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Complete List of Authors:	Jin, Longmei; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Yin, Anxin; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment Zhang, Xiaohua; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Jiang, Hong; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment; Fudan University, Minhang Branch, School of Public Health Zhou, Lu; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment Zhou, Xiaoyan; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Wang, Xiurui; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Qian, Xu; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment; Fudan University, Minhang Branch, School of Public Health
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Integrating contraceptive service into existing perinatal care: protocol for a community-based cluster randomized controlled trial in Shanghai, China

Longmei Jin[1,3#], Anxin Yin[2#], Xiaohua Zhang[1,3*], Hong Jiang[2,3*], Lu Zhou[2], Xiaoyan Zhou[1,3], Xiurui Wang[1,3], Xu Qian[2,3]

[1]Minhang District Maternal and Child Health Hospital, Room 504, No. 805 Gudai Road, Meilong Street, Minhang District, Shanghai 201102, China;
[2]School of Public Health, Key Laboratory of Health Technology Assessment (National Health Commission of the People's Republic of China), Fudan University, Mailbox 175, No. 138 Yixueyuan Road, Shanghai 200032, China;
[3]Minhang Branch, School of Public Health, Fudan University, Mailbox 175, No. 138 Yixueyuan Road, Shanghai 200032, China;

[#]These authors contributed equally.
[*]Corresponding author: Hong Jiang, h_jiang@fudan.edu.cn, School of Public Health, Key Laboratory of Health Technology Assessment, National Health Commission of the People's Republic of China, Fudan University, Mailbox 175, No. 138 Yixueyuan Road, Shanghai 200032, China;
[*]Corresponding author: Xiaohua Zhang, zxh_2046@126.com, Minhang District Maternal and Child Health Hospital, Room 504, No. 805 Gudai Road, Meilong Street, Minhang District, Shanghai 201102, China.

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ABSTRACT

Introduction: Postpartum contraception has been found essential to preventing unintended pregnancies and too short interpregnancy intervals. The first year after childbirth is the period with a high risk of unintended pregnancy and induced abortion. However, the current postpartum contraceptive service is weak in the existing maternal and child health care in China. Therefore, we propose to strengthen and integrate postpartum contraceptive services into existing perinatal care services and evaluate the effects via a design of cluster randomized controlled trial.

Methods and analysis: This is a cluster randomized controlled trial involving all 13 communities of Minhang District, Shanghai, China. All communities will be randomly allocated into the intervention or the control group, seven in the intervention group and six in the control group. A sample of 1300 women, 100 women in each community, will be recruited for the study. Women assigned to the intervention group will be provided with postpartum contraceptive counselling and guidance during pregnancy, childbirth hospitalization, postpartum home visit and 42-day postpartum check-up. Women in the control group will receive routine antenatal and postpartum care. All participants will be recruited in the 1st trimester during pregnancy and followed up to one year postpartum. The primary outcome is the incidence of unintended pregnancy within one year after childbirth.

Ethics and dissemination: The trial received ethical approval from the Ethics Committee of Shanghai Minhang District Maternal and Child Health Care Hospital (#[2020]KS-02, #[2020]KS-05, #[2020]KS-05-EX). Results will be published in academic journals and be disseminated in multiple formats for the professionals and the public such as academic papers and seminars.

Trial registration number: Chinese Clinical Trial Registry (ChiCTR2000034603)

Keywords: Postpartum contraception, Postpartum women, Postpartum family planning, Perinatal care, Cluster randomized controlled trial

STRENGTHS AND LIMITATIONS OF THIS STUDY:

1) The study will integrate postpartum contraceptive services into existing perinatal care services in China to improve the availability and access of the service.
2) The intervention strategy and components are designed by a multiple discipline team based on international and national guidelines.
3) The study used the strictest research design - cluster randomised controlled trial to understand the effectiveness of the intervention.
4) Due to the nature of the intervention, service providers and users will not be blinded to the group allocation.

INTRODUCTION

The importance of postpartum contraception to prevent unintended pregnancies and short intervals between pregnancies is evident[1]. According to the recommendations of the World Health Organization (WHO), the birth spacing should be at least 24 months to reduce the adverse pregnancy and birth outcomes and to improve child

health[2]. However, the link between maternal and child health care and the family planning service is weak in China and quality postpartum contraceptive services could not be easily accessed.

A WHO systematic analysis showed that 7.9% of maternal deaths were due to abortion worldwide[3]. In China, the rate of induced abortion led by unintended pregnancies has constantly increased, in which 50.3% were postpartum women[4]. The number of induced abortions within one year after childbirth accounted for 10.76% of the total number of induced abortions[5]. And 56.1% of the women who had induced abortions within one year postpartum did not take any contraception[5].

Interpregnancy intervals (IPIs), defined as the time interval between live birth and the beginning of the next pregnancy, are closely related to birth outcomes[1]. Short IPIs are associated with an increased risk of several adverse birth outcomes, such as preterm birth, low birth weight (LBW), small for gestational age (SGA) and perinatal death[6-9]. IPIs are also related to maternal outcomes. A systematic review showed that among women who had undergone a trial of labour and ended in low transverse caesarean section, short IPIs (<16 months) increased the risk of uterine rupture[2]. Women with short IPIs were more likely to experience chronic diseases, such as obesity and gestational diabetes[10 11]. Moreover, women with short IPIs had a significantly increased risk of maternal mortality, antenatal bleeding, premature rupture of membranes and anaemia, which seriously affected women's physical and mental health as well as family and social harmony[12].

A study by Gu et al in 2018 showed that the first year after childbirth was the period with a high risk of unintended pregnancy and induced abortion in women[13 14]. In China, at least 70% of pregnancies in the first year after childbirth were unintentional[15]. Accumulated evidence has shown there were various misunderstandings in postpartum contraception, which led to not taking contraception or not adopting efficient contraceptive methods among couples[16]. Some women believed that they would not get pregnant without menses resumption after childbirth. However, menstrual recurrence is not synchronized with ovulation. Two-thirds of the non-breastfeeding women ovulated before their first postpartum menses[17]. In addition, with the concern about the side effects on lactation and infant growth, a growing number of women chose short-term methods such as condoms rather than more reliable long-acting reversible contraception (LARC), which increased the risk of unintended pregnancy[18 19].

In China, postpartum women have the chance of receiving postpartum contraceptive education during postpartum care including two to three times of postpartum home visits within one month postpartum, and at 42-day postpartum outpatient clinic. However, obstetric staff providing postpartum care were found lacking contraceptive knowledge and service capability[20]. For example, they mainly recommended condoms as the postpartum contraceptive choice rather than more effective methods such as LARC[20]. Due to the inadequate guidance or counselling service provision and insufficient capacity of obstetric personnel, most women cannot get timely contraceptive guidance and services within one year after childbirth. Furthermore, as shown by literature, approximately half of women resumed sexual behaviour within six weeks after birth, which indicated family planning services provided only after childbirth might be too late to prevent unintended pregnancy[21 22].

At present, with the issuance of the three-child policy in China, the service strategy of postpartum family planning emphasizes the need to protect and preserve women 's reproductive health. Postpartum contraception is of great significance in promoting the physical and mental recovery of postpartum women, maintaining reasonable birth

spacing, improving early childhood development and enhancing family and social harmony. Therefore, we propose to develop a cluster randomized controlled trial to examine whether postpartum contraceptive interventions integrated into the existing perinatal care in China would reduce unintended pregnancy among women within one year after childbirth.

Study objectives and hypotheses

This study aims to integrate postpartum conception services into the existing perinatal care system in China to prevent unintended pregnancy among women within one year after childbirth. We hypothesize that the intervention will:

1) reduce the rate of unintended pregnancy within one year after childbirth.
2) improve women's knowledge of postpartum contraception.
3) improve the utilization of long-acting reversible contraception within one year after childbirth.
4) improve the postpartum contraceptive service capacity of obstetric medical personnel in Minhang District of Shanghai.

The study will provide evidence for establishing a service model of postpartum contraception integrated into the perinatal care system to meet the postpartum contraception service needs in Shanghai, China.

METHODS AND ANALYSIS

Study design

Using the cluster randomized control trial study design, all of the 13 communities in Minhang District will be involved as the research sites in Shanghai, China. Each community will be randomly allocated to either the intervention or the control group (see Fig. 1 for research flow). Ethical approval to conduct this trial has been granted by the Ethics Committee of Shanghai Minhang District Maternal and Child Health Care Hospital (#[2020]KS-02, #[2020]KS-05, #[2020]KS-05-EX). The research is registered with Chinese Clinical Trial Registry (#ChiCTR2000034603). The first participant was recruited on 21 September 2020. We anticipate completing our data collection by April 2023.

Participants and recruitment

This study will be conducted in Minhang District, Shanghai. Minhang District locates in the central region of Shanghai. It has a total of 13 communities, with a total population of 2,653,489 in 2021. The region's GDP reached 252.082 billion yuan in 2019, slightly lower than the average level of administrative districts of Shanghai.

All 13 communities of Minhang District will be included in this trial, and be randomly assigned to the intervention and control arms. Women who register early pregnancy in community health centres and are eligible for the study will be invited to participate in the study by research staff. Each participant will be required to sign a written informed consent.

Inclusion criteria

Pregnant women

1)With normal intelligence
2)With the plan to live in Minhang District from the early pregnancy registration to one year after childbirth
3)With the plan to give birth in a childbirth hospital in Minhang District
4)Consent to be followed up until one year after childbirth
5)With the WeChat account through which the online questionnaire survey can be fulfilled

Exclusion criteria

1)Miscarriage
2)Loss to follow-up after childbirth hospitalization

Randomization

Random allocation to the intervention and the control group will be determined by a computer-generated random number. We take one community as a cluster in the randomization and the total number of the clusters is 13. After randomization, there will be seven clusters in the intervention group and six clusters in the control group.

Blinding

Due to the nature of the intervention, service providers and users will not be blinded to the group allocation. The statistician will be blinded for the group allocation of participants during data analysis.

Intervention group

Training for service providers

Obstetric service providers responsible for early pregnancy registration in community health centres, postpartum home visit, and 42-day postpartum examination in hospitals will participate in face-to-face training on postpartum contraception services. The training contents were designed by the research group with experts in gynaecology and obstetrics, maternal and child health care and family planning areas based on international, national and local guidelines and service norms such as *Chinese experts' consensus on the clinical use of female contraceptive methods*[15], *The technical guide of long-acting reversible contraceptives for those post-abortion and postpartum women*[23] and *Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations*[24]. The guidelines were reviewed and streamlined to establish the essential contents of the training. The core training modules consist of five parts, including informed consent of project services, optimal time and duration of postpartum contraception, basic principles and methods of common contraception, recommendation of LARC methods, and need-based individualized contraceptive guidance. The service providers will also be trained in communication skills and the standard process of filling in questionnaires.

Before and after the training, quizzes will be carried out to evaluate the effect of the training. Practical training such as scenario-based role-play and counselling practice in the simulated situation will be held. Service providers will not participate in the intervention until they pass all the training tests.

Intervention for service users

We will carry out interventions at five stages during perinatal care. Firstly, at early pregnancy registration, participants will be recruited after informed consent. Then obstetric service providers in community health centres will offer the first consultation, with the emphasis on the importance of postpartum contraception and the link of educational videos via WeChat platform. The link could be watched repeatedly at convenient times with the introduction of the necessity of postpartum contraception and various contraceptive methods such as lactational amenorrhoea method (LAM) and LARC.

Then, during the second and third trimesters, participants will take postpartum contraception courses in pregnancy school, containing appropriate methods, common misunderstandings, and recommendations for postpartum contraception.

Third, from childbirth to discharge from the childbirth hospitalization, participants will be provided with guidance including ovulation resumption time of different breastfeeding methods, optimal IPIs, available contraceptive measures after childbirth and LAM criteria. Obstetricians will recommend exclusive breastfeeding and LARC to women without contraindications. Husbands will be encouraged to participate in the counselling. Additionally, couples will get a health educational prescription after the counselling. This stage aims to stimulate consideration of the postpartum contraceptive plan.

