The STress-And-coping suppoRT Intervention (START) for Chinese Women Undergoing Abortion: a Randomized Controlled Trial Protocol

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Study protocol

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Abstract

Background:

Undergoing an abortion is stressful. This protocol aims to assess the feasibility, acceptability, and primary effects of a complex intervention to promote positive coping behaviors and alleviating depression symptoms among Chinese women undergo abortion.

Methods:

A two-arm randomized controlled trial design will be used. Participants will be recruited at their first appointment with the abortion clinic, those who consent to participate will be randomly allocated to receive either the START intervention (in addition to standard abortion care) or standard care only. All participants will receive survey follow-up until six weeks post-abortion. Ethical has been granted by local and university ethics committees. This research was supported by an Australian Government Research Training Program (RTP) Scholarship

Discussion:

Results will assist refinement and further evaluations of the START intervention, contribute to improved abortion care practices in China, and enrich the literature evidence on improving women's psychological well-being following abortion in China

Trial registration:

Registered at the Chinese Clinical Trials.gov: ChiCTR2100046101. Date of registration: May 4, 2021

Plain English Summary

Although undergoing an abortion is stressful for most women, little attention has been given to promoting the psychosocial wellbeing of women undergoing an abortion. The Transactional Model of Stress and Coping suggests that by offering the support women need, they can adjust their coping behaviours and achieve a more positive psychological consequence of abortion. The research team developed the STress-And-coping suppoRT intervention (START) based on the Transactional Model, as well as insights from both Chinese abortion patients and abortion providers. The START intervention aims to provide women with information, coping skills, and support to help Chinese women achieve positive health outcomes following an abortion.

This protocol (ChiCTR2100046101) details a two-arm randomized controlled trial, with the aim of testing the feasibility, acceptability, and preliminary efficacy of the START intervention among Chinese abortion patients. Intervention feasibility will be examined based on process data on eligibility and actual intervention delivery. Acceptability will be estimated using both quantitative and qualitative data gathered from the participates from telephone interviews, at the close of the intervention. Efficacy of the START
intervention will be assessed multi-timepoint using psychological scales on depression (primary outcome), coping behaviours, self-efficacy, perceived social support, and post-abortion personal growth etc.

**Background**

Induced abortion is common around the world. In 2015-2019, a third of all pregnancies ended in abortion (approximately 77.3 million abortions each year) [1]. Accessing good quality abortion care is a fundamental human right, an important component of sexual and reproductive health services, and an essential way to achieve global health commitments [2] such as the Sustainable Development Goals (SDGs) [3]. Generally, abortion is physically safe when conducted using WHO-recommended methods by appropriately trained professionals [4]. For most women, the main challenge when choosing a first-trimester abortion is their emotional and psychological wellbeing [5]. Some women cope well with abortion and do not experience negative psychological consequences [6, 7]. Some might even find positive meaning and embrace healthy behaviours after an abortion [8, 9], whereas some report ongoing distress and mental health issues [5, 10].

The Transactional Model of Stress and Coping helps to explain the psychological variability of abortion [10, 11]. According to this model, abortion is a dynamic stressful life event that happens in response to an unwanted/unintended pregnancy. In this circumstance, a woman first appraises the significance/severity of the pregnancy and abortion, and then evaluates her options and coping resources at her disposal [10, 12]. A woman's appraisal mediates her coping behaviours and psychological consequences of abortion (see Figure 1) [12]. The Transactional Model of Stress and Coping suggests that by offering women the support they need, they can adjust their coping processes and achieving positive health outcomes.

Despite the critical role of support to women accessing abortion, little attention has been paid to the psychosocial aspects of care [13]. A recently published systematic review found that in the past ten years, only ten experimental studies had been conducted to address the psychological needs of women undergoing abortion [14]. All interventions used a single-component design (e.g., music therapy, information support, or implementation of mandated waiting or counselling policies), and none were informed by a theoretical framework. Conflicting outcomes and methodological limitations hindered conclusions about which intervention could reasonably be adopted to improve women's psychological well-being [14].

