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Effects of post-abortion family planning services on contraceptive practices in China: Protocol for a clustered randomized controlled trial

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Received: *November 19th, 2017*
Accepted: *December 4th, 2017*
Published: *December 6th, 2017*

Citation
Zhang WH, Li J, Wang S, Olsen J, Temmerman M. INPAC consortium. Effects of post-abortion family planning services on contraceptive practices in China: Protocol for a clustered randomized controlled trial. *Med Press*. 2017; 2(1): 33-41. doi: 10.28964/MedPress-2-106

ABSTRACT

Study objectives: To determine whether integrating post-abortion services in hospital settingsin China will increase the contraceptive use and decrease repeat abortion rates.
Study design: Three-arms cluster randomised controlled trial in which the unit of randomisation is hospital.
Participants: Women seeking induced abortion within 12 weeks of gestation age.
Sites: Ninety hospitals from 30 provinces in China will be randomised to the three arms of the study stratified by province. In each province, eligible hospitals will be matched on the characteristics of abortion departments, especially the volume of abortions in the 2 months in the situation survey.
Length of follow up: Six months.
Intervention: Multiple interventions that aim to increase the use of more effective contraceptive methods, improve user adherence to reduce the unintended pregnancies and repeat induced abortions.
Data collection: Data will be collected at four time points, one at baseline(month 0 at the time of enrolment) and twice during intervention (1st3rd and 6th month after enrolment, respectively).
Primary outcome: Unintended pregnancies or repeated induced abortions; immediate contraceptive uptake and the use of modern effective contraceptive methods.
Trial registration: International Standard Randomised Controlled Trial: ISRCTN01846583, registered on 23 October 2014.

KEY WORDS: Cluster randomised trial; Induced abortion; Contraception; Family planning; China.

ABBREVIATIONS: AU-DESC: Aarhus University – Danish Epidemiology Science Centre; CMA-CSFP: Chinese Society of Family Planning - Chinese Medical Association; EC: Emergency Contraception; FP: Family Planning; FU: Fudan University; HCo: Hospital Co-ordination; IEC: Information, Education and Communication ; INPAC: INtegrating Post-Abortion family planning services into China's existing abortion services in hospital settings; IUD: Intra Uterine Device; LSTM: Liverpool School of Tropical Medicine; NCo: National Co-ordination; NRIFP: National Research Institute for Family Planning; OCP: Oral Contraceptive Pills; PAC: Post Abortion Care; PAFP: Post-Abortion Family Planning; PCo: Provincial Co-ordination; PMT: Project Management Team; SCU: Sichuan University; TSC: Trial Steering Committee; UG-ICRH: International Centre for Reproductive Health, Ghent University; WHO: World Health Orgnization; WP: Work Package.

BACKGROUND AND SCIENTIFIC RATIONALE

Induced abortion in China

In China, induced abortion has increased from 10 millionin 2003 to 13 million in 2008,[1] of which one third of women have undergone repeat abortions.[2,3] It was estimated that direct medical costs for abortion were 3 billion Chinese Yuan in 2002 (326 million euro)[4] and it has been growing over time. Most abortions are performed in hospitals in urban areas.[5,6] Social changes in China have led to an abortion epidemic among young and unmarried women at average 20-years-old, accounting for 11-55% of total induced abortion according to previous studies[6,7] and up to 75% in a recent survey of 2008.[8]

Rationale for intervention

The large number of induced abortions in China is primarily due to contraceptive failures or less/no use of contraception.[9] In China, contraceptive methods are mainly delivered through family planning (FP) clinics which mainly target married couples and through pharmacies. Users obtained condoms and oral contraceptive pills (OCP) from pharmacies mostly rely on only non-medical sources for advice and information or on packaging instructions. These instructions do not include concrete information on contraceptive failures, nor on how to avoid them.