Fourth, at the postpartum home visit, the community health staff will guide participants to choose suitable contraceptive measures according to their conditions. Besides, participants will get educational pamphlets and be invited to a WeChat group, in which research staff will regularly send postpartum contraceptive information to reinforce the essential contents.

Last, at the 42-day postpartum check-up in the childbirth hospital, obstetricians and gynaecologists will assist postpartum women to implement their contraception plan by offering health prescriptions based on their preferred contraceptive method. Besides, participants will be informed about the access to free contraceptives and designated hospitals for the placement of subcutaneous implants or intrauterine devices (IUD). The intervention at different stages is summarised in Table 1.

Table 1. Summary of the intervention

Stage	Intervention contents	Approach
Early pregnancy registration	Project introduction and guidance by service providers to inform the importance of postpartum contraception	Face-to-face counselling Online video
Second and third trimesters	Courses in pregnancy school containing key knowledge of postpartum contraception	Course
Childbirth hospitalization	Counselling and health prescriptions offered by obstetricians to stimulate consideration of the postpartum contraceptive plan	Face-to-face counselling Prescription
Postpartum home visit	Counselling, educational pamphlets and WeChat group offering contraceptive knowledge and	Face-to-face counselling Pamphlet WeChat group

	guidance services to assist in making the postpartum contraceptive plan	
42-day postpartum check-up	Health prescriptions and guidance containing the access to postpartum services to promote the utilization of postpartum contraception	Face-to-face counselling Prescription

Control group

Postpartum contraceptive service providers in the control group will not receive additional training on postpartum contraception in this study. Women in the control group will receive routine perinatal care and regular postpartum contraceptive education at postpartum home visits and 42-day postpartum health check-ups. In the routine perinatal health care, the community health staff will remind women to consider postpartum contraception, ask about their postpartum contraceptive plan, and provide brief recommendations on postpartum contraception during the postpartum home visit. At 42-day postpartum health check-ups in the childbirth hospital, obstetricians will remind women to choose and implement appropriate postpartum contraception methods based on their conditions, but without specific instructions and consultations.

Sample size and statistical power calculation

Sample size calculation for primary outcome

There are a total of 13 communities in Minhang District, Shanghai. The sample size was calculated based on the primary outcome of the incidence of unintended pregnancy within one year postpartum. By use of PASS 15.0, a sample of 1040 pregnant women (80 in each community health service centre) will be needed to detect at least 6% of the difference[25] in the incidence of unintended pregnancy within one year after childbirth between the intervention group and the control group, based on an estimation of the incidence as 10% in the control group[26] and intracluster correlation coefficient (ICC) as 0.01[27], at 0.05 significance level with 80% statistic power. Given the rate of 20% loss to follow-up from recruitment to one year after childbirth, a total of 1300 women (100 in each community health service centre) will be required.

Calculation of statistical power for secondary outcomes

The power calculations for secondary outcomes include the utilization rate of LARC, induced abortion rate of unintended pregnancy, and knowledge of postpartum contraception.

Utilization rate of LARC

Given the initial sample size of 80 per cluster for detecting differences in the incidence of unintended pregnancy within one year after childbirth between the intervention and control groups, the proposed study will have 97.5% statistical power to detect an Odds Ratio of 1.6 between the two groups, with an estimation of 25% for the LARC utilization rate in the control group[28], at 0.05 significance level.

Rate of induced abortion due to unintended pregnancy

Given the initial sample size of 80 per cluster for detecting differences in the incidence of unintended pregnancy within one year after childbirth between the intervention and control groups, the proposed study will have 81.1% statistical power to detect an Odds Ratio of 0.5 between the two groups, with an estimation of 15% for

the induced abortion rate within one year postpartum in the control group[29 30], at 0.05 significance level.

Knowledge of postpartum contraception

Given the initial sample size of 80 per cluster for detecting differences in the incidence of unintended pregnancy within one year after childbirth between the intervention and control groups, the proposed study will have 93.6% statistical power to detect an Odds Ratio of 1.2 between the two groups, with an estimation of 65% for the accuracy rate of postpartum contraception questions in the control group[31], at 0.05 significance level.

Data collection

All participants will be followed up from antenatal to postnatal period and will be required to fill in the questionnaires at 1) early pregnancy registration; 2) postpartum home visit; 3) 42 days after childbirth; 4) half a year after childbirth; 5) one year after childbirth.

Baseline data

At the early pregnancy registration, a baseline questionnaire survey will be administered to collect information about demographic characteristics, obstetric history, awareness of contraceptive knowledge and the need for perinatal care guidance. Information will be collected by a self-administered online questionnaire, and medical history will be drawn from the medical records.

At postpartum home visit

Women will be required to fill out an online questionnaire at the first postpartum home visit, which includes the lactation plan, postpartum contraceptive knowledge test, informed choice and plan of postpartum contraception. Service providers will ensure participants' informed decision-making by providing them with information on the advantages, disadvantages and applicable conditions of various contraceptive methods.

On 42-day postpartum

At 42 days after childbirth, postpartum women are routinely required to return to the childbirth hospital for obstetric examinations. Women in the intervention group will be asked to complete an online questionnaire collecting their lactation and sexual behaviour information, reception of postpartum contraceptive guidance services, knowledge level and plan of postpartum contraception.

In half-year and one year postpartum

At half a year and one year after childbirth, information on participants' lactation and sexual behaviour, their selections of contraceptive methods, the utilization of the chosen contraception, postpartum pregnancy and abortion conditions as well as their plan for the next child will be collected by telephone interviews.

Primary outcome

Incidence of unintended pregnancy

The primary outcome of this study is the incidence of unintended pregnancy within one year after childbirth, which will be collected at one year postpartum via telephone

interviews. Research staff will ask participants whether they get pregnant after their childbirth or not, and confirm whether it is planned or unintended. The frequency, time and outcome of the pregnancy within one year after childbirth will also be collected. The incidence of unintended pregnancy will be calculated and compared between the intervention group and the control group.

Secondary outcomes

Utilization rate of LARC

At one year postpartum, participants will be asked whether they take postpartum contraception and the method they choose. The research staff will collect participants' contraceptive methods through a multiple-choice question with five response selections: common methods such as condoms and in vitro ejaculation, LARC such as IUD and subcutaneous implant, short-acting oral contraceptives, emergency contraception pills (ECPs), and sterilization. The utilization rate of LARC within one year after childbirth will be calculated based on the above question.

Rate of induced abortion due to unintended pregnancy

Postpartum women will be asked whether they get pregnant within one year after childbirth via telephone interviews. For pregnant women, research staff will ask whether the pregnancy is planned or unintended, and collect the outcomes including induced abortion and continued gestation. The rate of induced abortion due to unintended pregnancy within one year after childbirth will be calculated based on these questions.

Knowledge of postpartum contraception

Participants' knowledge of postpartum contraception will be assessed via online questionnaires at early pregnancy registration, postpartum home visit and 42 days after childbirth respectively. At the baseline survey during pregnancy registration, a list of contraceptive methods will be displayed and women will be asked to choose the methods that they have heard of or used before. At the postpartum home visit, the knowledge of LARC, recommended contraceptive methods with different lactation plans, LAM criteria and adverse impacts of short IPIs on mothers and children will be asked. At 42 days after childbirth, participants will be asked about recommended contraceptive methods with different lactation plans, LAM criteria, optimal IPIs, the recommended time of resuming sexual behaviour and the time when they need to take postpartum contraception after childbirth.

Data management

A unique identification number will be assigned to women once they agree to participate in the study at the early pregnancy registration. Personal information will be anonymised.

All information will be collected through the online questionnaire and stored on the questionnaire platform. The data will be secured with an account and password, and the access to information will be limited to research team members. Fudan University will be responsible for data analysis.

Data analysis

Descriptive analysis will be performed to examine all variables. For categorical variables, frequency and percentages will be reported, while mean ± SD will be reported for continuous variables.

The baseline characteristics of the intervention and the control group such as age and pregnancy history will be compared. All outcomes will be compared between the intervention and the control group. The difference between the two groups will be assessed by conducting parametric tests (t-test and ANOVA) or non-parametric tests (Wilcoxon, Kruskal-Wallis and Friedman tests) for continuous variables. The Chi-square test will be used for categorical variables. The effect of the intervention will be evaluated by generalized linear mixed model (GLMM). The evaluation of the study will be based on the "intention to treat" analysis. SPSS software (version 25.0, IBM Corporation) and R software (version 4.1.3) will be used to conduct the statistical tests.

Process evaluation

The process evaluation and quality control will be conducted by the research group in Shanghai Minhang District Maternal and Child Health Care Hospital and the participating community health centres. We will carry out pre-surveys to ensure the validity and reliability of the research questionnaires by checking ambiguities and semantic expression. Service providers will be trained according to the protocol to ensure the feasibility and quality of the intervention. To reduce invalid questionnaires, we will set logic checks for online questionnaires so that questionnaires with unreasonable responses or incomplete items would not be submitted. Both service providers and participants in the intervention group will be asked to sign a confirmation form after each face-to-face intervention at early pregnancy registration, postpartum hospitalization, postpartum home visit and 42-day postpartum check-up as an implementation process recording. Key components of the intervention at each specific stage will be listed on the form and participants will confirm receiving the intervention by signing at the end of the form. The project coordinators in each intervention community health centre will be responsible for the routine check of the forms to ensure the implementation consistent with the plan.

Patient and Public Involvement statement

During the study design, we asked the feedback on the current postpartum contraceptive service from women to understand their service needs. We also sought opinions and suggestions on intervention strategy from gynaecologists and obstetricians in maternal and child health institutions to ensure the feasibility of the intervention. Furthermore, we conducted a pilot survey among pregnant women during the first trimester and postpartum women, and improved the wording of the questionnaires based on their feedback.

DISCUSSION

A growing body of research have shown that contraceptive services are effective interventions to improve maternal and infant health outcomes[32-35]. The postpartum period is a critical time to implement effective contraceptive methods and reduce

unintended pregnancies[35]. To address the unmet service needs on postpartum contraception and tackle the challenges such as high numbers of unintended pregnancies, induced abortions[5], lack of relevant knowledge[13 14 36] and insufficient capacity of service providers[20 36], we propose this study to develop a service model of postpartum contraception integrated into the routine perinatal care to meet the postpartum contraception service needs via a cluster randomized controlled trial in Minhang District, Shanghai, China. We expect that our findings can arouse women's attention to postpartum contraception and raise decision makers' awareness of the importance of establishing a postpartum contraception service model.

In this proposed study, we will integrate postpartum contraceptive services into the current perinatal care from the first trimester to 42 days postpartum. It is hypothesized that the intervention will reduce the rate of unintended pregnancy and increase the utilization of LARC within one year after childbirth, as well as improve women's knowledge of postpartum contraception. If the intervention is proved effective, this service model will be generalized in all maternal and child health care institutions including community health centres in Minhang District of Shanghai, China.

In conclusion, this trial will develop and establish postpartum contraception intervention services for women based on their needs. The intervention strategies will help to promote the utilization of LARC and other highly effective contraception methods for decreasing the rate of unintended pregnancy in the first year after childbirth, protecting women's fertility and reducing the occurrence of high-risk pregnancies. It will contribute to postpartum women's physical and mental rehabilitation, maintaining a reasonable birth interval and achieving family and social harmony. The findings of our study could be served as evidence for developing service packages to improve postpartum contraception and promote appropriate IPIs. Furthermore, if the intervention is confirmed to be effective, it would provide evidence for other regions of China and developing countries with suitable social contexts to prevent unintended postpartum pregnancies and protect women's reproductive health.

Ethics and dissemination

The study has been approved by the Ethics Committee of Shanghai Minhang District Maternal and Child Health Hospital (#[2020]KS-02, #[2020]KS-05, #[2020]KS-05-EX). The research is registered with Chinese Clinical Trial Registry (#ChiCTR2000034603). All participants are required to provide written informed consent. All research activities will be carried out in accordance with relevant guidelines and regulations. The data will be confidential after the study completion. The data generated in this study will be available from the corresponding author on reasonable request. Results of the study will be published in academic journals and be disseminated in research seminars and other appropriate formats for the professionals and the public.