In the absence of available evidence, our research team developed the STress-And-coping suppoRT intervention (START). Underpinned by the Transactional Model of Stress and Coping, the START intervention aims to provide women with information, coping skills, and support to achieve positive short- and long-term health. The specific aims of the intervention are alleviating anxiety and depression symptoms, promoting active coping behaviours, and improving the general abortion experience among Chinese women. The intervention is innovative and based on (1) current available evidence; (2) a sound understanding of the target population; (3) informed by Medical Research Council (MRC) guidance for
complex interventions [15]; (4) the Intervention Mapping (IM) framework [16]; and (5) a five-step iterative pathway to gradually shape the intervention design [17].

**Study aim**

The aim of this trial is to explore the feasibility, acceptability, and preliminary effects of the START intervention among Chinese abortion patients in a real-world setting. The specific assessment objectives are to:

1. Determine the feasibility of the START intervention according to eligibility, recruitment, intervention delivery, and retention data
2. Evaluate the acceptability of the START intervention among participants based on the Theoretical Framework of Acceptability (TFA) of Health Care Intervention
3. Test preliminary efficacy of the START intervention on women’s depression and related cognitive, behavioral, and psychological outcomes, compared with women receiving standard abortion care

**Methods**

The study adopts a two-arm randomized controlled trial design with quantitative and qualitative information collected. Participants will be randomly allocated to receive either the START intervention in addition to the standard abortion care or standard abortion care only with a 1:1 allocation rate. The study design is directed by the CONSORT statement and its extensions [18, 19] and the SPIRIT 2013 guideline for protocols of randomized trials [20]. The research activities inconsistent with the real-world clinical practice are outlined in Figure 2.

1 **Setting**

This study will be conducted in the Family Planning and Reproductive Health Centre (FPRHC) of a tertiary hospital in Beijing, China. Participants will be recruited from the outpatient unit of the FPRHC, where abortion related services are normally provided.

2 **Participants**

Women will be invited to participate in the study if they meet the following criteria: 1) Chinese citizens or living in China; 2) can speak, read, and write in Chinese; 3) 18 years or older; 4) seeking termination of an intrauterine pregnancy for non-medical reasons; 5) less than 14 gestational weeks; 6) certain about their abortion decision and indicate the decision is of their free will; and 7) own a smartphone. They be excluded if they: 1) are presenting to FPRHC for post-abortion follow-up examination or secondary treatment of an incomplete abortion); 2) require an abortion for medical reasons; 3) currently receiving
mental or psychological treatment; or 4) unable to give informed consent (e.g., severe intellectual disability or dementia).

3 Interventions

Professionals who provide direct care will be responsible for maintaining the quality of care and women’s safety. See Table 1 for detailed description of the START intervention and standard abortion care according to the template for intervention description and replication (TIDieR) [21]. Generally, the START intervention involves three interacting components: 1) a 30-minute face-to-face consultation immediately after a woman’s enrollment; 2) information support including a printed booklet and an online information platform available to them from the consultation until closure of the project; and 3) timely communication channels with health providers valid until 6 weeks post-abortion. Table 2 presented the specific Content of the information booklet and platform.
### Table 1
Intervention description according to TIDieR checklist