Abortion is a common way to terminate an unintended pregnancy, although social discrimination associated with abortion remains, especially for unmarried women.[10] To our knowledge, the vast majority of induced abortions are performed in hospital settings, though family planning clinics also provide abortion services.[11,12] Post-Abortion Family Planning (PAFP) services are often lacking in hospital settings and women who have undergone abortion are usually not referred to family planning clinics for FP counselling and services.[8] The fragmentation of FP services is leaving high risk to vulnerable groups such as young and unmarried women, as well as rural-to-urban migrant women.

Recent studies showed that non-use and poor compliance of contraception were common among adolescents and young women, which indicated lack of knowledge and poor motivation.[13,14] Combination of educational and contraceptive interventions appeared to reduce unintended pregnancy among adolescents.[15] Abortion-experienced women were more motivated than other women to start effective and safe contraception after an abortion.[16] A study on PAFP conducted in three cities in China in 2006 has corroborated that the introduction of PAFP services in urban China increases the use of contraceptives methods and thus reduces the rates of unintended pregnancy and induced abortion.[17] The present study will evaluate the implementation of FP services after induced abortion in hospital settings in a 'real world' situation covering 30 provinces in China and to assess effectiveness, acceptability, and sustainability of this approach.

Rationale for use of a cluster randomised trial design

Our intention is to compare integrating post-abortion services in hospital settings with current services provided by the hospitals. It is essential that the whole hospital is randomised to intervention or to continue with their current practice, this will minimise contamination between the trial arms and will be as close as possible to real life situation. Therefore the unit of randomisation will be hospital.

OBJECTIVES

Overall objective of the research

This study aims to reduce unintended pregnancies and repeat abortions through integrating post-abortion family planning services into existing abortion services at hospital settings in China in order to strengthen healthcare delivery for equitable access and sustainable development.

Specific scientific and technical objectives

To assess the needs and feasibility of integrating PAFP into existing abortion services at hospitals through the review of China's FP policy and practice as well as strategies of delivering PAFP in developed and other developing countries.

- To assess practicability of integrating PAFP into existing abortion services at study hospitals through health system study involving stakeholders: policy makers, health managers, abortion service providers and women who have undergone abortions.
- To develop detailed intervention strategies for improving access to, and quality of FP services after induced abortion.
- To implement and monitor intervention processes, their impact on hospitals and problems incurred during the implementation.
- To evaluate the effectiveness of integrated PAFP regarding unwanted pregnancy and repeated abortion rate and to analyze health system determinants of the effectiveness through comparison across the intervention groups.
- To bridge the gap between research and policy through involving policy and decision makers at different level of governments.
- To draw conclusions regarding the feasibility, effectiveness and sustainability of the interventions and to disseminate the results nationally and internationally.

TRIAL DESIGN

This is a cluster randomized controlled intervention trial.

METHODS

This protocol follows the recommendations for elaborating randomised controlled trials described in the SPIRIT guideline.[18]

Study Setting

The study is conducted in 30 of the 31 administrative divisions

in mainland China (22 provinces, 4 municipalities, 4 autonomous regions).

Participants

Eligibility criteria for participating hospitals (cluster)

Hospital inclusion criteria was identified according to the findings of a baseline situation analysis and China's current hospital settings:

- Agreement with the randomized allocation
- Average number of abortions per month between 200 to 800
- Willing and able to carry out the intervention packages proposed by the study
- Availability to collect data at four time-points
- Consent given for involvement within an appropriate environment

Hospitals that do not meet the above inclusion criteria will not be considered eligible to this study.

Eligibility criteria for women

Women will be eligible to be interviewed and followed-up if they seek abortion at participating hospitals and meet the following inclusion criteria (all women visiting the participating hospitals will receive normal services regardless of their participation conditions).