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Authors' contributions

LMJ, HJ and XQ conceived the study and designed the community-based cluster randomized controlled trial. LMJ is responsible for funding application and data collection. XYZ and XRW contributed to the data collection. XHZ contributed to coordinating the data collection. AXY is responsible for drafting the manuscript. LZ contributed to the drafting. HJ, LMJ and XQ provided critical comments and revised the manuscript. All authors have approved the final article.

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Data statement

The data will be confidential after the study completion. The data generated in this study will be available from the corresponding author on reasonable request.

Competing interests

None declared.

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Fig. 1 Research flow chart

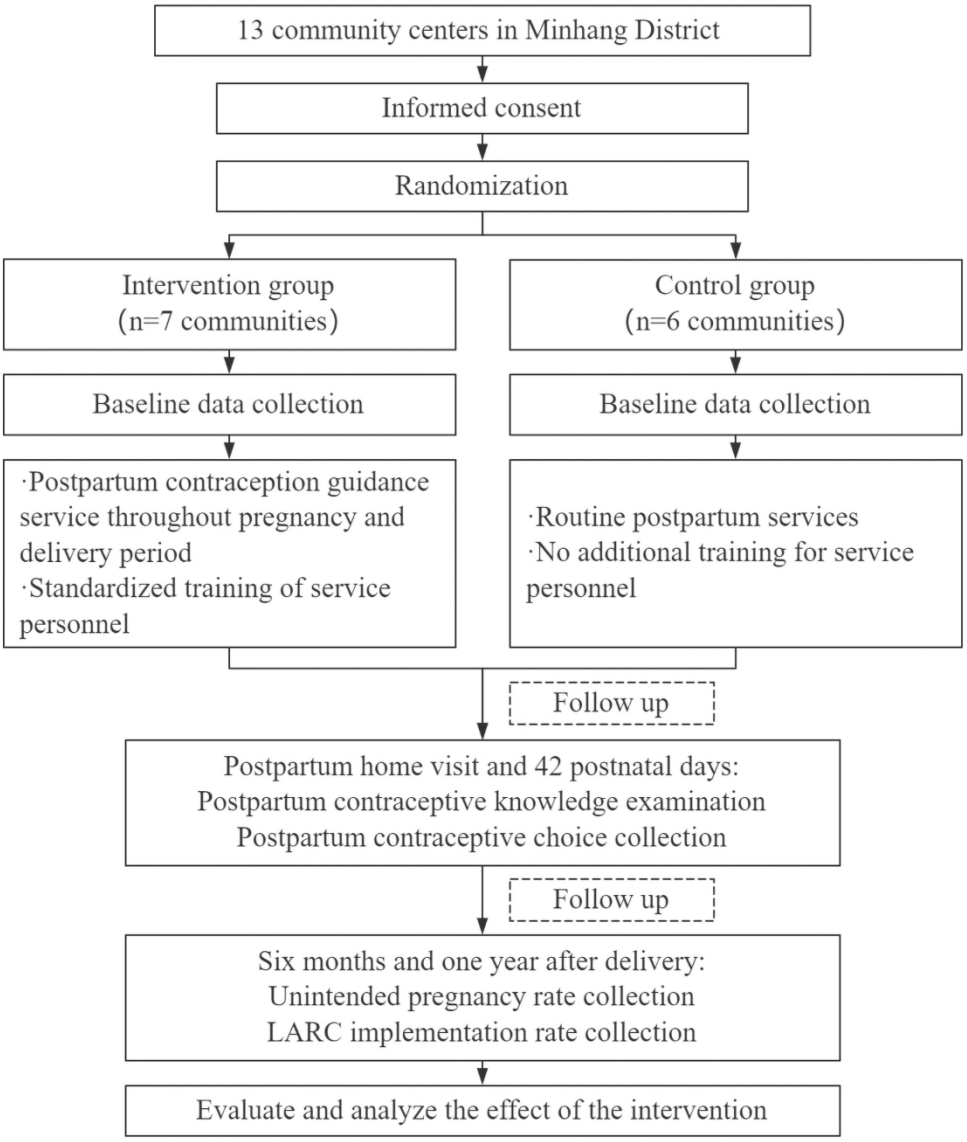

Fig. 1 Research flow chart

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym Response: Yes; no trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry Response: Abstract, paragraph 4
	2b	All items from the World Health Organization Trial Registration Data Set Response: Yes, the Chinese Clinical Trial Registry (ChiCTR)
Protocol version	3	Date and version identifier Response: 11 April 2020, first draft
Funding	4	Sources and types of financial, material, and other support Response: Funding section
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors Response: Author's contributions section
	5b	Name and contact information for the trial sponsor Response: Funding section
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities Response: Funding section
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) Response: Data management, paragraph 2
Introduction		

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention Response: Background, paragraph 1-6
	6b	Explanation for choice of comparators Response: Background, paragraph 4,6
Objectives	7	Specific objectives or hypotheses Response: Study objectives and hypotheses, paragraph 1-6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) Response: Study design, paragraph 1
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained Response: Participants and recruitment, paragraph 1-2
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) Response: Inclusion criteria, paragraph 1-6; Exclusion criteria, paragraph 1-2
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered Response: Intervention group, paragraph 1-7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) Response: N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) Response: Process evaluation, paragraph 1
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial Response: Control group, paragraph 1

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended Response: Primary outcome, paragraph 1; Secondary outcomes, paragraph 1-3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) Response: Research flow chart, figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations Response: Sample size and statistical power calculation, paragraph 1-5
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size Response: Participants and recruitment, paragraph 2

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions Response: Randomization, paragraph 1
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned Response: Randomization, paragraph 1
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions Response: Randomization, paragraph 1
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how Response: Blinding, paragraph 1

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial Response: Randomization, paragraph 1
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol Response: Data collection, paragraph 1-5; Primary outcome, paragraph 1; Secondary outcomes, paragraph 1-3
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols Response: Process evaluation, paragraph 1
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol Response: Data management, paragraph 1-2
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol Response: Data analysis, paragraph 1-2
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) Response: Data analysis, paragraph 2
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) Response: Data analysis, paragraph 2
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed Response: Process evaluation, paragraph 1

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial Response: Process evaluation, paragraph 1
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct Response: Process evaluation, paragraph 1
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor Response: Process evaluation, paragraph 1

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval Response: Study design, paragraph 1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) Response: N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) Response: Participants and recruitment, paragraph 2
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable Response: N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial Response: Data management, paragraph 1-2
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site Response: Funding section
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators Response: Data management, paragraph 2

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation Response: N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions Response: Ethics and dissemination, paragraph 1
	31b	Authorship eligibility guidelines and any intended use of professional writers Response: N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code Response: Ethics and dissemination, paragraph 1
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates Response: Yes
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable Response: N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Integrating contraceptive services into existing perinatal care: protocol for a community-based cluster randomized controlled trial in Shanghai, China

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Complete List of Authors:	Jin, Longmei; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Yin, Anxin; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment Zhang, Xiaohua; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Jiang, Hong; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment; Fudan University, Minhang Branch, School of Public Health Zhou, Lu; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment Zhou, Xiaoyan; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Wang, Xiurui; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Qian, Xu; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment; Fudan University, Minhang Branch, School of Public Health
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Integrating contraceptive services into existing perinatal care: protocol for a community-based cluster randomized controlled trial in Shanghai, China

Longmei Jin[1,3#], Anxin Yin[2#], Xiaohua Zhang[1,3*], Hong Jiang[2,3*], Lu Zhou[2], Xiaoyan Zhou[1,3], Xiurui Wang[1,3], Xu Qian[2,3]

[1]Minhang District Maternal and Child Health Hospital, Room 504, No. 805 Gudai Road, Meilong Street, Minhang District, Shanghai 201102, China;
[2]School of Public Health, Key Laboratory of Health Technology Assessment (National Health Commission of the People's Republic of China), Fudan University, Mailbox 175, No. 138 Yixueyuan Road, Shanghai 200032, China;
[3]Minhang Branch, School of Public Health, Fudan University, Mailbox 175, No. 138 Yixueyuan Road, Shanghai 200032, China;

[#]These authors contributed equally.
[*]Corresponding author: Hong Jiang, h_jiang@fudan.edu.cn, School of Public Health, Key Laboratory of Health Technology Assessment, National Health Commission of the People's Republic of China, Fudan University, Mailbox 175, No. 138 Yixueyuan Road, Shanghai 200032, China;
[*]Corresponding author: Xiaohua Zhang, zxh_2046@126.com, Minhang District Maternal and Child Health Hospital, Room 504, No. 805 Gudai Road, Meilong Street, Minhang District, Shanghai 201102, China.

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ABSTRACT

Introduction: Postpartum contraception is essential to preventing unintended pregnancies and short interpregnancy intervals. The first year after childbirth is the critical period with a high risk of unintended pregnancy and induced abortion. However, the postpartum contraceptive services are weak in China's existing maternal and child health care. We propose to evaluate the effects of integrating postpartum contraceptive services into the existing perinatal care services via a cluster randomized controlled trial.

Methods and analysis: This cluster randomized controlled trial involves all 13 communities of Minhang District, Shanghai, China. Communities will be randomly allocated, seven in the intervention group and six in the control group. One thousand and three hundred women, 100 women in each community, will be recruited in the study. Women assigned to the intervention group will receive postpartum contraceptive education and counselling during pregnancy, childbirth hospitalization, postpartum home visits, and the 42-day postpartum clinic check-up. Women in the control group will receive routine antenatal and postpartum care. Participants will be recruited in the 1st trimester during pregnancy and followed up to one year postpartum. The primary outcome is the incidence of unintended pregnancy within one year after childbirth.

Ethics and dissemination: The trial received ethical approval from the Ethics Committee of Shanghai Minhang District Maternal and Child Health Care Hospital (#[2020]KS-02, #[2020]KS-05, #[2020]KS-05-EX). Results will be published in academic journals and disseminated in multiple formats for the health professionals and the public.

Trial registration number: Chinese Clinical Trial Registry (ChiCTR2000034603)

Keywords: Postpartum contraception, Postpartum women, Postpartum family planning, Perinatal care, Cluster randomized controlled trial

STRENGTHS AND LIMITATIONS OF THIS STUDY:

1) The study will integrate postpartum contraceptive services into the existing perinatal care system and provide evidence and an example to improve the availability and access to the services in China.
2) The intervention strategy and components are designed by a multiple-discipline team based on international and national guidelines.
3) The study used the strictest research design - cluster randomised controlled trial to test the effectiveness of the intervention.
4) Due to the nature of the intervention, service providers and users will not be blinded to the group allocation.
5) The study will be conducted in one urban district of Shanghai, China, the external validity of the results in other areas might be limited.

INTRODUCTION

Postpartum contraception plays an important role in preventing unintended pregnancies and short intervals between pregnancies[1]. The World Health Organization (WHO) recommends birth spacing should be at least 24 months to reduce adverse pregnancy and birth outcomes and to improve child health[2].

Interpregnancy intervals (IPIs), defined as the time interval between live birth and the beginning of the next pregnancy, are closely related to birth outcomes[1]. Short IPIs are associated with an increased risk of several adverse birth outcomes, such as preterm birth, low birth weight (LBW), small for gestational age (SGA) and perinatal death[3-6]. IPIs are also related to maternal outcomes. A systematic review showed that among women who had undergone a trial of labour and ended in low transverse caesarean section, short IPIs (<16 months) increased the risk of uterine rupture[2]. Women with short IPIs were more likely to experience chronic diseases, such as obesity and gestational diabetes[7 8]. Moreover, women with short IPIs had a significantly increased risk of maternal mortality, antenatal bleeding, premature rupture of membranes and anaemia, which seriously affected women's physical and mental health as well as family and social harmony[9].