| TIDieR Item | Intervention group | Control group |
|-------------|--------------------|---------------|
| **1. BRIEF NAME** | The START intervention | Standard abortion care |
| **2. WHY** | Based on the Transactional Model of Stress and Coping, the START intervention intends to help Chinese women cope with abortion experience by addressing the specific stressors they face in the Chinese context, hence promoting their short-term and long-term well-being | —— |
| **3. WHAT - Material** | An information booklet, a WeChat-based public profile page (also called ‘official account’), and a hotline | —— |
| **4. WHAT - Procedure** | All women allocated to the intervention group will be offered a 30 mins’ face-to-face consultation after women made their abortion appointment. The consultation includes a brief introduction of the content and features of the START platform, talking with women, answering women’s questions, and offering emotional support and information on available coping resources. A printed informational booklet will be provided to participants during the consultation. Meanwhile, by scan the QR code of the START Platform, women were endowed with unlimited access to the START platform till the closure of the project. A hotline women can dial in to speak with an abortion care provider during work hours throughout the program will be offered as well. | Standard abortion care includes: 1) prior abortion consultation on informed choice of pregnancy; 2) abortion preparation education on abortion practice, steps involved, and cooperative requires for women; 3) a brief discharge education on warning signs of potential complications and post-abortion contraception; and 4) a regular 2-weeks post-abortion exam to determine the completion of the abortion. |
| **5. WHO PROVIDED** | The consultation, offering informational booklet, and managing the START platform will be carry out by the primary researcher who is a qualified abortion counselor with 5 years’ experience in abortion care. Hotline will be answered by the nurse coordinator, a registered nurse who has more than 10 years’ clinical experience in abortion care | Prior abortion consultation and the post-abortion exam were provided by doctors. Abortion preparation and discharge education were provided by nurses |
| **6. HOW** | Consultation (face to face) Informational booklet (face to face) The START platform (internet) Hotline (telephone) | Face to face |
| TIDieR Item | Intervention group | Control group |
|-------------|--------------------|---------------|
| **7. WHERE** | Consultation (the consultation room) | Health center's facilities |
| | Informational booklet (the consultation room) | |
| | The START platform (WeChat based) | |
| | Hotline (telephone-base) | |
| **8. WHEN and HOW MUCH** | Consultation (after women made their abortion appointment, 30 mins) | Prior abortion consultation was provided at women's first appointment (10-20 minutes); Abortion preparation education was provided after women made their abortion appointment (5-10 minutes); Post-abortion education was provided before women been discharged (10 minutes); The post-abortion exam was carried out 2 weeks after abortion (depends on women's health condition, normal an ultrasound exam is required) |
| | Informational booklet (during the consultation, one copy participants can bring home) | |
| | The START platform (since the consultation, unlimited access till the closure of the project) | |
| | Hotline (since the consultation, available during workhours) | |
| **9. TAILORING** | Participants in the intervention group will receive the same intervention | —— |
| **10. MODIFICATION** | Cannot be reported until the study is complete | —— |
| **11. HOW WELL** | The research nurse and the reception nurses involved in the trial will be trained initially. A researcher logbook will be kept recording intervention delivery of each participant. Adherence to the intervention will be assessed by participants self-reported usage info collected during follow-ups | —— |
| **12. ACTUAL** | Cannot be reported until the study is complete | —— |
| Categories            | Themes                           | Example items                                                                                                                                 |
|-----------------------|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| **Abortion**          | Facts about abortion             | • General information about abortion  
                          • Pregnancy calculation and ectopic pregnancy  
                          • Abortion practice in Beijing                                                             |
|                       | Different types of abortion      | • Medical abortion and steps involved  
                          • Aspiration/surgical abortion and steps involved  
                          • Features of aspiration abortion and medical abortion                                    |
| **Q & A**             |                                  | • How is your legal position, e.g., gestation age limits; no need for husbands’ or partners’ permission; and Nation ID required etc.        
                          • How much does abortion cost?  
                          • Does abortion hurt and what is painless induced abortions?  
                          • What will you experience during an abortion?  
                          • How could you know your abortion is complete?  
                          • Will an abortion cause infertility?  
                          • How will you feel if you have an abortion                                              |
|                       | Aftercare and follow-up examination | • Follow-up examination and why it is necessary  
                          • Symptoms requiring contacting your health provider, going to local emergency room, or calling 120 for Emergency Health Aid. |
| **Intimate Relationship** | A healthy relationship          | • Important characteristics of a healthy relationship  
                          • Rights and responsibility in a relationship  
                          • Equality in intimate relationships                                                      |
|                       | Identify and deal with a dangerous relationship | • Signals of unhealthy relationships  
                          • Options for women experiencing an unhealthy/dangerous relationship  
                          • Knowing IPV  
                          • Options for women experiencing IPV                                                      |
|                       | About sex                         | • Consent and your legal position  
                          • Options for women who were forced to engage in a sexually activity                    |
| Categories              | Themes                                          | Example items                                                                 |
|-------------------------|------------------------------------------------|-------------------------------------------------------------------------------|
| Available Coping Resources | Coping with abortion experience                | • Suggestions from experts                                                    |
|                         |                                                | • Suggestions from women experienced abortion                                 |
|                         | Taking care your emotions                      | • Talk to someone you trusted: Tips on finding a reliable person to talk to    |
|                         |                                                | • Medication: free medication Apps recommendation e.g., Tide                  |
|                         |                                                | • Reading: book recommendation e.g., Trauma and Recovery by Judith Herman _Chinese version |
|                         |                                                | • Post-abortion counsellor                                                    |
|                         | Cope with IPV or sexual violence experience    | • Free social support services e.g., Beijing Women's Federation hotline; The maple women's psychological counselling centre hotlines etc. |
|                         |                                                | • Self-help guides e.g., Guidelines for dealing with Sexual assault (Marie Stopes China) |
|                         |                                                | • Suggestions from police                                                     |
|                         |                                                | • Stories of IPV survivors                                                   |