- Unintended pregnancies seeking induced abortion
- Gestation age less than 12 weeks
- Aged ≥18 and ≤40 years
- Sexually active women of childbearing potential and not planning to become pregnant during the study
- No physical and mental problem that may affect subject enrolment or follow-up
- Willing to give informed consent in writing
- Willing and able to response the scheduled surveys and to comply with the study procedures

Exclusion criteria

- Having intention to become pregnant during the study

INTERVENTION

Intervention packages and trial arms

The intervention packages were developed based on the findings from the situation analysis and the existing post abortion care (PAC) program in selected hospitals in China,[19] as well as the World Health Organization (WHO) guidelines on preventing early pregnancy and safe abortion.[20,21] This trial includes three-arms: two intervention groups and one control group.

Intervention group 1: Standard PAFP Package

Training of abortion service providers and managers

- **Target population:** all abortion service providers (doctors or nurse) and department/hospital managers.
- **Contents of the training:** Family planning counselling knowledge, delivery of contraceptive services (e.g., OCP, intra uterine device - IUD, implants), youth-friendly (no judgement) and client-centred counselling/communication skills. Standard service guidelines and PAFP procedure will be developed and introduced.
- **Modes of the training:** The appropriate training materials (e.g. interactive video and booklet, group face-to-face training, workshop, remote/online training courses and all training materials at project website) will be developed in English and local language.

Providing relevant Information, Education and Communication (IEC) to women and their partners by abortion service providers

- **Target population:** All women seeking abortion at the participating hospitals.
- **Contents of the IEC:** Basic knowledge on reproductive health, information on the prevention of unintended pregnancy and sexually transmitted diseases, health risks of repeat abortion, the need to start contraception immediately after induced abortion and the management of contraceptive failure and emergency contraception (EC), as well as the different available contraceptive methods and their advantages / disadvantages.
- **Modes of providing the IEC:** Written materials, video or audio recording or group counselling at waiting (pre-abortion) and resting (post-abortion) areas.

Providing individual counselling to women (and their partners) at pre- and post –abortion by abortion service providers

Women and their partners who presented at the moment will be invited to participate in a face-to-face counselling in a recovery room in a homely environment, service providers are non-judgemental and considerate in their dealing with women (in the way of client-centred/ youth-friendly and personalized counselling). Service providers will understand the reason of induced abortion and provide the personalized recommendations and technical support to prevent future unintended pregnancy. This session will also provide psychological counselling accordingly and suggest referral for those who need.

Offering modern contraceptive methods

(e.g., The modern contraceptive methods according to the availability of participating hospitals will be offered to the women immediately) to the women immediately after the abortion.

Continuous PAFP service/follow-up counselling

- Continuous PAFP services will include inviting visits or phone calls to control the complications of abortion within 4 weeks after the abortion (such as infection, bleeding).
- And phone SMS or face-to-face counselling for those who visit the hospitals at 12 and 24 weeks after the abortion to meet women's needs on FP.

Intervention Group 2: Standard PAFP Package + incentive mechanismto service providers

- Beside the standard PAFP Package used in intervention group 2, the financial incentive to service providers will be proposed in order to strengthen their motivation and to ensure quality of care.
- Such as the inclusion of PAFP service provision in institutional and provider's assessment criteria, bonus or income to doctors or nurses, job promotion, etc. This accountability mechanism will be integrated into existing hospital management system, it might vary among participating hospitals. This intervention will be reached through the advocating the hospital's managers and supervision mechanism.

Group 3: Control group

- Care given as usual without any intervention.

Trial processes and quality control

Trainers from universities or hospitals who are FP experts will provide special sessions of in-service training on PAFP services to the abortion service providers and hospital/department managers from hospitals allocated in intervention group 1 and group 2. Guidelines for health managers and service providers will be introduced. The technical support will be available during the whole study period.

A set of training evaluation strategies will be developed in order to ensure the quality of training, such as pre- and post- training tests and interactive communication between trainers and trainees during and after training sessions.