In China, the rate of induced abortion due to unintended pregnancies has constantly increased, 50.3% were postpartum women[10]. A study in 2018 showed that the first year after childbirth was the period with a high risk of unintended pregnancy and induced abortion[11 12]. At least 70% of pregnancies in the first year after childbirth were unintentional[13]. The number of induced abortions within one year after childbirth accounted for 10.76% of the total number of induced abortions[14]. More than half (56.1%) of the women who had induced abortions within one year postpartum did not take any contraception[14]. Accumulated evidence has shown there were various misunderstandings in postpartum contraception, which led to not taking contraception or not adopting efficient contraceptive methods among couples[15]. Some women believed that they would not get pregnant after childbirth before menstruation resuming[16]. In addition, with the concern about the side effects on lactation and infant growth, a growing number of women chose short-term methods, such as condoms rather than more reliable long-acting reversible contraception (LARC), which increased the risk of unintended pregnancy[17 18].

In China, women register their pregnancy and have their first antenatal examinations in community health centres (CHCs) within three months. After registration at CHC, they will have regular antenatal examinations and antenatal classes provided by obstetricians and obstetric nurses in local hospitals before childbirth. After childbirth, women will stay in maternity wards for at least 24 hours for observation and receive maternal and neonatal health care. Then, at 3-7 days and 14-28 days after hospital discharge, health staff in CHCs will conduct postpartum home visits to check mothers' and newborns' health status as well as provide health care advice. At 42 days after childbirth, women and their newborns will return to the childbirth hospitals for check-ups by obstetricians. Currently, women only have chances of receiving simple postpartum contraceptive education after childbirth including two to three times of postpartum home visits within one month postpartum, and at the 42-day postpartum outpatient clinic. However, obstetric staff providing postpartum care were found to lack contraceptive knowledge and service capability[19]. For example, they mainly recommended condoms as the postpartum contraceptive choice rather than more effective methods such as LARC[19]. Due to insufficient obstetric personnel capacity and other constraints, most women cannot get timely contraceptive services within one

year after childbirth. Furthermore, approximately half of the women resumed sexual intercourse within six weeks after childbirth, which indicated family planning services provided after childbirth might be too late to prevent unintended pregnancy[20 21]. However, the link between maternal health care and the family planning services is weak in China, and access to quality postpartum contraceptive services is often difficult.

With China's new policy encouraging couples to have three children[22], postpartum contraception is even more critical in promoting the physical and mental recovery of postpartum women, maintaining reasonable birth spacing, improving early childhood development and enhancing family and social harmony. Therefore, we propose a cluster randomized controlled trial to examine whether postpartum contraceptive interventions integrated into the existing perinatal care system would reduce unintended pregnancy among women within one year after childbirth in Shanghai, China.

Study objectives and hypotheses

This study aims to assess the effectiveness of integrating postpartum conception services into the existing perinatal care system in Shanghai, China, to prevent unintended pregnancy among women within one year after childbirth. We hypothesize that the intervention will:

1) reduce the rate of unintended pregnancy within one year after childbirth.
2) improve women's knowledge of postpartum contraception.
3) improve the utilization of long-acting reversible contraception within one year after childbirth.
4) improve the postpartum contraceptive service capacity of obstetric medical personnel in Minhang District of Shanghai.

The study will provide evidence for establishing a service model of postpartum contraception integrated into the perinatal care system to meet the postpartum contraception service needs in Shanghai, China.

METHODS AND ANALYSIS

Study design

Using the cluster randomized control trial study design, all of the 13 communities in Minhang District will be involved as the research sites in Shanghai, China. Each community will be randomly allocated to either the intervention or the control group (see Fig. 1 for research flow). Ethical approval to conduct this trial has been granted by the Ethics Committee of Shanghai Minhang District Maternal and Child Health Care Hospital (#[2020]KS-02, #[2020]KS-05, #[2020]KS-05-EX). The research is registered with Chinese Clinical Trial Registry (#ChiCTR2000034603). The first participant was recruited on 21 September 2020. We anticipate completing our data collection by April 2023.

Participants and recruitment

This study will be conducted in Minhang District, in the central region of Shanghai. It has 13 communities, with a total population of 2,653,489 in 2021. The region's GDP was slightly lower than the average level of administrative districts of Shanghai.

All 13 communities in the district will be included in this trial and be randomly assigned to the intervention and control groups. In China, women register their pregnancy in community health centres (CHCs) within three months after pregnancy. They will receive perinatal care in the hospitals they choose to give birth and CHCs until 42 days postpartum. Women who register their pregnancy in CHCs and are eligible for the study will be invited to participate in the study by the health staff in CHCs. Each participant will be required to sign a written informed consent.

Inclusion criteria

Pregnant women

1)With the ability to read and understand Chinese
2)With the plan to live in Minhang District from the pregnancy registration to one year after childbirth
3)With the plan to give birth in a childbirth hospital in Minhang District
4)Consent to be followed up until one year after childbirth
5)With the WeChat account through which the online questionnaire survey can be fulfilled

Exclusion criteria

1)Miscarriage
2)Stillbirth
3)Baby in special care nursery
4)Loss to follow-up after discharge from hospital following childbirth

Randomization

Random allocation to the intervention and the control group will be determined by a computer-generated random number. We take one community as a cluster in the randomization and the total number of the clusters is 13. After randomization, there will be seven clusters in the intervention group and six clusters in the control group[23].

Blinding

Due to the nature of the intervention, service providers and users will not be blinded to the group allocation. The statistician will be blinded for the group allocation of participants during data analysis.

Intervention group

Training for service providers

Face-to-face training on postpartum contraception services was provided for community health staff responsible for pregnancy registration in CHCs and postpartum home visit, and obstetricians and obstetric nurses responsible for antenatal classes, maternity ward care and 42-day postpartum examination in hospitals.

The training material contents were designed by the research group with experts in gynaecology and obstetrics, maternal and child health care and family planning. International, national and local guidelines and service norms, including *Chinese*

experts' consensus on the clinical use of female contraceptive methods[13], *The technical guide of long-acting reversible contraceptives for those post-abortion and postpartum women*[24] and *Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations*[25] were used. The experts reviewed and streamlined the resources to establish the essential contents of the training into modules. The core training modules consist of five parts, including informed consent of project services, optimal time and duration of postpartum contraception, basic principles and methods of common contraception, recommendation of LARC methods, and need-based individualized contraceptive counselling. The service providers were also trained in communication skills and the standard process of filling in questionnaires.

Before and after the training, quizzes were carried out to evaluate the effect of the training. Practical training such as scenario-based role-play and counselling practice in the simulated situation was held. There were two theoretical and four practical training sessions, and one reinforcement session. Each session lasted for one day. Service providers will not participate in the intervention until they complete all the training sessions and pass the training tests.

Intervention for service users

We will carry out interventions at five stages in alignment with the current perinatal care system of China.

1. Participants will be recruited after giving informed consent at pregnancy registration. Then health staff in CHCs will offer the first consultation for the intervention group, emphasize the importance of postpartum contraception, and provide educational videos via the WeChat platform. The videos could be watched repeatedly at convenient times and contain the introduction of the necessity of postpartum contraception and various contraceptive methods such as the lactational amenorrhoea method (LAM) and LARC.
2. At the second and third trimesters, the intervention aims to stimulate interest in a postpartum contraceptive plan. Participants in the intervention group will take a 45-minute postpartum contraception class given by obstetricians and obstetric nurses in the hospital antenatal classes, which include appropriate methods, common misunderstandings, and recommendations for postpartum contraception. Specifically, when participants have their antenatal examinations, obstetricians will make an appointment for them to attend this postpartum contraception class. Obstetricians and obstetric nurses will use the same multimedia materials and video prepared by our research team and provide explanations face to face during the contraception class.
3. From childbirth to discharge from hospital, participants will be provided with education and advice by obstetricians and obstetric nurses in maternity wards, the key messages including ovulation resumption time of different breastfeeding methods, optimal IPIs, available contraceptive measures after childbirth, and LAM criteria. Obstetricians will conduct contraceptive counselling and recommend exclusive breastfeeding and LARC to women without contraindications. The husbands will be encouraged to participate in the counselling with their wives, and support postpartum contraception. Additionally, couples will get a health educational prescription after the counselling.
4. At the postpartum home visits (3-7 days and 14-28 days after discharge), the community health staff will help participants to choose suitable contraceptive

measures according to their conditions. Further, participants will receive educational pamphlets containing knowledge on postpartum contraception.

5. At the 42-day postpartum check-up in the childbirth hospital, obstetricians will provide participants with face-to-face counselling and an individualized health prescription based on the contraceptive method they choose. To promote the implementation of postpartum contraception, participants will be informed about the access to free contraceptives and designated hospitals for the placement of subcutaneous implants or intrauterine devices (IUD). The interventions at different stages are summarised in Table 1.

Table 1. Summary of the intervention

Stage	Intervention contents	Service providers	Approach
Pregnancy registration	Project introduction, counselling, and educational videos to inform the importance of postpartum contraception	Health staff in CHCs	Face-to-face counselling Online video
Second and third trimesters	Class in hospitals containing key knowledge of postpartum contraception to stimulate interest in a postpartum contraceptive plan	Obstetricians and obstetric nurses	Class in hospital
Childbirth hospitalization	Counselling and health prescriptions to facilitate making the postpartum contraceptive plan	Obstetricians and obstetric nurses in maternity wards	Face-to-face counselling Prescription
Postpartum home visit	Counselling and educational pamphlets offering contraceptive knowledge and advice to assist in completing the postpartum contraceptive plan	Health staff in CHCs	Face-to-face counselling Pamphlet
42-day postpartum check-up	Counselling, health prescriptions, and information about the access to postpartum services to promote the utilization of postpartum contraception	Obstetricians in childbirth hospitals	Face-to-face counselling Prescription

*CHCs, community health centres

Control group

Postpartum contraceptive service providers in the control group will not receive additional training on postpartum contraception. Women in the control group will receive routine perinatal care and regular postpartum contraceptive education at postpartum home visits and 42-day postpartum health check-ups. In routine perinatal health care, the community health staff will remind women to consider postpartum contraception, ask about their postpartum contraceptive plan, and provide brief recommendations on postpartum contraception (mainly condoms) during the postpartum home visit. At 42-day postpartum health check-ups in the childbirth hospital, obstetricians will remind women to choose and implement appropriate postpartum contraception methods based on their conditions, but without specific consultation and instructions.

Data collection

All participants will be followed up from the first trimester antenatal to 42 days postnatal period. They will be asked to complete the questionnaires at five time points:1)

pregnancy registration; 2) first postpartum home visit at 3-7 days; 3) 42 days after childbirth; 4) six months after childbirth; 5) one year after childbirth.

At baseline data

In China, pregnant women register their pregnancy in CHCs to establish pregnancy records and have their first antenatal examinations. At the pregnancy registration, health staff in CHCs will ask participants to complete a self-administered questionnaire via scanning the QR code or clicking the link of the questionnaire website to collect their baseline information. The baseline information will include participants' demographic characteristics (age, residence, educational level, occupation), obstetric history, contraceptive knowledge and their need for postpartum contraception services.

At postpartum home visit

The health staff in the CHCs will conduct the first postpartum home visit for women in 3-7 days after hospital discharge. Participants in both groups will complete an online questionnaire, which includes questions about their delivery outcomes, a postpartum contraceptive knowledge test, and their plans for the next pregnancy and postpartum contraception. Participants in the intervention group will fill in their contraception plan after the postpartum contraception counselling. Health staff in CHCs will ensure participants' informed decision-making by providing them with information on the advantages, disadvantages, and applicable conditions of various contraceptive methods.

On 42-day postpartum check-up

At 42 days after childbirth, postpartum women will return to the childbirth hospital for obstetric examinations. Women in the intervention group will be asked to complete an online questionnaire. Through the questionnaire, obstetricians of the childbirth hospital will collect their lactation and sexual behaviour information as well as their postpartum contraception condition, and confirm whether they receive the postpartum contraceptive intervention services of each stage. For those who haven't initiate any contraception, obstetricians will collect their plan for postpartum contraception after the counselling. In addition, another postpartum contraceptive knowledge test will be included in the questionnaire to collect participants' knowledge of postpartum contraception.