### 4 Outcomes

#### 4.1 Feasibility outcomes

Feasibility outcomes include eligibility and intervention delivery data, which will be collect by a research logbook and participants’ completion of questionnaires. The specific outcomes are:

- proportion of women who meet the eligibility criteria
- proportion of eligible women who are recruited
- proportion of recruited women who receive the allocated intervention to which they are randomized
- Withdrawal or loss to follow-up rate
- Missing data rate

#### 4.2 Acceptability outcomes

Acceptability refers to retrospective acceptability assessed after participating in the intervention. Phone calls will be made to all participants in the intervention group at the last follow-up. A questionnaire developed based on the TFA framework of Health Care Intervention [22] will guide the recorded phone interview. The questionnaire will include closed-ended and open-ended questions representing all seven
component constructs of intervention acceptability: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy. Responses on closed-ended questions are on a Likert Scale from 1 to 5, and response labels vary depending on the item. For example, ‘to what extent was the intervention useful to you?’ has response options of 1 ‘not at all useful’ to 5 ‘extremely useful’. Responses to opened-ended questions will be noted and recorded. Examples of opened-ended questions are ‘how do you feel about the intervention’, ‘which component of the intervention was most/least useful and why?’, and ‘did you encounter any barriers when participating in the intervention? 

4.3 Effectiveness outcomes

Effectiveness outcomes include women's depression symptom (Primary), coping behaviours, self-efficacy, perceived support level, intimate relationship satisfaction, post-abortion personal growth, and abortion relevant outcomes. Specific measures include:

Depression

Changes in women's depression symptoms will be measured by DSM-5 Severity Measure for Depression for Adult (SMD-A) [23]. The 9 item SMD-A will be administered at the initial patient interview and monitor progress. Participants will be asked to rate the severity of their depressive symptoms on a 4-point scale (0 = Not at all; 1 = Several days; 2 = More than half the days; and 3 = Nearly every day). The 9 items cover symptoms associated with experiencing pleasure, feeling down, and self-esteem. The total score can range from 0 to 27, with higher scores indicating greater severity of depression. The tool has been translated and found to be valid and reliable for use among the Chinese population [24].

