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BMJ Open Efficacy of a smartphone-based care support programme in improving post-traumatic stress in families with childhood cancer: protocol of a randomised controlled trial

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ABSTRACT

Introduction Diagnosis and treatment represent distressing experiences for the families of children with cancer. Psychosocial challenges are faced by these families in China because of limited health services and resources for psychosocial oncology care. Effective interventions tailored to the knowledge level and cultural values of this population are needed. The goal of this study is to evaluate a smartphone-based care support (SBCS) programme for the families of children with cancer in China.

Methods and analysis A parallel randomised controlled trial will be conducted to examine the efficacy of an evidence-based and culturally tailored SBCS programme for the families of children with cancer in China. A total of 180 families will be recruited. The intervention will consist of an introduction session and four main sessions and will be conducted sequentially on a single weekend day. Participating families will be included in the intervention group. The post-traumatic stress and quality of life of families will be evaluated at baseline, during the intervention, immediately after the intervention, and 2 and 6 months after the intervention.

Ethics and dissemination Ethical approval for this protocol has been obtained from the Nursing and Behavioural Medicine Research Ethics Review Committee, Xiangya School of Nursing, Central South University (Protocol #: E2020125). The findings of the trial will be disseminated through conference presentations and publications in peer-reviewed journals.

Trial registration number ChiCTR2000040510.

INTRODUCTION

Background and rationale

Cancer is one of the leading causes of death among children worldwide.¹ The Chinese National Central Cancer Registry reported that the estimated age-standardised (5–15 years) incidence and mortality rates of paediatric cancer are 7.38–10.62 and 3.44–4.46/1000, respectively,² and the incidence has increased by 2.8% annually in the past

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The major strength of the proposed study is that smartphone-based care support (SBCS) integrates cognitive-behavioural therapy with family-based intervention into a smartphone-based approach.
- ⇒ The major limitation of this study is that any long-term effect of the SBCS programme on the health outcomes of children with cancer and their families will be difficult to show through this proposed project because of the limited timeframe.
- ⇒ Given that the intervention area of the proposed study is Hunan Province, China, study findings may have limited generalisability to other regions and countries.

10 years. Moreover, the incidence might be underestimated because of limited registry coverage and missing data from seasonal migrant workers and patients who abandoned treatment.

Being diagnosed with cancer is a traumatic event for children and their families,³ and long and painful therapeutic courses after diagnosis cause extremely distressful and traumatic experiences with far-reaching psychological aftermath.⁴ The families of children with cancer might suffer from severe psychosocial problems, including depression, anxiety, adjustment difficulties, post-traumatic stress, decreased family functioning and reduced health-related quality of life (QOL),^{5,6} especially post-traumatic stress disorder and related symptoms (PTSD/PTSS), which are frequently reported psychological consequences faced by paediatric oncology patients and their caregivers.⁷ The construct of PTSS/PTSD provides a means for understanding psychological distress in these families.⁸ Subclinical PTSS is broader and more normative than the psychiatric diagnosis of



PTSD. PTSS comprises intrusive thoughts about a child's diagnosis or other particularly salient moments during the child's treatment, physiological arousal at reminders of cancer, and thoughts about preventing cancer and its treatment, which are closely linked to clinical care and persistence among the families of children with cancer.⁹ The symptoms of PTSS are common within the Chinese population. For example, 9% of children with cancer and 33% of their parents experience severe levels of PTSS.³ Children and their families in China face many psychosocial challenges because of limited health services and resources for psychosocial oncology care. Hence, the provision of evidence-based psychosocial support to this underserved group in China is critically needed.

Many interventions, including cognitive-behavioural therapy (CBT),¹⁰ joint CBT and physical exercise therapy,¹¹ family-based interventions,¹² therapeutic music videos,¹³ self-coping strategies,¹⁴ wish fulfilment interventions¹⁵ and joint family-based interventions and CBT,⁸ have demonstrated potential efficacy in relieving the psychosocial problems of children living with cancer and their families. A meta-analysis and systematic review have demonstrated that multicomponent family-based interventions in combination with individualised cognitive-behavioural strategies—such as the Surviving Cancer Competently Intervention Programme (SCCIP)^{9 16}—are effective in promoting psychological well-being and QOL, and are cost-effective.¹⁴ However, inadequate evidence in this area has been obtained from China.¹⁷