During the study period, some additional qualitative information will be collected by the monitors who are responsible for the monitoring of intervention implementation at each hospital:

- Technical contents of the information provided to trainees
- Quality of the interpersonal communication between trainers and trainees at sub-sample

These monitors will spend several days in the selected hospitals for observing and monitoring the training process and evaluate in clinical practice (e.g., service provider - patient interactions when given the informed consent, answering questions, etc.). Although, such observation may be subject to the Hawthorne effect (also called observer effect whereby providers change their behaviour when observed), but it has still been found to provide valuable information on the purpose of improving service provision in other settings. The prompt feedback will be discussed with the trainers and the project consortium to develop strategy enhancing the implementation.

Prior to participation, each hospital will be contacted by the National Coordinator or their nominated deputy. Study design of INPAC project and the interventions approaches as well as the data collection instrument will be informed to hospital/department managers and the persons in charge of the study.

The implementation of intervention packages is planned to start from April 01, 2014. All participants is planned to be followed up at month 1, month 3 and month 6 after their enrolment. The intervention implementation will be supervised and monitored by provincial coordinators in each province under direction of national coordinators. The regular implementation supervision, monitoring and quality control during the implementation period will be conducted by national coordinators and project leader.

OUTCOME

Primary Outcome

The primary outcome includes the following indicators:

1. **Unintended pregnancies** including clinical or self-reported unintended pregnancies at the time of follow-up interviews.
2. **Repeat induced abortions** induced abortion and ongoing pregnancies that women did not want to give birth to a baby among all follow-up women during the follow-up period.
3. **Use of modern contraceptive methods** including OCP, IUDs, implants, male/female condoms, others barrier methods (such as diaphragms, the cervical cap and spermicides), emergency contraception, sterilisation (male/female) during follow-up period.

Secondary Outcome

1. Immediate contraceptive uptake: including IUD, OCP, sterilization, injection, implant, etc.
2. Contraceptive practices: use of any contraceptive methods, including condom, natural methods (periodic abstinence or withdrawal), IUDs, OCP, EC, sterilization, injection, implants, diaphragm, spermicide, etc. during follow-up period.
3. Consistent use, correct use, and both consistent and correct use of condom among condom users during the follow-up period.
4. Changes in knowledge and attitudes about the risk of unintended pregnancies.
5. Morbidity/mortality related to abortion
6. Sexually transmitted infections (including HIV)
7. Satisfaction regarding abortion and family planning services.
8. Post-abortion family planning services received during abortion services among all participants, including group education,

individual counselling, free contraceptives and referral to other family planning services.
9. Pregnancies among all follow-up women during the follow-up period.
10. Reported direct cost related to the abortion

Participant timeline

Figure 1 shows the flow of the enrolment, interventions and assessment.