Coping behaviours

The Carver Brief COPE Inventory [25] will be used to measure changes in women's coping efforts and styles. The inventory is a 28-item multidimensional measure of the frequency with which a person uses different coping strategies. Participants score themselves from 1 = I haven't been doing this at all, to 4= I've been doing this a lot. The first coping style is avoidant coping characterized by strategies like self-distraction, denial, substance use, and self-blame. The second is approach coping, which reflects strategies like active coping, use of emotional support, planning, and acceptance. The Brief COPE was tested with a Chinese sample, modified, and renamed as COPE-Revised. The revised version has adequate psychometric properties (Cronbach's alpha coefficients of all subscales > 0.60) [26].

Self-Efficacy

The General Self-Efficacy scale (GSE-10) [27] has 10 items measuring optimistic self-beliefs to cope with difficulties in life. It is valid, reliable and has been translated into more than 30 languages, including Chinese [28]. The internal inconsistency of the Chinese version was 0.91 [28].

Perceived Social Support

The abbreviated version of the Medical Outcomes Study Social Support Scale (MOSSS-5) [29] and 7 study-specific questions will be used to measure changes in perceived support. The SS-5 is a 5-item
reliable measure of perceived social support. Each item is scored on a 5-point Likert scale and the items are summed for a total score ranging from 5–25. Its Chinese version has adequate test-retest reliability (0.89) and internal consistency (0.97) [30]. The seven additional questions focus on women's perceived support regarding specific stressors they commonly faced during the abortion process. These stressors (identified from our earlier interviews with the target population) include choosing a type of abortion, and support to manage emotions and support from their intimate relationship.

**Intimate relationship**

The 4-item Couples Satisfaction Index (CSI-4) [31] will be used to measure changes in intimate relationship satisfaction. The scale has different response formats. Total scores range from 0 to 21, with higher scores indicating greater satisfaction. The Cronbach's α reliability of the translated version in Chinese woman is 0.88 [32].

**Post-abortion growth**

The Post-traumatic Growth Inventory Short Form (PTGI-SF) was developed to evaluate personal growth following traumatic, challenging and stressful life circumstances [33]. PTGI-SF comprises 10 items rated on a 6-point Likert scale (ranging from 0 to 5), with a total score ranging from 0 to 50. Higher scores indicated higher PTG. The 5 subscales include relating to others, new possibilities, personal strength, spiritual change, and appreciation of life. The Chinese version has acceptable internal consistency with a Cronbach α of 0.86 [34].

**Abortion related outcomes**

Abortion related outcomes will be measured according to women's gestational weeks at abortion, type of abortion, complications, and follow up exam attendance.

**5 Sample size**

A formal sample size calculation is not necessary for research objectives 1 and 2 [18]. For objective 3, G*Power software was used to determine reasonable sample size for the estimation of differences between intervention and control groups. The effect size on depression reported by similar interventions ranged from 0.39 to 1.06 [35–37]. G*power indicated a total of 72 participants will be required to detect a 0.39 effect size for depression, two tailed, with alpha at 0.05 and power at 90%. Anticipating a 20% attrition rate, recruitment was set at 90 (45 women per group).

**6 Recruitment and consent**

When women present at the FPRHC seeking an abortion, they receive a consultation to ensure informed choice and a medical appointment to assess their physical health. If the woman confirms her decision to terminate the pregnancy, she speaks with the nurses at reception to make an abortion appointment
booking. As reception nurses have an ongoing relationship with patients and are available during clinic hours, they will screen women based on the inclusion and exclusion criteria. If eligible, the reception nurse will provide brief explanation about the study and ask women if they are interested in participating. If yes, women will be referred to the primary researcher, who will discuss the study in more depth, answer any questions, and provide the Participant Information and Consent Forms. The potential participant will be given adequate time to read the forms, talk with her support person, and ask questions before deciding to participate or decline. Participants will be assured they can withdraw from the study at any time, and it will not influence their treatment in any way.