A national push towards the use of information technology in healthcare is currently occurring in China. mHealth interventions in which mobile communication technologies are used to enhance or replace the traditional in-person models of psychosocial or medical care present a unique opportunity to deliver or improve psychosocial interventions for the families of children with cancer. Compared with face-to-face intervention methods and other remote intervention methods (eg, website-based interventions), smartphone-based interventions are advantageous because they are easily accessible, made widely available among people and highly flexible in terms of intervention hours. The method has a low cost, given that 91% of Chinese people own smartphones. The rapid development and widespread use of smartphones make smartphone-based interventions feasible in China. The initial results of a study by Canter *et al*¹⁸ showed a technology-based multicomponent support intervention that can facilitate the dissemination of evidence-based interventions to families of children with cancer and can potentially improve children's and parents' outcomes. However, little is known about the efficacy of smartphone-based care support (SBCS) programmes for the families of children with cancer in China.

Objectives

The overall aim of this project is to test the efficacy of an SBCS programme.

The primary objectives are as follows: (1) to evaluate the efficacy of the programme in improving post-traumatic stress among caregivers who take care of children with cancer and (2) to evaluate the efficacy of the programme in improving post-traumatic stress among children with cancer. The secondary objectives are as follows: (1) to evaluate the efficacy of the programme in improving the QOL of childhood cancer patients and (2) to evaluate the efficacy of the SBCS in improving other psychosocial outcomes (QOL, social support, caregiving self-efficacy and family functioning). The changes in primary outcome PTSS between preintervention and postintervention at 6 months will be collected and compared with usual care before and during the intervention, immediately after the intervention, and 2 and 6 months after the intervention, by comparison between intervention and control groups. The PTSS among caregivers will be evaluated using the Impact of Event Scale-Revised (IES-R), and among children using the 22-item self-report University of California, Los Angeles PTSD Reaction Index (PTSD-RI).

The following hypotheses are proposed: the SBCS programme will (1) reduce post-traumatic stress among caregivers in the intervention group; (2) reduce post-traumatic stress among childhood cancer patients in the intervention group; (3) improve the QOL of childhood cancer patients in the intervention group and (4) improve other psychosocial outcomes (QOL, social support, caregiving self-efficacy and family functioning) in the primary caregivers of childhood cancer patients in the intervention group.

METHODS AND ANALYSIS

This study protocol was written according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013.

Study design and setting

This study is designed as a parallel randomised controlled trial to investigate the efficacy of an SBCS intervention in improving the psychosocial outcomes of children with cancer and their primary caregivers in China. At present, the researchers are adapting and finalising the intervention programme materials. Recruitment of participants will begin in January 2023, and the intervention and follow-up are expected to be completed by December 2023.

All intervention and data collection procedures in this study will be conducted through the Chinese social media application WeChat, and the participants will be recruited from the three affiliated hospitals of Central South University in Hunan Province. Hunan is a representative province of central south China in terms of geography (mixed plains and mountainous areas), climate (humid subtropical), culture, demographics (Han and multiple minorities), economy, health policy and lifestyle. The three affiliated hospitals of Central South University, as the three largest general hospitals in Hunan Province,

accept patients with serious diseases. The recruitment of research participants from these hospitals can make the samples sufficiently representative.

Participant recruitment

Potential participants will be recruited in two ways. First, the health records of children in the related wards of the three hospitals will be reviewed by a trained registered nurse (RN). Second, referrals from health professionals and family caregivers will be used to recruit participants. Eligible children and family caregivers will be contacted by trained RNs for a 5–15 min enrolment interview and will be notified about how to join the programme. A full explanation of the programme will be provided. All families can withdraw their participation at any time during the study. The reasons for declining to participate and discontinuing participation will be recorded.

Eligibility criteria

The eligibility criteria are as follows: (1) having a child diagnosed with cancer; (2) the child with cancer is 7–17 years; (3) the child is undergoing cancer treatment, such as radiation and chemotherapy, and has not yet entered the phase of long-term survival¹⁹; (4) the child and their primary caregiver can read and speak Mandarin Chinese and can complete a basic cognitive skills test and (5) the child and their caregiver are willing to participate in the study. The exclusion criteria are as follows: (1) the child's cancer is a relapsed or end-stage cancer; (2) the child is unable to complete the interview; (3) the child is currently participating in or has been involved in other similar intervention studies and (4) the child has other serious health problems, such as thyroid disease, asthma or hypertension. For children whose parents are not primary caregivers, other primary caregivers, such as grandparents, will be identified and recruited.