At half-year and one year postpartum

At half a year and one year after childbirth, information on participants' selections of contraceptive methods, their utilization frequency and satisfaction of the chosen contraception, conception condition and abortion experience will be collected via telephone interviews by health staff in CHCs.

Primary outcome

Incidence of unintended pregnancy

The primary outcome of this study is the incidence of unintended pregnancy within one year after childbirth, which will be collected at one year postpartum via telephone interviews. Health staff in CHCs will ask participants whether they fall pregnant after childbirth or not, and whether it is planned or unintended. The information on frequency, time, and outcome of the pregnancy within one year after childbirth will also be

collected. The incidence of unintended pregnancy will be calculated and compared between the intervention group and the control group.

Secondary outcomes

Utilization rate of LARC

At one year postpartum, participants will be asked whether they take postpartum contraception and the method they choose via telephone interviews. The health staff in CHCs will collect information on contraceptive methods participants use through a multiple-choice question with five response selections: common methods such as condoms and in vitro ejaculation, LARC such as IUD and subcutaneous implant, short-acting oral contraceptives, emergency contraception pills (ECPs), and sterilization. Participants will also be asked about their utilization frequency of the chosen contraception. The utilization rate of LARC within one year after childbirth will be calculated based on the above information.

Rate of induced abortion due to unintended pregnancy

Postpartum women will be asked whether they fall pregnant via telephone interviews at one year after childbirth. For pregnant women, health staff in CHCs will ask whether the pregnancy is planned or unintended, and the outcomes, including induced abortion and continued gestation. The rate of induced abortion due to unintended pregnancy within one year after childbirth will be calculated.

Knowledge of postpartum contraception

Participants' knowledge of postpartum contraception will be assessed via online questionnaires at pregnancy registration, postpartum home visit and 42 days after childbirth respectively. At the baseline survey during pregnancy registration, a list of contraceptive methods will be displayed and women will be asked to choose the methods that they have heard of or used before. At the postpartum home visit, a knowledge test including questions about LARC, recommended contraceptive methods with different lactation plans, LAM criteria and adverse impacts of short IPIs on mothers and children will be conducted. At 42 days after childbirth, participants in the intervention group will complete another knowledge test, and they will be asked about recommended contraceptive methods with different lactation plans, LAM criteria, optimal IPIs, the recommended time of resuming sexual behaviour and taking postpartum contraception after childbirth.

Sample size and statistical power calculation

Sample size calculation for primary outcome

There are a total of 13 communities in Minhang District, Shanghai. The sample size was calculated based on the primary outcome of the incidence of unintended pregnancy within one year postpartum. We used PASS 15.0 to calculate the sample size. The estimated incidence of unintended pregnancy within one year postpartum was 10% in the control group[26], the expected difference between the intervention group and the control group was 6%[27], and the intracluster correlation coefficient (ICC) was 0.01[28]. A sample size of 1040 pregnant women (80 in each CHC) will be needed at 0.05 significance level and 80% statistical power. Given the 20% anticipated rate of loss to follow-up from recruitment to one year after childbirth, a total of 1300 women (100 in each community health service centre) will be required.

Calculation of statistical power for secondary outcomes

The power calculations for secondary outcomes include the utilization rate of LARC, induced abortion rate of unintended pregnancy, and knowledge of postpartum contraception.

Utilization rate of LARC

The estimated LARC utilization rate in the control group was 25% and the expected Odds Ratio was 1.6 between the two groups[29]. Given the calculated sample size of 80 per cluster based on the primary outcome, the statistical power will be 97.5% for the utilization rate of LARC at 0.05 significance level.

Rate of induced abortion due to unintended pregnancy

The estimated induced abortion rate within one year postpartum in the control group was 10%, and the expected Odds Ratio was 0.4 between the two groups[30 31]. Given the calculated sample size of 80 per cluster based on the primary outcome, the statistical power will be 80.0% for the rate of induced abortion due to unintended pregnancy at 0.05 significance level.

Knowledge of postpartum contraception

The estimated accuracy rate of postpartum contraception questions in the control group was 65%, and the expected Odds Ratio was 1.2 between the two groups[32]. Given the calculated sample size of 80 per cluster based on the primary outcome, the statistical power will be 93.6% for the postpartum contraception knowledge at 0.05 significance level.

Data management

A unique identification number will be assigned to women once they agree to participate in the study at the pregnancy registration. Personal information will not be identifiable.

All information will be collected through the online questionnaire and stored on the questionnaire platform. The data will be secured with an account and password, and access to information will be limited to research team members. Researchers of Fudan University will be responsible for data security.

Data analysis

Descriptive analysis will be performed to examine all variables. For categorical variables, frequency and percentages will be reported, while mean ± SD will be reported for continuous variables.

The baseline characteristics of the intervention and the control group such as age and pregnancy history will be compared. All outcomes will be compared between the intervention and the control group. The difference between the two groups will be assessed by conducting parametric tests (t-test and ANOVA) or non-parametric tests (Wilcoxon, Kruskal-Wallis and Friedman tests) for continuous variables. The Chi-square test will be used for categorical variables. The effect of the intervention will be

evaluated by generalized linear mixed model (GLMM). The evaluation of the study will be based on the "intention to treat" analysis. SPSS software (version 25.0, IBM Corporation) and R software (version 4.1.3) will be used to conduct the statistical tests.

Process evaluation

The process evaluation and quality control will be conducted by the research group in Minhang District Maternal and Child Health Care Hospital and the participating CHCs. We will conduct pre-surveys to ensure the validity and reliability of the research questionnaires by checking ambiguities and semantic expressions. Service providers will be trained according to the protocol to ensure the feasibility and quality of the intervention. To reduce invalid questionnaires, we will set logic checks for online questionnaires so that questionnaires with unreasonable responses or incomplete items will not be submitted. The designated project managers and investigators will act as quality controllers, and will be responsible for monitoring the recruitment process on the sites and making records. During the intervention, both service providers and participants in the intervention group will be asked to sign a confirmation form after each face-to-face intervention at pregnancy registration, postpartum hospitalization, postpartum home visits, and 42-day postpartum check-up as an implementation process recording. Key components of the intervention at each stage will be listed on the form, and the participants will confirm whether they received the intervention by signing at the end of the form. The quality controllers will check these forms routinely to ensure the implementation is consistent with the plan. In addition, based on the records and periodical summary of site supervision, we will hold regular meetings with experts and staff of CHCs and childbirth hospitals every two months to solve the existing problems and ensure intervention protocol compliance.

Patient and Public Involvement statement

During the study design, we conducted a formative study on the current postpartum contraceptive services from women to understand their service needs. We also sought opinions and suggestions on intervention strategy from obstetricians and obstetric nurses in maternal and child health institutions to ensure the feasibility of the intervention. Furthermore, we conducted a pilot survey among ten pregnant women during the first trimester and ten postpartum women, and improved the questionnaires based on their feedback. All pilot participants have confirmed that the questionnaires were easy to understand without ambiguity or obscurity. Postpartum women suggested adding a satisfaction survey for intervention services to monitor and improve the intervention process. In addition, participants of the pilot survey proposed to add a question collecting the specific contraceptive method recommended by service providers during the counselling.

DISCUSSION

A growing body of research has shown that contraceptive services are effective interventions to improve maternal and infant health outcomes[33-36]. The postpartum period is critical to adopt appropriate and effective contraceptive methods to reduce

unintended pregnancies[36]. To address the unmet service needs on postpartum contraception and tackle the challenges, in this proposed study, we will integrate postpartum contraceptive services into the current perinatal care from the first trimester to 42 days postpartum. We hypothesize that the intervention will reduce the rate of unintended pregnancy and increase the utilization of LARC within one year after childbirth, as well as improve women's knowledge of postpartum contraception. If the intervention is proven effective, this service model will be up-scaled in all maternal and child health care institutions, including CHCs and hospitals in Minhang District of Shanghai, China. We expect that our findings will promote postpartum contraception, support women in making informed contraception decisions, and improve postpartum contraception services.

This trial will develop and evaluate a postpartum contraception intervention for women based on their needs. The intervention strategies will help to reduce the rate of unintended pregnancy in the first year after childbirth. It will potentially contribute to postpartum women's physical and mental rehabilitation, maintaining a reasonable birth interval and achieving family and social harmony.

There are several anticipated limitations of this study. First, the intervention model was designed based on the current perinatal care system in urban areas of Shanghai, China, so it may not be applicable to rural areas. Second, participant retention may be challenging as the follow-up will be about 20 months, i.e., from pregnancy to one year postpartum. To minimize the rate of loss to follow-up, we will implement the intervention in the existing maternal care system, tapping in the usual care to deliver the intervention contents.

Ethics and dissemination

The study has been approved by the Ethics Committee of Shanghai Minhang District Maternal and Child Health Hospital (#[2020]KS-02, #[2020]KS-05, #[2020]KS-05-EX). The research is registered with Chinese Clinical Trial Registry (#ChiCTR2000034603). All participants are required to provide written informed consent. All research activities will be carried out in accordance with relevant guidelines and regulations. The data will be confidential after the study completion. The data generated in this study will be available from the corresponding author on reasonable request. Results of the study will be published in academic journals and be disseminated in research seminars and other appropriate formats for the professionals and the public.

Acknowledgements

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Authors' contributions

LMJ, HJ and XQ conceived the study and designed the community-based cluster randomized controlled trial. LMJ is responsible for funding application and data collection. XYZ and XRW contributed to the data collection. XHZ contributed to coordinating the data collection. AXY is responsible for drafting the manuscript. LZ

contributed to the drafting. HJ, LMJ and XQ provided critical comments and revised the manuscript. All authors have approved the final article.

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Data statement

The data will be confidential after the study completion. The data generated in this study will be available from the corresponding author on reasonable request.

Competing interests

None declared.

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Fig. 1 Research flow chart

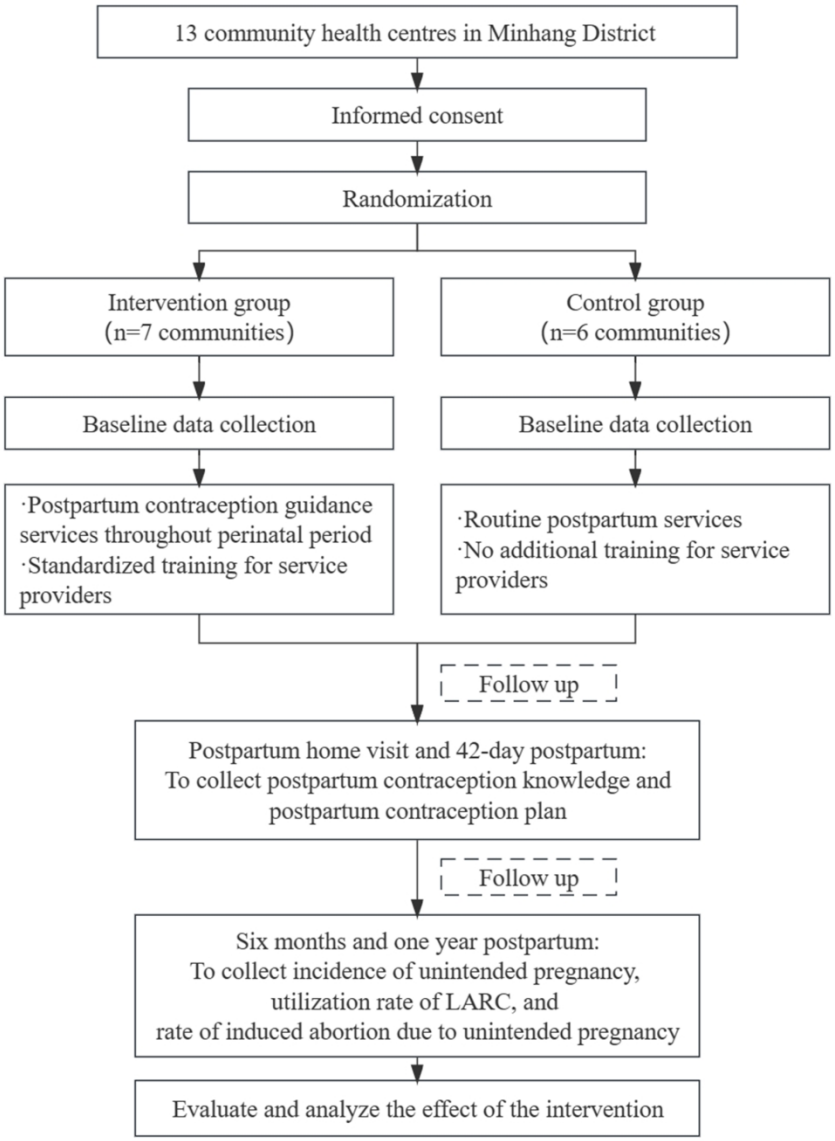

Fig. 1 Research flow chart

84x105mm (600 x 600 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym Response: Yes; no trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry Response: Abstract, paragraph 4
	2b	All items from the World Health Organization Trial Registration Data Set Response: Yes, the Chinese Clinical Trial Registry (ChiCTR)
Protocol version	3	Date and version identifier Response: 11 April 2020, first draft
Funding	4	Sources and types of financial, material, and other support Response: Funding section
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors Response: Author's contributions section
	5b	Name and contact information for the trial sponsor Response: Funding section
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities Response: Funding section
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) Response: Data management, paragraph 2
Introduction		