7 Assignment and blinding

Considering the small sample size, block randomization will be used to reduce bias and ensure an equal balance between the intervention and control groups [38]. Block size of four with six possible balanced combinations of assignment within the block, is considered appropriate for this study. The nurse coordinator will generate a random number sequence using Microsoft Excel and place the assignments into sealed envelopes. After informed consent, the primary researcher will open a sequential envelope to determine the group allocation of each participant. Given the nature of the intervention, it is not feasible to blind participants, intervention providers and researchers who collect data. To prevent contamination, women in the intervention group will be asked to not share information or materials of the study with other abortion patients before completion of the study.

8 Data collection

Data collection will happen at five timeframes: T-0, during recruitment before randomization; T-1, at abortion day before discharge (normally 2 hours post-abortion procedure); T-2, during women's post-abortion exam visit, normally 2 weeks post-abortion; T-3, 6 weeks post-abortion; and T-4, post completion of all follow-ups of all participants. See Table 3 for detailed information on data collection, including What data, Who, When, Where, How, and by What would the data be collected.
Table 3  
Data collection schedule and analysis method

| Concept (What)               | Time (When) | Method (Who, Where, and How)                                                                 | Measure (by What)                                                                                           | Method of analysis                                                                                           |
|------------------------------|-------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| Participant characteristics  | T-0         | The primary researcher, at the recruitment room, face to face                               | Self-design questionnaire on sociodemographic characteristics, health history, and current gestation       | • Descriptive statistics                                                                                     |
|                              |             |                                                                                            |                                                                                                           | • $X^2$ test comparing differences between groups of categorical/dichotomous variables                        |
|                              |             |                                                                                            |                                                                                                           | • t-test/Mann–Whitney U test comparing differences between groups of continuous variables                   |

Feasibility outcomes

- Eligibility T-0  
  The reception nurses, at the reception station, face to face  
  Eligibility screening checklist  
  • Descriptive statistics

- Intervention delivery T-4  
  The primary researcher, at clinic facilities, researcher logbook review  
  Feasibility indexes include intervention fidelity, retention rate, and missing data rate  
  • Descriptive statistics

Acceptability outcomes

- Acceptability T-3  
  The primary researcher, at clinic facilities, telephone-interview  
  Self-design questionnaire including closed-ended and open-ended questions  
  | Quantitative data                                                                 |
  | • Descriptive statistics                                                      |
  | • Chi Square test comparing differences between groups of categorical variables |
  | Qualitative data                                                               |
  | • A deductive approach of content analysis                                    |

Effectiveness outcomes
| Concept (What)      | Time (When) | Method (Who, Where, and How)                                                                 | Measure (by What) | Method of analysis                                                                                                                                 |
|--------------------|-------------|-----------------------------------------------------------------------------------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Depression         | T-0, 1, 2, 3| The primary researcher (T0, 3) and the nurse coordinator (T-1, 2); at clinic facilities; face to face (T-0, 1, 2) and by telephone (T-3) | SMD-A             | • Descriptive statistics  
  • t-test/Mann–Whitney U test comparing baseline to T-3  
  • t-test/Mann–Whitney U test comparing differences between groups at T-3  
  • Linear regression measuring change over time |
| Perceived support  | T-0, 1, 2, 3| As above                                                                                      | MOS-SSS           | • As above                                                                                                                                      |
| Intimate relationship | T-0, 1, 2, 3| As above                                                                                      | CSI-4             | • As above                                                                                                                                      |
| Coping behaviours  | T-0, 2, 3   | As above                                                                                      | CBCI              | • Descriptive statistics  
  • t-test/Mann–Whitney U test comparing baseline to T-3 of each coping style  
  • t-test/Mann–Whitney U test comparing differences between groups of each coping style at T-2 and T-3 |
| Self-efficacy      | T-0, 2, 3   | As above                                                                                      | GSE-10            | • Descriptive statistics  
  • t-test/Mann–Whitney U test comparing baseline to T-3  
  • t-test/Mann–Whitney U test comparing differences between groups at T-2 and T-3 |
| Post-abortion growth | T-2, 3     | As above                                                                                      | PTGI-SF           | • Descriptive statistics  
  • t-test/Mann–Whitney U test comparing T-2 to T-3  
  • t-test/Mann–Whitney U test comparing differences between groups at T-2 and T-3 |
| Concept (What)          | Time (When) | Method (Who, Where, and How) | Measure (by What)                  | Method of analysis                                                                 |
|------------------------|-------------|-----------------------------|-----------------------------------|------------------------------------------------------------------------------------|
| Abortion outcomes      | T-3         | As above                    | Self-design questions             | • Descriptive statistics                                                           |
|                        |             |                             |                                   | • Chi Square test comparing differences between groups at T-3                      |