Sample size

Sample size calculation is based on testing the primary hypothesis: The intervention will reduce the PTSS among caregivers. A previous study showed that the average score of IES-R (full scoring 110) among caregivers without any intervention was 48.5 with an SD of 9.2.²⁰ We define a 10% reduction in the IES-R score as the clinical significance of the intervention at the end of intervention at a 6-month follow-up. A sample size of 70 in each study group is needed to achieve a statistical power of 80% to test the 10% difference by assuming a two-sided test with $\alpha=0.025$ (calculated using software G*Power 3.1.9.7). An adjustment for 20% attrition in each group at a 6-month follow-up inflates the sample size by a factor of 1.2. Variance inflation due to clustering in six patient blocks further inflates the sample size by $[1 + (0.015)5] = 1.075$, based on an assumed intraclass correlation coefficient of 0.015. These two adjustments yield an inflation factor of 1.29, giving a required sample size of 90 caregivers per group. Therefore, we will include 180 families

in this trial, including 180 children with cancers and 180 their caregivers.

Allocation

Eligible children and their primary caregivers will be randomly assigned (1:1) to SBCS or standard of care (SOC) arms, using an internet-based random number generator (<http://stattrek.com/statistics/random-number-generator.aspx>). Randomisation will be performed by an external biostatistician who will not be involved in the study intervention or data analysis.

Blinding

Owing to the nature of the intervention programme, we cannot blind the implementers and subjects of the intervention, but the surveyors and data analysts will be blinded to the study.

Interventions

SBCS (intervention group)

The SBCS intervention process will be conducted for 6 months and will include an introduction session, four main WeChat-based counselling sessions and a maintenance phase of intervention. In the WeChat group, there will be a capacity for screen sharing and video conferencing with up to 500 people.

The main sessions will be conducted sequentially on 4 weekend days with the groups of participant families. Sessions 1 and 2 will focus on the use of cognitive-behavioural principles in reducing individual and family distress,^{4,17} and sessions 3 and 4 will be conducted using a multifamily discussion group format,¹⁶ which invites participating families to engage with common themes and provides a structure in which participants can observe the discussions of other families.⁸ Discussions will prompt families to discuss topics that they rarely talk about openly. Themed animated cartoons will be used as intervention materials.

Introduction session

A psychologist and a paediatric oncologist will welcome participants. All participants will watch animated cartoons about the benefits of integrating the mind and body in cancer treatment and the process of the SBCS programme.

Session 1: how cancer has affected me and my family

This 45 min session will be done independently for each family. A psychologist will present a cartoon about the perspectives of caregivers and children on 'How post-traumatic stress events may continue to be worrisome.' The cartoon will depict a potentially upsetting memory that is related to cancer diagnosis and treatment.⁴ Then, the children and their primary caregivers will be asked to fill in a reflection worksheet according to their actual situations.

Session 2: coping skills

This 60 min session will be done independently for each family. The topic addressed in the presented cartoon is

**Table 1** Explanation of the Adversity-Beliefs-Consequences model and Reframe

Adversity	Have cancer themselves or their children have cancer
Belief	Thoughts that we have about our adversities
Consequence	Emotional consequences or feelings about adversity
Reframe	(1)Accept the uncontrollable; (2) focus on the controllable and (3) use the positive

mental self-talk, which is defined as a conversation that runs in our heads and helps us analyse and interpret events. The ABC Adversity-Belief-Consequence-Reframe (ABC-R)^{21 22} (table 1) will be introduced. After the animated cartoon presentation, all families will need to fill in the ABC-R worksheets according to their actual situations.

Session 3: cancer and families

In this 60 min session, 90 families will join a WeChat group. The topic addressed in the presented cartoon is 'Do a self-talk about how your beliefs about cancer are affecting your family today'²³ and 'How should we deal with one another's grief'.¹⁸ After the animated cartoon presentation, the psychologist will invite four volunteer families who will share their stories.^{24 25} As assignments, the members of the 90 families will be prompted by a trained project field coordinator individually to respond to the same topic through WeChat.