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention Response: INTRODUCTION, paragraph 1-5
	6b	Explanation for choice of comparators Response: INTRODUCTION, paragraph 3-5
Objectives	7	Specific objectives or hypotheses Response: Study objectives and hypotheses, paragraph 1-6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) Response: Study design, paragraph 1
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained Response: Participants and recruitment, paragraph 1-2
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) Response: Inclusion criteria, paragraph 1-6; Exclusion criteria, paragraph 1-4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered Response: Intervention group, paragraph 1-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) Response: N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) Response: Process evaluation, paragraph 1
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial Response: Control group, paragraph 1

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended Response: Primary outcome, paragraph 1; Secondary outcomes, paragraph 1-3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) Response: Research flow chart, figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations Response: Sample size and statistical power calculation, paragraph 1-5
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size Response: Participants and recruitment, paragraph 2
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions Response: Randomization, paragraph 1
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned Response: Randomization, paragraph 1
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions Response: Randomization, paragraph 1
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how Response: Blinding, paragraph 1

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial Response: Randomization, paragraph 1
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol Response: Data collection, paragraph 1-5; Primary outcome, paragraph 1; Secondary outcomes, paragraph 1-3
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols Response: Process evaluation, paragraph 1
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol Response: Data management, paragraph 1-2
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol Response: Data analysis, paragraph 1-2
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) Response: Data analysis, paragraph 2
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) Response: Data analysis, paragraph 2
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed Response: Process evaluation, paragraph 1

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial Response: Process evaluation, paragraph 1
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct Response: Process evaluation, paragraph 1
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor Response: Process evaluation, paragraph 1
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval Response: Study design, paragraph 1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) Response: N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) Response: Participants and recruitment, paragraph 2
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable Response: N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial Response: Data management, paragraph 1-2
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site Response: Funding section
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators Response: Data management, paragraph 2

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation Response: N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions Response: Ethics and dissemination, paragraph 1
	31b	Authorship eligibility guidelines and any intended use of professional writers Response: N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code Response: Ethics and dissemination, paragraph 1
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates Response: Yes
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable Response: N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Integrating contraceptive services into existing perinatal care: protocol for a community-based cluster randomized controlled trial in Shanghai, China

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Complete List of Authors:	Jin, Longmei; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Yin, Anxin; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment Zhang, Xiaohua; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Jiang, Hong; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment; Fudan University, Minhang Branch, School of Public Health Zhou, Lu; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment Zhou, Xiaoyan; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Wang, Xiurui; Minhang District Maternal and Child Health Hospital; Fudan University, Minhang Branch, School of Public Health Qian, Xu; Fudan University, School of Public Health, Key Laboratory of Health Technology Assessment; Fudan University, Minhang Branch, School of Public Health
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Integrating contraceptive services into existing perinatal care: protocol for a community-based cluster randomised controlled trial in Shanghai, China

Longmei Jin[1,3#], Anxin Yin[2#], Xiaohua Zhang[1,3*], Hong Jiang[2,3*], Lu Zhou[2], Xiaoyan Zhou[1,3], Xiurui Wang[1,3], Xu Qian[2,3]

[1]Minhang District Maternal and Child Health Hospital, Room 504, No. 805 Gudai Road, Meilong Street, Minhang District, Shanghai 201102, China;
[2]School of Public Health, Key Laboratory of Health Technology Assessment (National Health Commission of the People's Republic of China), Fudan University, Mailbox 175, No. 138 Yixueyuan Road, Shanghai 200032, China;
[3]Minhang Branch, School of Public Health, Fudan University, Mailbox 175, No. 138 Yixueyuan Road, Shanghai 200032, China;

[#]These authors contributed equally.
[*]Corresponding author: Hong Jiang, h_jiang@fudan.edu.cn, School of Public Health, Key Laboratory of Health Technology Assessment, National Health Commission of the People's Republic of China, Fudan University, Mailbox 175, No. 138 Yixueyuan Road, Shanghai 200032, China;
[*]Corresponding author: Xiaohua Zhang, zxh_2046@126.com, Minhang District Maternal and Child Health Hospital, Room 504, No. 805 Gudai Road, Meilong Street, Minhang District, Shanghai 201102, China.

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ABSTRACT

Introduction: Postpartum contraception is essential to preventing unintended pregnancies and short interpregnancy intervals. The first year after childbirth is a critical period with a high risk of unintended pregnancy and induced abortion. However, the postpartum contraceptive services are weak in China's existing maternal and child health care system. We propose to evaluate the effects of integrating postpartum contraceptive services into the existing perinatal care system via a cluster randomised controlled trial.

Methods and analysis: This cluster randomised controlled trial involves all 13 communities of Minhang District, Shanghai, China. Communities will be randomly allocated, seven in the intervention group and six in the control group. One thousand and three hundred women, 100 women in each community, will be recruited in the study. Women assigned to the intervention group will receive postpartum contraceptive education and counselling during pregnancy, childbirth hospitalization, postpartum home visits, and the 42-day postpartum clinic check-up. Women in the control group will receive routine antenatal and postpartum care. Participants will be recruited in the first trimester during pregnancy and followed up to one year postpartum. The primary outcome is the incidence of unintended pregnancy within one year after childbirth.

Ethics and dissemination: The trial received ethical approval from the Ethics Committee of Shanghai Minhang District Maternal and Child Health Care Hospital (#[2020]KS-02, #[2020]KS-05, #[2020]KS-05-EX). Results will be published in academic journals and disseminated in multiple formats for the health professionals and the public.

Trial registration number: Chinese Clinical Trial Registry (ChiCTR2000034603)

Keywords: Postpartum contraception, Postpartum women, Postpartum family planning, Perinatal care, Cluster randomised controlled trial

STRENGTHS AND LIMITATIONS OF THIS STUDY:

1) The study will integrate postpartum contraceptive services into the existing perinatal care system and provide evidence and an example to improve the availability and access to the services in China.
2) The intervention strategy and components are designed by a multiple-discipline team based on international and national guidelines.
3) The study used the strictest research design - cluster randomised controlled trial to test the effectiveness of the intervention.
4) Due to the nature of the intervention, service providers and users will not be blinded to the group allocation.
5) The study will be conducted in one urban district of Shanghai, China, the external validity of the results in other areas might be limited.

INTRODUCTION

Postpartum contraception plays an important role in preventing unintended pregnancies and short intervals between pregnancies[1]. The World Health Organization (WHO) recommends birth spacing should be at least 24 months to reduce adverse pregnancy and birth outcomes and to improve child health[2].

Interpregnancy intervals (IPIs), defined as the time interval between live birth and the beginning of the next pregnancy, are closely related to birth outcomes[1]. Short IPIs are associated with an increased risk of several adverse birth outcomes, such as preterm birth, low birth weight (LBW), small for gestational age (SGA) and perinatal death[3-6]. IPIs are also related to maternal outcomes. A systematic review showed that among women who had undergone a trial of labour and ended in low transverse caesarean section, short IPIs (<16 months) increased the risk of uterine rupture[2]. Women with short IPIs were more likely to experience chronic diseases, such as obesity and gestational diabetes[7 8]. Moreover, women with short IPIs had a significantly increased risk of maternal mortality, antenatal bleeding, premature rupture of membranes and anaemia, which seriously affected women's physical and mental health as well as family and social harmony[9].

In China, the rate of induced abortion due to unintended pregnancies has constantly increased, 50.3% were postpartum women[10]. A study in 2018 showed that the first year after childbirth was a period with a high risk of unintended pregnancy and induced abortion[11 12]. At least 70% of pregnancies in the first year after childbirth were unintentional[13]. The number of induced abortions within one year after childbirth accounted for 10.76% of the total number of induced abortions[14]. More than half (56.1%) of the women who had induced abortions within one year postpartum did not take any contraception[14]. Accumulated evidence has shown there were various misunderstandings in postpartum contraception, which led to not taking contraception or not adopting efficient contraceptive methods among couples[15]. Some women believed that they would not get pregnant after childbirth before menstruation resuming[16]. In addition, with the concern about the side effects on lactation and infant growth, a growing number of women chose short-term methods, such as condoms rather than more reliable long-acting reversible contraception (LARC), which increased the risk of unintended pregnancy[17 18].

In China, women register their pregnancy and have their first antenatal examinations in community health centres (CHCs) within three months. After registration at CHC, they will have regular antenatal examinations and antenatal classes provided by obstetricians and obstetric nurses in local hospitals before childbirth. After childbirth, women will stay in maternity wards for at least 24 hours for observation and receive maternal and neonatal health care. Then, at 3-7 days and 14-28 days after hospital discharge, health staff in CHCs will conduct postpartum home visits to check mothers' and newborns' health status as well as provide health care advice. At 42 days after childbirth, women and their newborns will return to the childbirth hospitals for check-ups by obstetricians. Currently, women only have chances of receiving simple postpartum contraceptive education after childbirth, including two times of postpartum home visits and the 42-day postpartum check-up. However, obstetric staff providing postpartum care in China were found to lack contraceptive knowledge and service capability[19]. For example, they mainly recommended condoms as the postpartum contraceptive choice rather than more effective methods such as LARC[19]. Due to insufficient obstetric personnel capacity and other constraints, most women cannot get timely contraceptive services within one year after childbirth. Furthermore,

approximately half of the women resumed sexual intercourse within six weeks after childbirth, which indicated family planning services provided after childbirth might be too late to prevent unintended pregnancy[20 21]. However, the link between maternal health care and the family planning services is weak in China, and access to quality postpartum contraceptive services is often difficult.

With China's new policy encouraging couples to have three children[22], postpartum contraception is even more critical in promoting the physical and mental recovery of postpartum women, maintaining reasonable birth spacing, improving early childhood development and enhancing family and social harmony. Therefore, we propose a cluster randomised controlled trial to examine whether postpartum contraceptive interventions integrated into the existing perinatal care system would reduce unintended pregnancy among women within one year after childbirth in Shanghai, China.

Study objectives and hypotheses

This study aims to assess the effectiveness of integrating postpartum conception services into the existing perinatal care system in Shanghai, China, to prevent unintended pregnancy among women within one year after childbirth. We hypothesise that the intervention will:

1) reduce the rate of unintended pregnancy within one year after childbirth.
2) improve women's knowledge of postpartum contraception.
3) improve the utilization of long-acting reversible contraception within one year after childbirth.
4) improve the postpartum contraceptive service capacity of obstetric medical personnel in Minhang District of Shanghai.

The study will provide evidence for establishing a service model of postpartum contraception integrated into the perinatal care system to meet the postpartum contraception service needs in Shanghai, China.