### 9 Data analysis

Participant characteristics, feasibility outcomes, and quantitative acceptability outcome data will be summarized with descriptive statistics, including frequency counts and percentages (categorical variables) and mean with 95% confidence intervals (CIs) or standard deviation (continuous variables). Intervention feasibility and acceptability will be assessed against the following criteria: eligibility: $\geq 60\%$ of patients screened will be eligible; recruitment: $\geq 80\%$ of eligible participants will agree to participate; protocol fidelity: $\geq 90\%$ of patients randomized to each group will receive the allocated intervention; retention: $< 20\%$ of patients will be lost at 6 weeks after abortion; and missing data: $< 20\%$ of data will be missing. Between-group differences of participant characteristics, baseline data, and effectiveness outcomes will be detected using Statistical Package for the Social Sciences (SPSS)® version 23 [39]. Specifically, Chi square tests will be used for categorical/dichotomous variables, and t-tests or Mann–Whitney U tests for continuous variables (depending on normality). To capture changes of effect outcomes over time, a general linear regression analysis will be performed. See Table 3 for the specific analysis approaches.

For qualitative data, audiotapes of telephone interviews will be transcribed and de-identified by the primary researcher. Transcripts and notes will be analyzed using the deductive approach of content analysis [40]. First, a structured analysis matrix will be developed based on the aim of the study and the TFA of Health Care Intervention. Then the primary researcher and nurse coordinator will independently review all de-identified data, and content fit the matrix will be selected. They will work together to group similar content within the matrix boundaries as categories, and then main categories. After abstraction of each category, the primary researcher and nurse coordinator will make a joint decision on how to model and report the results. Any discrepancies along the process will be discussed with a third reviewer until agreement is reached. To preserve the original meaning of women's statements, the data analysis process will be conducted using Chinese. Development of the analysis matrix and reporting process will use Chinese and English to reduce potential bias and build a shared vision among the research team.

### 10 Progress to date
Following trial registration in May 2021, participant enrolment began in July 2021. As we observed a higher-than-expected drop-out rate at the six-week post-abortion time point, we increased the sample size from 90 (calculated on a 20% attrition rate) to 102 (calculated on a 30% attrition rate) in September 2021 to achieve precision for estimation of the effect size. To date, we have recruited 94 participants. We anticipate completing recruitment in Jan 2022. The intervention delivery and data collection will be ongoing until the last recruited participant finishes follow-up. We aim to disseminate results of the study in May 2022.

Discussion

We propose a two-armed randomized randomized trial among Chinese women undergoing abortion, to assess the feasibility, acceptability, and potential effects of the START intervention. To our knowledge, this study will be the first trial to address Chinese abortion patients’ behavioural and psychological wellbeing by providing a comprehensive supportive intervention that aimed to address their real-world needs and the transactional model of stress and coping [17]. This innovative intervention contains different active components that will be delivered in different methods. Findings from this trial will allow us to evaluate the feasibility and acceptability of the various patterns of the intervention design, which will inform intervention refinement [15]. The findings will also help to identify potential barriers and facilitators for implementing the intervention in the Chinese context [41]. As the preliminary effectiveness and effect of the intervention will also be described, the study could have important implications for relevant policymakers, practitioners, researchers, or other stakeholders [42].