Session 4: family health and our future

This 60 min session has the same procedure as session 3. The topics addressed in the presented animated cartoon are 'How do family members recognise the disease and put it in the right place?'²³ and 'Once cancer is diagnosed, how does the family continue to grow?'.²⁶ After

the animated cartoon presentation and sharing among volunteers, a trained project field coordinator will collect all participants' stories about the same topic through WeChat.

After the four intensive sessions, the participants will go on to the maintenance phase of the intervention, which involves WeChat consultation sessions on a monthly basis for 2 months. The maintenance WeChat consultation will last no more than 20 min per consultation. Information about the timeline of the intervention activities is provided in table 2.

SOC (control group)

The participants in the control group (n=90) will receive SOC during the intervention phase. During this time, they will continue with their usual activities and can use their usual care services without any restriction. In our previous studies with this population, we found that few families in China received any psychosocial support beyond care from family members; thus, we do not expect any factors about the SOC to influence outcomes. The participants will complete the same measurements at the same time intervals as the SBCS group. After completion of this study, we will deliver the SBCS programme to all interested families in the control group.

Outcomes

The primary outcome of this study is the post-traumatic stress of children with cancer and their primary caregivers.

The PTSS of children with cancer will be assessed using the Chinese version of the 22-item self-report University of California, Los Angeles PTSD-RI for the Fifth of Version Diagnostic and Statistical Manual of Mental Disorders (DSM-IV).²⁷ A five-point scale from 0 (never before) to 4 (most of the time) will be used by the children when scoring medical treatment received in the last month. The total score ranges from 0 to 88, and a value of 38 or above on the full scale suggests high sensitivity and specificity of PTSD diagnosis.²⁷ The Chinese version of

Table 2 Timeline of intervention activities

Intervention time	0 month											
	Baseline	0 week	1 week	2 weeks	3 weeks	1 month	2 months	3 months	4 months	5 months	6 months	
SBCS group												
Intervention section		S0,1	S2	S3	S4							
Maintenance phase						M1	M2					
Testing	T0		T1		T2, I		T3				T4	
Control group												
Intervention section												
Maintenance phase												
Testing	T0		T1		T2, I		T3				T4	

S0–S4: The introduction section and four SBCS intervention sections; M1–M2: Maintenance phase on a monthly basis for 2 months to preserve testing adherence; T0–T4: Effect measurements in both study groups; I: in-depth interviews.
SBCS, smartphone-based care support.

