale items were missing, the median of the scores of the same items in the remaining students was used to replace the missing data. The baseline characteristics of the participants were described with the mean (SD) if the variable follows a normal distribution, and if the data did not follow a normal distribution, the median (IQR) was used. Independent sample t test or Wilcoxon rank sum test was used to compare differences for continuous variables between two groups while Chi-square test or Fisher exact test was used for analyzing the categorical variables. The statistical differences between the baseline and follow up scores for each outcome separately in intervention and control group were
also compared using the paired t test, in which the difference between the baseline and follow up data was calculated and compared. All of the statistical analysis were performed using SAS (version 9.4, USA). A P value < 0.05 was considered to be statistically significant.

Results

Cohort and baseline characters

We initially recruited 160 third and fourth-year medical students. After screening, a total of 146 students were enrolled and were randomized into two arms (74 students in interventional group and 72 students in control group) as showed in Figure 1. Among all collected surveys, 15 missing values were found and none of the scales were excluded from the analysis. No significant difference in gender and age were observed between the intervention and control group. In addition, the basal level of SE (26.1 ± 4.4 vs 25.8 ± 5.6; P = .76), QoL (31.0 [IQR 29.0, 34.0] vs 31.0 [IQR 29.0, 34.0]; P = .62), depression (15.3% vs 24.3%; Chi-square test, P = .17), burnout (33.3% vs 35.1%; Chi-square test, P = .82) and empathy (110.5 [IQR 101.5, 119] vs 110 [IQR 103, 116]; P = .98) between the two group were no significantly different (Table 1).

Short-term outcomes of Randomized arms

Compared to the control group, students in the interventional group had significantly higher scores of QoL (32.0 [IQR 28.0, 35.0] vs 29.5 [IQR 26.0, 34.0]; P = .04), empathy (111.0 [IQR 102.0, 118.0] vs 106.0 [IQR 93.0, 111.5]; P = .01), and lower rate of depression (13.5% vs 29.2%; Chi-square test, P = .02) (Figure 2; Table 2). The score of burnout in the intervention group was lower than that in the control group (45.1 ± 13.6 vs 49.6 ± 13.1; P = .04), however, no statistical difference was observed in the burnout rate between the two groups (27.0% vs 34.7%; Chi-square test, P = .31) (Table 2). The students in the two groups had similar scores of SE with no significant difference (25.6 ± 4.8 vs 24.3 ± 6.3; P = .16) (Table 2).

We also compared the statistical differences between the baseline and follow up scores for each outcome separately in intervention and control group. The data showed that the control group had decreased scores of follow-up SE (1.79, [95% CI: 0.01, 3.57], P=0.05), QoL (1.9, [95% CI: 0.23, 3.58], P=0.027), Empathy (5.44, [95% CI: 5.81, 10.08], P=0.023), increased scores of the depression (-1.68, [95% CI: -2.91, -0.4], P=0.008) and unchanged level of the burnout (-0.54, [95% CI: -4.46, 3.37], P=0.787), compared to the baseline data.

The intervention group had decreased scores of follow-up depression (1.12, [95% CI: 0.5, 2.45], P=0.028), and unchanged level of SE (0.15, [95% CI: -1.5, 1.79], P=0.862), QoL (0.48, [95% CI: -0.97, 1.92], P=0.52), Empathy (2.04, [95% CI: -1.69, 5.76], P=0.023) and burnout (2.71, [95% CI: -0.62, 6.03], P=0.787), compared to the baseline data.