We are employing a rigorous study design to ensure the internal and external validity of findings. This trial responds to the call for well-designed, rigorously conducted scientific research in abortion care in developing countries [1]. Randomization and statistical analysis adjusted for any difference in baseline characteristics between groups will protect against selection bias, and ultimately warrant internal validity [43]. The study will be performed under real-world clinical practice, which will enhance external validity and generalizability of results. All instruments that will be used in this study are previously validated in the Chinese population, which will also enhance the reliability of findings.

A further strength is we have adopted a series of appropriate guidelines to ensure the normalization, transparency, and replication of the study. The TIDieR checklist has been used to describe the intervention [21]. Application of the CONSORT statements [18, 19] and the SPIRIT 2013 Checklist [20] have been followed.

Limitations, however, need to be considered. The emotional period between a woman’s initial appointment with the clinic and 6 weeks post-abortion [44], as well as the sensitive nature of the topic, could challenge women’s adherence and completion of the study. Strategies like keeping information simple, offering the intervention in confidential formats, and repeated reminders that are known to be effective in improving intervention adherence will be employed [45]. Another challenge lays in the uncertainties of the COVID-19 pandemic. We will follow and document all local, national, and
international measures that may impact our study progress. The actual delivery of the intervention and identified barriers and facilitators of implementing the intervention will be well-recorded to inform future studies.

Conclusion

This paper proposes a protocol of a clinical trial to assess the feasibility, acceptability, and potential effects of a comprehensive supportive intervention that was developed to address the psychological health of Chinese women undergoing an abortion. Results will be used to assist intervention refinement and direct a future full-powered trial. Practical experience will be gained during the conduct of the clinical trial which would also provide evidence for further implementation of the intervention.

List Of Abbreviations
**Declarations**

**Ethics approval statement**

The study was approved by the Institutional Ethical Review Boards of Peking University People's Hospital (2021PHB003-001) in March 2021, and the Human Research Ethics Committee of Griffith University (2021/410) in June 2021 respectively. Written consent will be obtained from all participants. All data collected will be stored properly under the supervision of the data monitor committee of the study setting. As this study involves multiple contact points, identifiable information will be necessary to keep track of participants. If women do not want to use their real name, they will be offered a unique identification number at recruitment. All data will be made non-identifiable using pseudonyms or coding numbers at the point of analysis and reporting.
Consent for publication

Written consent for publication has been obtained from all participants during the informed consent process.

Availability of data and materials

The data involved in this study will be provided upon reasonable request to the corresponding author.

Competing interests

The authors declare that they have no competing interests that might be perceived to influence the results and/or discussion reported in this paper.

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Authors’ contributions

NW, JG, JA, HL and DC contributed to the conceptualization and design of the study protocol. NW and XZ designed data collection instruments. QZ, and JG led ethics applications. NW, QZ and EE developed the intervention prototype. NW wrote the first draft of the protocol, and all other authors read and provided comments on the subsequent drafts of the manuscript. All authors approved the final version for submission.

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Figures
Figure 1

The Transactional Model of Stress and Coping
### Timeline

| Timeframe | Clinical practice activities | Research activities |
|-----------|-----------------------------|---------------------|
| Pre-enrolment |  | Program preparation  |
| T0 | First appointment | Meeting with stakeholders  |
|      |      | Research assistant training  |
| T1: T0+3–7天 | Abortion | Recruitment  |
|      |      | Confirm eligibility  |
|      |      | Complete informed consent  |
|      |      | Obtain baseline date  |
|      |      | Randomisation  |
| T2: T1+ 2weeks (± 3days) | Post-abortion exam appointment |  |
| T3: T1+ 6weeks (± 3days) | Telephone follow-up | START intervention + standard abortion care (N=45)  |
|      |      | Standard abortion care (N=45)  |
| T4: at the end of the program |  | Project closure  |
|      |      | Medical record review  |
|      |      | Research logbook review  |

**Figure 2**

SPIRIT standard flow diagram

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