METHODS AND ANALYSIS

Study design

Using the cluster randomised control trial study design, all of the 13 communities in Minhang District will be involved as the research sites in Shanghai, China. Each community will be randomly allocated to either the intervention or the control group (see Fig. 1 for research flow). Ethical approval to conduct this trial has been granted by the Ethics Committee of Shanghai Minhang District Maternal and Child Health Care Hospital (#[2020]KS-02, #[2020]KS-05, #[2020]KS-05-EX). The research is registered with Chinese Clinical Trial Registry (#ChiCTR2000034603). The first participant was recruited on 21 September 2020. We anticipate completing our data collection by April 2023.

Participants and recruitment

This study will be conducted in Minhang District, in the central region of Shanghai. It has 13 communities, with a total population of 2,653,489 in 2021. The region's GDP was slightly lower than the average level of administrative districts of Shanghai.

All 13 communities in the district will be included in this trial and be randomly assigned to the intervention and control groups. In China, women register their pregnancy in community health centres (CHCs) within three months after pregnancy. They will receive perinatal care in the hospitals they choose to give birth and CHCs until 42 days postpartum. Women who register their pregnancy in CHCs and are eligible for the study will be invited to participate in the study by the health staff in CHCs. Each participant will be required to sign a written informed consent.

Inclusion criteria

Pregnant women

1)With the ability to read and understand Chinese
2)With the plan to live in Minhang District from the pregnancy registration to one year after childbirth
3)With the plan to give birth in a childbirth hospital in Minhang District
4)Consent to be followed up until one year after childbirth
5)With the WeChat account through which the online questionnaire survey can be fulfilled

Exclusion criteria

1)Miscarriage
2)Stillbirth
3)Baby in special care nursery
4)Loss to follow-up after discharge from hospital following childbirth

Randomization

Random allocation to the intervention and the control group will be determined by a computer-generated random number. We take one community as a cluster in the randomization and the total number of the clusters is 13. After randomization, there will be seven clusters in the intervention group and six clusters in the control group[23].

Blinding

Due to the nature of the intervention, service providers and users will not be blinded to the group allocation. The statistician will be blinded for the group allocation of participants during data analysis.

Intervention group

Training for service providers

Face-to-face training on postpartum contraception services was provided for community health staff responsible for pregnancy registration in CHCs and postpartum home visits, and obstetricians and obstetric nurses responsible for antenatal classes, maternity ward care and 42-day postpartum examination in hospitals.

The training material contents were designed by the research group with experts in gynaecology and obstetrics, maternal and child health care and family planning. International, national and local guidelines and service norms, including *Chinese*

experts' consensus on the clinical use of female contraceptive methods[13], *The technical guide of long-acting reversible contraceptives for those post-abortion and postpartum women*[24] and *Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations*[25] were used. The experts reviewed and streamlined the resources to establish the essential contents of the training into modules. The core training modules consist of five parts, including informed consent of project services, optimal time and duration of postpartum contraception, basic principles and methods of common contraception, recommendation of LARC methods, and need-based individualised contraceptive counselling. The service providers were also trained in communication skills and the standard process of filling in questionnaires.

Before and after the training, quizzes were carried out to evaluate the effect of the training. Practical training such as scenario-based role-play and counselling practice in the simulated situation was held. There were two theoretical and four practical training sessions, and one reinforcement session. Each session lasted for one day. Service providers will not participate in the intervention until they complete all the training sessions and pass the training tests.

Intervention for service users

We will carry out interventions at five stages in alignment with the current perinatal care system of China.

1. Participants will be recruited after giving informed consent at pregnancy registration. Then health staff in CHCs will offer the first consultation for the intervention group, emphasise the importance of postpartum contraception, and provide educational videos via the WeChat platform. The videos could be watched repeatedly at convenient times and contain the introduction of the necessity of postpartum contraception and various contraceptive methods such as the lactational amenorrhoea method (LAM) and LARC.
2. At the second and third trimesters, the intervention aims to stimulate interest in a postpartum contraceptive plan. Participants in the intervention group will take a 45-minute postpartum contraception class given by obstetricians and obstetric nurses in the hospital antenatal classes, which include appropriate methods, common misunderstandings, and recommendations for postpartum contraception. Specifically, when participants have their antenatal examinations, obstetricians will make an appointment for them to attend this postpartum contraception class. Obstetricians and obstetric nurses will use the same multimedia materials and video prepared by our research team and provide explanations face to face during the contraception class.
3. From childbirth to discharge from hospital, participants will be provided with education and advice by obstetricians and obstetric nurses in maternity wards. The key messages will include the ovulation resumption time of different breastfeeding methods, optimal IPIs, available contraceptive measures after childbirth, and LAM criteria. Obstetricians will conduct contraceptive counselling and recommend exclusive breastfeeding and LARC to women without contraindications. The husbands will be encouraged to participate in the counselling with their wives, and support postpartum contraception. Additionally, couples will get a health educational prescription after the counselling.
4. At the postpartum home visits (3-7 days and 14-28 days after discharge), the community health staff will help participants to choose suitable contraceptive

measures according to their conditions. Further, participants will receive educational pamphlets containing knowledge on postpartum contraception.

5. At the 42-day postpartum check-up in the childbirth hospital, obstetricians will provide participants with face-to-face counselling and an individualised health prescription based on the contraceptive method they choose. To promote the implementation of postpartum contraception, participants will be informed about the access to free contraceptives and designated hospitals for the placement of subcutaneous implants or intrauterine devices (IUD). The interventions at different stages are summarized in Table 1.

Table 1. Summary of the intervention

Stage	Intervention contents	Service providers	Approach
Pregnancy registration	Project introduction, counselling, and educational videos to inform the importance of postpartum contraception	Health staff in CHCs	Face-to-face counselling Online video
Second and third trimesters	Class in hospitals containing key knowledge of postpartum contraception to stimulate interest in a postpartum contraceptive plan	Obstetricians and obstetric nurses	Class in hospital
Childbirth hospitalization	Counselling and health prescriptions to facilitate making the postpartum contraceptive plan	Obstetricians and obstetric nurses in maternity wards	Face-to-face counselling Prescription
Postpartum home visit	Counselling and educational pamphlets offering contraceptive knowledge and advice to assist in completing the postpartum contraceptive plan	Health staff in CHCs	Face-to-face counselling Pamphlet
42-day postpartum check-up	Counselling, health prescriptions, and information about the access to postpartum services to promote the utilization of postpartum contraception	Obstetricians in childbirth hospitals	Face-to-face counselling Prescription

*CHCs, community health centres

Control group

Postpartum contraceptive service providers in the control group will not receive additional training on postpartum contraception. Women in the control group will receive routine perinatal care and regular postpartum contraceptive education at postpartum home visits and 42-day postpartum health check-ups. In routine perinatal health care, the community health staff will remind women to consider postpartum contraception, ask about their postpartum contraceptive plan, and provide brief recommendations on postpartum contraception (mainly condoms) during the postpartum home visit. At 42-day postpartum health check-ups in the childbirth hospital, obstetricians will remind women to choose and implement appropriate postpartum contraception methods based on their conditions, but without specific consultation and instructions.

Data collection

All participants will be followed up from the first trimester antenatal to 42 days postnatal period. They will be asked to complete the questionnaires at five time points:1)

pregnancy registration; 2) first postpartum home visit at 3-7 days; 3) 42 days after childbirth; 4) six months after childbirth; 5) one year after childbirth.

At baseline data

In China, pregnant women register their pregnancy in CHCs to establish pregnancy records and have their first antenatal examinations. At the pregnancy registration, health staff in CHCs will ask participants to complete a self-administered questionnaire via scanning the QR code or clicking the link of the questionnaire website to collect their baseline information. The baseline information will include participants' demographic characteristics (age, residence, educational level, occupation), obstetric history, contraceptive knowledge and their need for postpartum contraception services.

At postpartum home visit

The health staff in the CHCs will conduct the first postpartum home visit for women in 3-7 days after hospital discharge. Participants in both groups will complete an online questionnaire, which includes questions about their delivery outcomes, a postpartum contraceptive knowledge test, and their plans for the next pregnancy and postpartum contraception. Participants in the intervention group will fill in their contraception plan after the postpartum contraception counselling. Health staff in CHCs will ensure participants' informed decision-making by providing them with information on the advantages, disadvantages, and applicable conditions of various contraceptive methods.

On 42-day postpartum check-up

At 42 days after childbirth, postpartum women will return to the childbirth hospital for obstetric examinations. Women in the intervention group will be asked to complete an online questionnaire. Through the questionnaire, obstetricians of the childbirth hospital will collect their lactation and sexual behaviour information as well as their postpartum contraception condition, and confirm whether they receive the postpartum contraceptive intervention services of each stage. For those who haven't initiate any contraception, obstetricians will collect their plan for postpartum contraception after the counselling. In addition, another postpartum contraceptive knowledge test will be included in the questionnaire to collect participants' knowledge of postpartum contraception.

At half-year and one year postpartum

At half a year and one year after childbirth, information on participants' selections of contraceptive methods, their utilization frequency and satisfaction of the chosen contraception, conception condition and abortion experience will be collected via telephone interviews by health staff in CHCs.

Primary outcome

Incidence of unintended pregnancy

The primary outcome of this study is the incidence of unintended pregnancy within one year after childbirth, which will be collected at one year postpartum via telephone interviews. Health staff in CHCs will ask participants whether they fall pregnant after childbirth or not, and whether it is planned or unintended. The information on frequency, time, and outcome of the pregnancy within one year after childbirth will also be

collected. The incidence of unintended pregnancy will be calculated and compared between the intervention group and the control group.

Secondary outcomes

Utilization rate of LARC

At one year postpartum, participants will be asked whether they take postpartum contraception and the method they choose via telephone interviews. The health staff in CHCs will collect information on contraceptive methods participants use through a multiple-choice question with five response selections: common methods such as condoms and in vitro ejaculation, LARC such as IUD and subcutaneous implant, short-acting oral contraceptives, emergency contraception pills (ECPs), and sterilization. Participants will also be asked about their utilization frequency of the chosen contraception. The utilization rate of LARC within one year after childbirth will be calculated based on the above information.

Rate of induced abortion due to unintended pregnancy

Postpartum women will be asked whether they fall pregnant via telephone interviews at one year after childbirth. For pregnant women, health staff in CHCs will ask whether the pregnancy is planned or unintended, and the outcomes, including induced abortion and continued gestation. The rate of induced abortion due to unintended pregnancy within one year after childbirth will be calculated.

Knowledge of postpartum contraception

Participants' knowledge of postpartum contraception will be assessed via online questionnaires at pregnancy registration, postpartum home visit and 42 days after childbirth respectively. At the baseline survey during pregnancy registration, a list of contraceptive methods will be displayed and women will be asked to choose the methods that they have heard of or used before. At the postpartum home visit, a knowledge test including questions about LARC, recommended contraceptive methods with different lactation plans, LAM criteria and adverse impacts of short IPIs on mothers and children will be conducted. At 42 days after childbirth, participants in the intervention group will complete another knowledge test, and they will be asked about recommended contraceptive methods with different lactation plans, LAM criteria, optimal IPIs, the recommended time of resuming sexual behaviour and taking postpartum contraception after childbirth.

Sample size and statistical power calculation

Sample size calculation for primary outcome

There are a total of 13 communities in Minhang District, Shanghai. The sample size was calculated based on the primary outcome of the incidence of unintended pregnancy within one year postpartum. We used PASS 15.0 to calculate the sample size. The estimated incidence of unintended pregnancy within one year postpartum was 10% in the control group[26], the expected difference between the intervention group and the control group was 6%[27], and the intracluster correlation coefficient (ICC) was 0.01[28]. A sample size of 1040 pregnant women (80 in each CHC) will be needed at 0.05 significance level and 80% statistical power. Given the 20% anticipated rate of loss to follow-up from recruitment to one year after childbirth, a total of 1300 women (100 in each community health service centre) will be required.

Calculation of statistical power for secondary outcomes

The power calculations for secondary outcomes include the utilization rate of LARC, induced abortion rate of unintended pregnancy, and knowledge of postpartum contraception.

Utilization rate of LARC

The estimated LARC utilization rate in the control group was 25% and the expected Odds Ratio was 1.6 between the two groups[29]. Given the calculated sample size of 80 per cluster based on the primary outcome, the statistical power will be 97.5% for the utilization rate of LARC at 0.05 significance level.