Long-term efficacy of the interventional courses
We got twenty-one replies with a response rate of 25.6%. While referred to the first question (Please write down the most impressive story you remember from the interventional course?), it was striking that 15 of the 21 students wrote down one of the stories in the “Means for Efficient Patient-Doctor Communication” module. The stories in the “Strategies to Manage Medical Errors” were recalled by five students, while one student was impressed with the story in “Establishing the sense of Achievement” module. In response to the second question, all the students reported the positive aspects of the intervention course and its positive and constructive influence on their daily practice and long-term careers. Besides learning the strategies and skills, the students also reported the importance of emotional connection with the patients. They reflected on the shift in their perception of doctor-patient relation and medical errors. The aim of the third question was asked to observe that if the interventions were internalized in these students and helped them face the intensive clinical work. In response to this question, most of the students reported that they learned to pay special attention to teachers’ conversation skills, as well as the expressions and attitudes of patient and their families in their daily work. In addition, careful history taking, body examination and multidisciplinary clinical decision were also mentioned to reduce the medical errors. Therefore, the “Means for Efficient Patient-Doctor Communication” and “Strategies to Manage Medical Errors” modules in this trial seemed to be the most helpful and rewarding for the student's mental health and empathy. “Emotional connection” and “Strategy and skill” were the two themes concluded from the qualitative data.

The top ranked story that impressed the students was briefly quoted as follows: “I have met one patient who was suffering from the chronic liver disease and his condition was turning relatively serious. The following treatment was very expensive. His wife went to ask me whether she should continue the treatment because they had three kids to raise and the current family economy was poor. The first step what I do is to tell her all the advantages and disadvantages of the continuing treatment within the scope of professional requirement. Next, I gave my own opinion that “If I were you, I would continue the treatment as long as the charge won't bankrupt and hurting our family”. In the end, I fully understand the woman's tough situation, so I gently told her that “I knew your pain, so I would understand and respect your final decision whatever you selected”. Please never try to morally comment or to condemn the patient's or the family members’ choice but learn think and communication from the perspective of patients. In the following treatment, both of the patient and his wife trust me a lot.”

Some representative quotes from the participants’ replies were as follows: “I still remember one story: when the patients' wife asked whether she should keep trying to treat her chronically-ill husband with a huge cost, the teacher answered “If I were you, I would try to save him as long as there is hope and comfort for him without going bankrupt and hurting yourself.” I felt this story very touching and I am now using this way of discussion in my clinical practice when facing similar situation.”

“I remembered sharing my fears of making clinical mistakes and my course teacher told us not to be fear of making mistakes because a clinical decision was always made in the consensus view of the clinical team. We are always supported by our senior colleagues when facing new and complex clinical
situations. The courses have provided me courage, clinical empathy and confidence to learn new techniques and explore novel surgical operations for the best interests of patients’ care.”

**Discussion**

In this study, we investigated the impact of a well-designed educational intervention on the mental health and empathy of the senior Chinese medical students. Generally, the problem-oriented and physician-guided courses showed positive effects on the students’ well-being, as evidenced by the significantly improved QoL, depression and empathy.

In China, the 3rd and 4th year of the clinical medicine is an important transitional stage. In our center these students had the heaviest academic load (e.g., pass of 9 clinical subjects in the final examination and various Objective Structured Clinical Examination [OSCE]) and faced the clinical work with few experiences. Some interventions should be developed to help the students through this stage. Several previous trials have reported some useful methods like MBSR-based exercises, psychological counseling and peer communication that reduced the distress or stress [20, 21, 23, 46]. Nevertheless, the knowledge of mental problem or trouble of this subset of Chinese medical students was limited. The pre-trial pilot study offered important clues that these students need more clinical guidance and communication skill support, besides the psychological comfort. The improved QoL, depression and empathy at one month after the intervention and the positive effects on the perception and clinical ability reflected by some of the students after 2 years revealed the efficacy of the designed courses. Our data provided the representative example that the problem-oriented educational intervention might be useful. Besides the reported methods, such method presented by the current study could be explored to settle with the mental health or empathy problems in the specific medical student population.

Another different design in the present study from most of the previous work was that the whole interventional courses were guided by the experienced physicians. We take the emotional transmission and sincerity into account in this trial since the emotion had a positive effect on the learning efficiency and internalization of the clinical skills and knowledge [25, 47]. It’s inspiring to find that the courses have served part of the students in their future clinical practice. This result indicated the importance of emotion and professionalism in the intervention involved with the senior Chinese medical students.