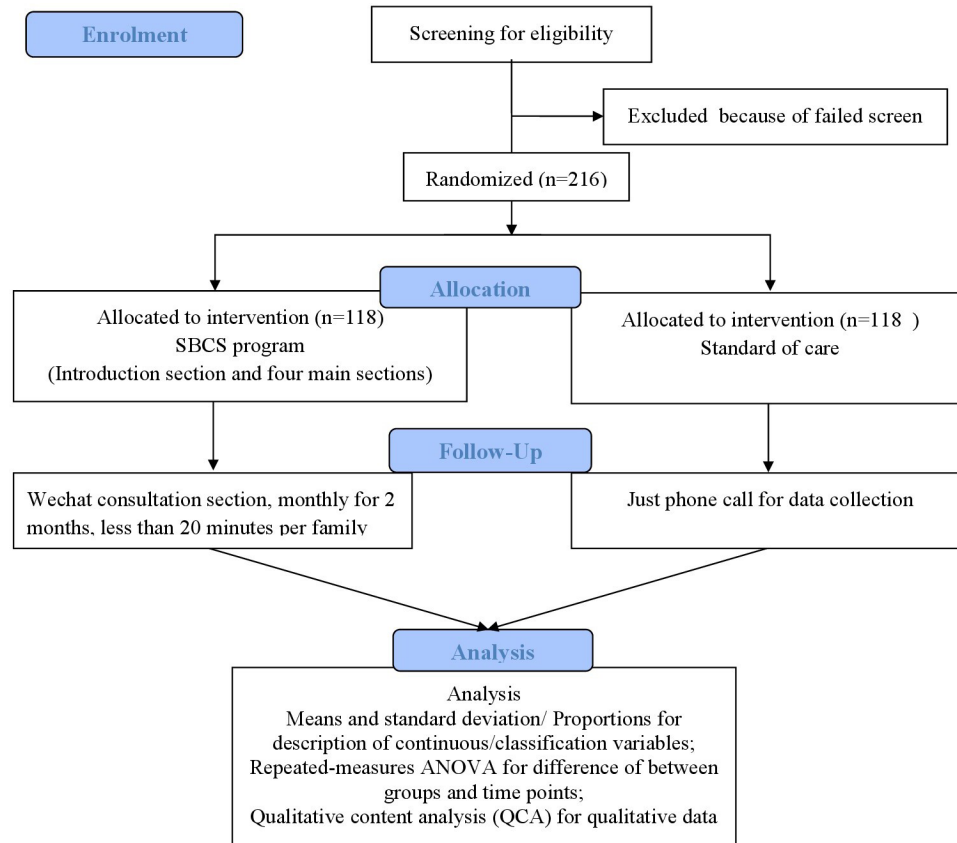


Figure 1 Flow diagram of study design. SBCS, smartphone-based care support. Analysis of Variance, ANOVA.

the PTSD-RI has shown good psychometric performance in adolescents aged 7–18 years, with a Cronbach's α of 0.892.⁴

The PTSS of caregivers will be assessed at each time point (T0–T4) with the IES-R,^{28 29} which consists of 22 items reflecting intrusive thoughts, avoidant behaviours and hyperarousal related to stressful life events as specified in the DSM-IV. A five-point scale from 1 (never) to 5 (all the time) will be used by the caregivers when scoring the frequency of symptoms experienced during the past month. The total score ranges from 22 to 110, and a high score indicates severe PTSS.^{28 29}

The secondary outcomes include caregivers' health-related QOL,³⁰ social support,³¹ caregiving self-efficacy,³² family functioning³³ and children's health-related QOL.³⁴ Each measure will be used in operationalising theoretical constructs. The selected measures have been used in Chinese populations and demonstrated adequate psychometric properties. Covariates, such as sociodemographic factors, disease diagnoses and treatment variables, will be collected.

Data collection and management

The research team will measure outcomes at baseline (T0), immediately after intervention (T2), 2 months after intervention (T3), and 6 months after intervention (T4) (figure 1). All measures employed in the proposed study will be collected by trained project field coordinators who are blinded to participants' group assignment.

To quantify the possible effects of other potentially traumatic events during the intervention on the effectiveness of the intervention, we will collect PTSS scores during the intervention (T1).

At the end of the intensive intervention, families will be asked whether they would like to participate in in-depth interviews. We will select and obtain informed consent from 20 to 25 families totally, sampled from both the control and intervention groups. The interviews will explore families' experiences (especially some potential traumatic events) during the period from baseline through intervention. The interview in the intervention group will explore families' satisfaction with the SBCS programme implementation. Ideas concerning potential improvements to the SBCS programme will be obtained from the in-depth interviews. Each interview will last approximately 45 min.

Personal data will be collected on paper and electronic data storage devices. Sensitive data will be stored in password-protected digital files or a locked cabinet.

The list that links personal data to other data will be destroyed for the sake of anonymisation after the data analysis. Data will be stored on a laptop, on an external hard drive, and a decentralised server of the Central South University and will be archived for at least 10 years on millennial discs. Backups will be implemented regularly.



Statistical methods

Quantitative data

All statistical analyses for this study will be performed using SPSS V.19.0 (SPSS). Two independent samples t-tests and χ^2 tests will be used in assessing baseline data, such as sociodemographic factors, disease diagnosis and treatment variables, healthcare utilisation, cultural practices and beliefs, and differences between intervention and control groups. Appropriate descriptive statistics will be calculated, including means, SD and percentage frequencies, for all variables. We will use repeated measures Analysis of Variance to explore how PTSS and all other secondary outcomes change across times and between groups and to test the interaction between times and groups. Repeated measures models with two levels of treatment variables (intervention group, control group) and five time points (T0, T1, T2, T3 and T4) will be used in examining the effectiveness of this intervention in reducing PTSS. Statistical significance will be represented as p values (two sided) of less than 0.025, because the intervention has two primary objectives and 0.025 was used in the sample size calculation. Four time points (T0, T2, T3 and T4) will be used to examine effectiveness in improving secondary outcomes, including QOL, social support, caregiving self-efficacy and family functioning, with statistical significance represented as p values (two sided) of less than 0.05. The intention to treat will be adopted in the four time-point measurements.