Rate of induced abortion due to unintended pregnancy

The estimated induced abortion rate within one year postpartum in the control group was 10%, and the expected Odds Ratio was 0.4 between the two groups[30 31]. Given the calculated sample size of 80 per cluster based on the primary outcome, the statistical power will be 80.0% for the rate of induced abortion due to unintended pregnancy at 0.05 significance level.

Knowledge of postpartum contraception

The estimated accuracy rate of postpartum contraception questions in the control group was 65%, and the expected Odds Ratio was 1.2 between the two groups[32]. Given the calculated sample size of 80 per cluster based on the primary outcome, the statistical power will be 93.6% for the postpartum contraception knowledge at 0.05 significance level.

Data management

A unique identification number will be assigned to women once they agree to participate in the study at the pregnancy registration. Personal information will not be identifiable.

All information will be collected through the online questionnaire and stored on the questionnaire platform. The data will be secured with an account and password, and access to information will be limited to research team members. Researchers of Fudan University will be responsible for data security.

Data analysis

Descriptive analysis will be performed to examine all variables. For categorical variables, frequency and percentages will be reported, while mean ± SD will be reported for continuous variables.

The baseline characteristics of the intervention and the control group such as age and pregnancy history will be compared. All outcomes will be compared between the intervention and the control group. The difference between the two groups will be assessed by conducting parametric tests (t-test and ANOVA) or non-parametric tests (Wilcoxon, Kruskal-Wallis and Friedman tests) for continuous variables. The Chi-square test will be used for categorical variables. The effect of the intervention will be

evaluated by generalised linear mixed model (GLMM). The evaluation of the study will be based on the "intention to treat" analysis. SPSS software (version 25.0, IBM Corporation) and R software (version 4.1.3) will be used to conduct the statistical tests.

Process evaluation

The process evaluation and quality control will be conducted by the research group in Minhang District Maternal and Child Health Care Hospital and the participating CHCs. We will conduct pre-surveys to ensure the validity and reliability of the research questionnaires by checking ambiguities and semantic expressions. Service providers will be trained according to the protocol to ensure the feasibility and quality of the intervention. To reduce invalid questionnaires, we will set logic checks for online questionnaires so that questionnaires with unreasonable responses or incomplete items will not be submitted. The designated project managers and investigators will act as quality controllers, and will be responsible for monitoring the recruitment process on the sites and making records. During the intervention, both service providers and participants in the intervention group will be asked to sign a confirmation form after each face-to-face intervention at pregnancy registration, postpartum hospitalization, postpartum home visits, and 42-day postpartum check-up as an implementation process recording. Key components of the intervention at each stage will be listed on the form, and the participants will confirm whether they received the intervention by signing at the end of the form. The quality controllers will check these forms routinely to ensure the implementation is consistent with the plan. In addition, based on the records and periodical summary of site supervision, we will hold regular meetings with experts and staff of CHCs and childbirth hospitals every two months to solve the existing problems and ensure intervention protocol compliance.

Patient and Public Involvement statement

During the study design, we conducted a formative study on the current postpartum contraceptive services from women to understand their service needs. We also sought opinions and suggestions on intervention strategy from obstetricians and obstetric nurses in maternal and child health institutions to ensure the feasibility of the intervention. Furthermore, we conducted a pilot survey among ten pregnant women during the first trimester and ten postpartum women, and improved the questionnaires based on their feedback. All pilot participants have confirmed that the questionnaires were easy to understand without ambiguity or obscurity. Postpartum women suggested adding a satisfaction survey for intervention services to monitor and improve the intervention process. In addition, participants of the pilot survey proposed to add a question collecting the specific contraceptive method recommended by service providers during the counselling.

DISCUSSION

A growing body of research has shown that contraceptive services are effective interventions to improve maternal and infant health outcomes[33-36]. The postpartum period is critical to adopt appropriate and effective contraceptive methods to reduce

unintended pregnancies[36]. To address the unmet service needs on postpartum contraception and tackle the challenges, in this proposed study, we will integrate postpartum contraceptive services into the current perinatal care system from the first trimester to 42 days postpartum. We hypothesise that the intervention will reduce the rate of unintended pregnancy and increase the utilization of LARC within one year after childbirth, as well as improve women's knowledge of postpartum contraception. If the intervention is proven effective, this service model will be up-scaled in all maternal and child health care institutions, including CHCs and hospitals in Minhang District of Shanghai, China. We expect that our findings will promote postpartum contraception, support women in making informed contraception decisions, and improve postpartum contraception services.

This trial will develop and evaluate a postpartum contraception intervention for women based on their needs. The intervention strategies will help to reduce the rate of unintended pregnancy in the first year after childbirth. It will potentially contribute to postpartum women's physical and mental rehabilitation, maintaining a reasonable birth interval and achieving family and social harmony.

There are several anticipated limitations of this study. First, the intervention model was designed based on the current perinatal care system in urban areas of Shanghai, China, so it may not be applicable to rural areas. Second, participant retention may be challenging as the follow-up will be about 20 months, i.e., from pregnancy to one year postpartum. To minimise the rate of loss to follow-up, we will implement the intervention in the existing maternal care system, tapping in the usual care to deliver the intervention contents.

Ethics and dissemination

The study has been approved by the Ethics Committee of Shanghai Minhang District Maternal and Child Health Hospital (#[2020]KS-02, #[2020]KS-05, #[2020]KS-05-EX). The research is registered with Chinese Clinical Trial Registry (#ChiCTR2000034603). All participants are required to provide written informed consent. All research activities will be carried out in accordance with relevant guidelines and regulations. The data will be confidential after the study completion. The data generated in this study will be available from the corresponding author on reasonable request. Results of the study will be published in academic journals and be disseminated in research seminars and other appropriate formats for the professionals and the public.

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Authors' contributions

LMJ, HJ and XQ conceived the study and designed the community-based cluster randomised controlled trial. LMJ is responsible for funding application and data collection. XYZ and XRW contributed to the data collection. XHZ contributed to coordinating the data collection. AXY is responsible for drafting the manuscript. LZ

contributed to the drafting. HJ, LMJ and XQ provided critical comments and revised the manuscript. All authors have approved the final article.

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Data statement

The data will be confidential after the study completion. The data generated in this study will be available from the corresponding author on reasonable request.

Competing interests

None declared.

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Fig. 1 Research flow chart

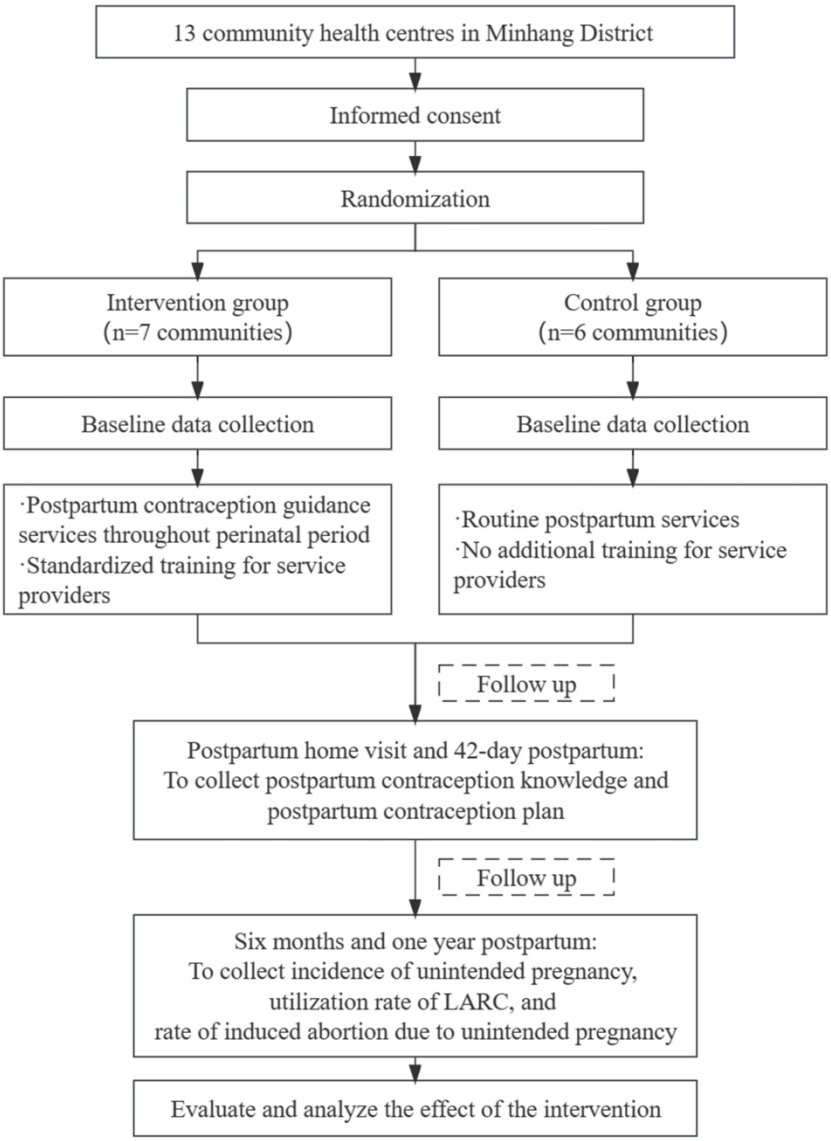

Fig. 1 Research flow chart

84x105mm (1200 x 1200 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym Response: Yes; no trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry Response: Abstract, paragraph 4
	2b	All items from the World Health Organization Trial Registration Data Set Response: Yes, the Chinese Clinical Trial Registry (ChiCTR)
Protocol version	3	Date and version identifier Response: 11 April 2020, first draft
Funding	4	Sources and types of financial, material, and other support Response: Funding section
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors Response: Author's contributions section
	5b	Name and contact information for the trial sponsor Response: Funding section
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities Response: Funding section
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) Response: Data management, paragraph 2
Introduction		

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention Response: INTRODUCTION, paragraph 1-5
	6b	Explanation for choice of comparators Response: INTRODUCTION, paragraph 3-5
Objectives	7	Specific objectives or hypotheses Response: Study objectives and hypotheses, paragraph 1-6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) Response: Study design, paragraph 1
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained Response: Participants and recruitment, paragraph 1-2
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) Response: Inclusion criteria, paragraph 1-6; Exclusion criteria, paragraph 1-4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered Response: Intervention group, paragraph 1-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) Response: N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) Response: Process evaluation, paragraph 1
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial Response: Control group, paragraph 1

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended Response: Primary outcome, paragraph 1; Secondary outcomes, paragraph 1-3
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) Response: Research flow chart, figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations Response: Sample size and statistical power calculation, paragraph 1-5
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size Response: Participants and recruitment, paragraph 2
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions Response: Randomization, paragraph 1
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned Response: Randomization, paragraph 1
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions Response: Randomization, paragraph 1
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how Response: Blinding, paragraph 1

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial Response: Randomization, paragraph 1
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol Response: Data collection, paragraph 1-5; Primary outcome, paragraph 1; Secondary outcomes, paragraph 1-3
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols Response: Process evaluation, paragraph 1
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol Response: Data management, paragraph 1-2
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol Response: Data analysis, paragraph 1-2
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) Response: Data analysis, paragraph 2
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) Response: Data analysis, paragraph 2
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed Response: Process evaluation, paragraph 1

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial Response: Process evaluation, paragraph 1
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct Response: Process evaluation, paragraph 1
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor Response: Process evaluation, paragraph 1
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval Response: Study design, paragraph 1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) Response: N/A
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) Response: Participants and recruitment, paragraph 2
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable Response: N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial Response: Data management, paragraph 1-2
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site Response: Funding section
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators Response: Data management, paragraph 2

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation Response: N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions Response: Ethics and dissemination, paragraph 1
	31b	Authorship eligibility guidelines and any intended use of professional writers Response: N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code Response: Ethics and dissemination, paragraph 1
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates Response: Yes
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable Response: N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.