Previous studies have showed that the prevalence of mental health problems in the medical students was significantly higher than that in general population and became worse in senior medical students [48-50]. Similarly, we also observed the high prevalence of depression and burnout in this study. After intervention, compared to the control group, the QoL and depression of the students in the intervention showed significant improvement. The depression also reduced after courses compared to the baseline in the intervention group, indicating a benefit on the relieve of mental stress. Of note, we observed that the depression rate of students in the control group significantly increased. The possible explanation might be that the final exams was coming, which brought huge pressure to the students, as
the 3rd and 4th year medical students in our university needed to pass 9 clinical subjects and various OSCE-based test in the final examination. Such pressure was also likely to explain that not only depression but also the SE, QoL, and empathy were getting worse in the control group, while the mental health level of the students in the intervention group after courses showed improvement or unchanged level compared to the baseline. This phenomenon might imply the positive effect of the intervention to help the students face the daily stress and keep a stable mental state. In the study, the SE and burnout didn’t show significant improvement. This could be attributed to the relatively short duration of the interventional course. Future studies with longer interventional courses would be required.

Empathy was another important ability of medical students, especially for the senior Chinese medical students. Over the past 20 years, many violent incidents perpetrated by the patients have been reported, which turned the doctor in China into a high-risk job [13, 27] and affect the students’ career faith [19]. Poor doctor-patient relationship might lower the students’ clinical empathy which could further exacerbate the doctor-patient communication ultimately affecting the patients’ prognosis [51, 52]. Empathy could be of great help in the better doctor-patient communication to achieve the best mutual understanding [53], and was also important to patient care by enhancing patients’ satisfaction, comfort, self-efficacy and trust leading to accurate diagnosis, shared decision making and therapy adherence [54]. In this study, we introduced the patient-doctor communication skills by narrating and sharing the real stories, eventually effectively improving the empathy of medical students in the intervention group compared to the control group. More importantly, as described in the follow-up emails, the students still remembered the stories and emphasized the skills learning.

This study also has several limitations. First of all, this was a single-center trial. Multicenter studies should be carried out in the future to further validate the efficacy of the similar interventions. In addition, although all of the five scales of Chinese version have been validated in the previous studies [35-42], however, it’s difficult to absolutely guarantee the complete preservation of the original intention due to the translation. Third, there were few missing data in some scale items, though the proportion is less than 1%. Another small limitation was that it’s hard to prevent the student participants’ communication after courses and difficult to guarantee anonymization which might lead to the bias of the follow-up data.

**Conclusions**

The interventional courses guided by the clinicians sharing real-life experiences significantly improve QoL, promote empathy and reduce depression among the senior Chinese medical students. Our results pave the way towards a novel strategy for the course reform of the education curriculum in Chinese medical school by adding the accessible, lowcost and easy to implement educational intervention to improve the stress-related mental health and empathy.

**Abbreviations**
Declarations

Ethics approval and consent to participate

The study was approved by the institutional ethic review board of Zhongshan School of Medicine and all enrolled participants read and signed the written informed consent before commencing the study.

Consent for publication

Not applicable.

Availability of data and materials

The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

RR and JLG conceived the design. MK and HPX supervised the study. WC, WYC, ZHD and YBZ performed all procedures of the clinical trial. RR, JLG and YBZ analyzed the data. RR and ZHD wrote the manuscript. MK and HPX reviewed the manuscript. All authors reviewed and approved the manuscript.