Qualitative data

Semistructured interviews will be analysed using qualitative content analysis, which will focus on variations in participants' satisfaction and experiences participating in the intervention, and will present the results in categories and themes.

Monitoring

The Nursing and Behavioural Medicine Research Ethics Review Committee, Xiangya School of Nursing, Central South University, may withdraw particular participants from the study if any new information indicates that continuing participation is not in their best interests. Adverse events or unintended effects reported by participants will be described in the final trial report. Adherence to the therapy manual will be monitored by the ethics review committee through a standardised therapy documentation form and weekly supervision for participating SBCS. No independent auditing procedures, official data monitoring committee, or interim analysis will be used because the study will only examine behaviour and use noninvasive speech and language therapy; therefore, we expect no serious risks or harm to participants.

Patient and public involvement

Patients and the public were not involved in the design, conduct, assessment of burden or reporting and dissemination plans. However, family caregivers will be involved in the recruitment of participants.

Ethics and dissemination

The study has been approved by the Nursing and Behavioural Medicine Research Ethics Review Committee, Xiangya School of Nursing, Central South University, (Protocol #: E2020125). Written informed consent will be obtained from children and their primary caregivers, and they will be enrolled in this project only when the children and primary caregivers both agree to participate. Results will be disseminated as soon as possible, regardless of the magnitude or the direction of effect, in journals that focus on the symptom management of paediatric cancer. All important protocol modifications will be communicated to the ethics committee.

DISCUSSION

The families of children with cancer in China are at high risk of encountering psychosocial challenges because of limited health services providing psychosocial oncology care. Effective interventions tailored to families' knowledge and educational levels and cultural values are much needed in paediatric oncology care in China.

Several psychosocial interventions have shown to potentially increase children's medical compliance, improve children's psychosocial functioning, and reduce PTSS in parents.^{8 35–37} However, evidence has mainly come from large urban cities in developed countries.

A study was previously conducted in China to explore the effects of CBT on psychological adjustment among Chinese paediatric cancer patients receiving chemotherapy.¹⁷ The results indicated that CBT can effectively help Chinese paediatric cancer patients modify distorted cognition and alleviate negative moods.¹⁷ However, this study only addressed the health needs of children, rather than the whole family. In the USA, Kazak *et al* developed a SCCIP to help families cope with the distressing and lingering psychological aftereffects of cancer and corresponding treatment, integrating CBT with the family-based intervention.^{8 16} The results supported the notion that brief intervention decreases negative psychosocial events, such as post-traumatic stress and other psychosocial outcomes.⁸ Given the advantages of smartphone-based interventions in terms of accessibility and flexibility, we will integrate the core components of SCCIP into a smartphone-based approach (through WeChat). The opportunity for families to connect with other families who have experienced serious paediatric illness is another important feature of the novel design of our study given that isolation, within families and between families or individuals in a society, is a risk factor for ongoing distress and the development of individual and family psychopathology.

Limitations

Limitations of the proposed study include limited generalisability, reliance on self-reported data and

limited geographical region (only Hunan Province). Any long-term effect of the SBCS programme on the health outcomes of children or adolescents with cancer and their families will be difficult to show through this proposed project because of the limited timeframe.

Despite the challenges of the SBCS, which integrates a multidisciplinary approach incorporating clinical nursing and psychosocial care, this study will provide important data in mainland China on the potential efficacy of the intervention in reducing the related burden of negative psychosocial events, such as post-traumatic stress and other psychosocial outcomes; could serve as a basis for disseminating the SBCS programme to a greater number of families of children with cancer; and could provide a blueprint for clinical guidelines for improving quality of care for children with cancer. Such guidelines are critical to the development of evidence-based health policy in China.

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Contributors JM and CG were responsible for the study conception and design. JM and JH developed the statistical analysis plan. CG, JM and YP were responsible for the drafting of the manuscript. H-ZQ, JH, YX and CG revised the manuscript. CG and MY obtained funding and supervised the study.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

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