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Tables

**Table 1.** Baseline Characteristics of 146 senior medical students between intervention and control group
| Variables                        | Total      | Control group (n = 72) | Intervention group (n = 74) | Statistics | P value |
|----------------------------------|------------|------------------------|-----------------------------|------------|---------|
| Age, year (range)                | 21.0 (20.0, 21.0) | 20.5 (20.0, 21.0) | 21.0 (20.0, 21.0) | 3250 | 0.42 |
| Gender                           |            |                        |                             |            |         |
| Males                            | 76 (52.1%) | 37 (51.4%)             | 39 (52.7%)                  | 0.025 | 0.87 |
| Females                          | 70 (47.9%) | 35 (48.6%)             | 35 (47.3%)                  |         |       |
| SE, mean (SD)                    | 26.0 (5.0) | 26.1 (4.4)             | 25.8 (5.6)                  | 0.360 | 0.76 |
| QOL, median (IQR)                | 31.0 (29.0, 34.0) | 31.0 (28.5, 34.0) | 31.0 (29.0, 34.0) | 2679 | 0.62 |
| Depression (PHQ-9), mean (SD)    | 6.3 (3.4)  | 5.9 (3.0)              | 6.6 (3.7)                   | 1.276 | 0.20 |
| Depression (PHQ-9), N (%)        |            |                        |                             | 1.876 | 0.17 |
| No                               | 117 (80.1%) | 61 (84.7%)             | 56 (75.7%)                  |         |       |
| Yes                              | 29 (19.9%)  | 11 (15.3%)             | 18 (24.3%)                  |         |       |
| Burnout (MBI), mean (SD)         | 46.3 (14.7) | 46.8 (14.6)            | 46 (15.0)                   | -0.336 | 0.74 |
| Burnout (MBI), N (%)             | 96 (65.8%)  | 48 (66.7%)             | 48 (64.9%)                  | 0.053 | 0.82 |
| No                               | 50 (34.2%)  | 24 (33.3%)             | 26 (35.1%)                  |         |       |
| Yes                              | 45 (30.8%)  | 25 (34.7%)             | 20 (27.0%)                  |         |       |
| Empathy (JSE-HPS), median (IQR)  | 110 (102, 118) | 110.5 (101.5, 119) | 110 (103, 116)             | 2514 | 0.98 |

Notes: Continuous variables are presented as mean (SD), median (IQR), and N (min, max). If the variable follows a normal distribution, it is described with the mean (SD) and if it does not follow a normal distribution, the median (IQR) is used. Categorical variables are presented as n (%) according to different levels.

 superscript a t-test results for continuous variables with normal distribution, Wilcoxon test results for continuous variables with abnormal distribution, and Chi-square test results for categorical variables.

Abbreviations: SD, standard deviation; IQR, inter-quartile range; SE, self-efficacy; QOL, quality of life; MBI, Maslach Burnout Inventory; PHQ-9, the Patient Health Questionnaire-9; JSE-HPS, the Jefferson Scale of Empathy-Health care Provider Student version.
Note: Continuous variables are presented as mean (standard deviation, SD) and median (inter-quartile range, IQR). If the variable follows a normal distribution, it is described with the mean (SD) and if it does not follow a normal distribution, the median (IQR) is used. Categorical variables are presented as n (%) according to different levels.

Abbreviations: SD, standard deviation; IQR, inter-quartile range; SE, self-efficacy; QOL, quality of life; MBI, Maslach Burnout Inventory; PHQ-9, the Patient Health Questionnaire-9; JSE-HPS, the Jefferson Scale of Empathy-Health care Provider Student version.

Figures

Enrollment

Assessed for eligibility (n=160)

Excluded (n=14)
- Not meeting inclusion criteria (n=2)
- Declined to participate (n=4)
- Other reasons (n=8)

Randomized (n=146)

Allocated to intervention (n=74)
- Received allocated intervention (n=74)
- Did not receive allocated intervention (give reasons) (n=0)

Allocated to control (n=72)
- Received allocated control (n=72)
- Did not receive allocated control (give reasons) (n=0)

Follow-up

Allocated to intervention (n=74)
- Lost to follow-up (give reasons) (n=0)
- Discontinued intervention (give reasons) (n=0)

Allocated to control (n=72)
- Lost to follow-up (give reasons) (n=0)
- Discontinued control (give reasons) (n=0)

Analysis

Analysed (n=74)
- Excluded from analysis (give reasons) (n=0)

Analysed (n=72)
- Excluded from analysis (give reasons) (n=0)

Figure 1
Flowchart of the inclusion of study participants according to CONSORT diagram.

Figure 2

The scatter plot of (a) median of QoL, (b) proportion of depression (PHQ-9), and (c) median of empathy (JSE-HPS) before and after intervention for each group. Red represents data from control group and blue from intervention group. Bars mean 95% confidence interval.

Supplementary Files

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- Additionalfile1.docx