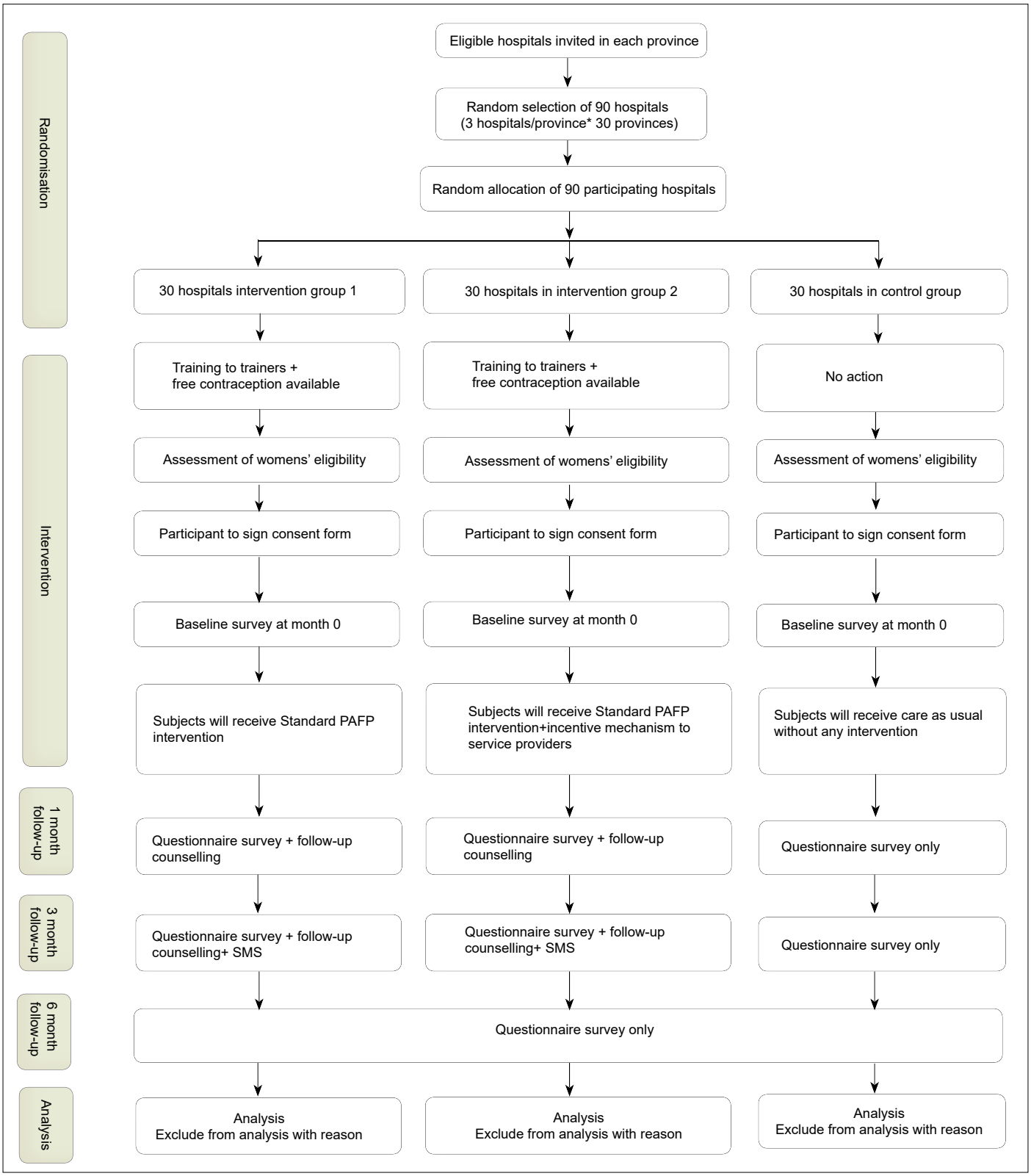

Figure 1: Participant timeline.

Sample size estimation

This isa three–arm trial, there are two alternative intervention arms (group 1 and group 2), the expected difference of outcome between intervention group 1 and group 2 would be smaller than the expected difference between either of the two study arms and the control arm.The sample size calculation was based on the comparison of two intervention arms for getting large sample which could provide adequate power for comparisons between either of two intervention groups and the control group.

Sample size calculation was used the methods proposed by Donner and Klar.[22]

- When the reduction of repeat induced abortion rate as the measurement of effect.Taking into account the intra-cluster correlation coefficient (r) as 0,02[23] with 80% of power, a 2-sided significance level of 5%, and an average cluster size of 100 women, minimum 84 clusters (28 in each arm of the trial) were required to detect the decreased repeat abortion rate from 3.5% to 1.5%[18] where the inflation factor [1 + (m–1) r] is 2,98. A follow-up survey will be designed to be conducted after 6 months of the abortion. Given 50% drop-out of target population, an average of 200 abortions will be required for each participating hospital.Taking into account the province as the stratification factor, three hospitals in each province will be recruited and allocated, a total of ninety hospitals (30 in each arm) will participate in the study.
- When the increased modern contraceptive use as the measurement of effect. Taking into account the intra-cluster correlation coefficient (r) as 0,02[23] with 80% ofpower, a 2-sided significance level of 5%, and an average cluster size of 100 women, minimum 36 clusters (12 in each arm of the trial) were required to detect the increased use of modern contraceptive methods from 53-63%.[24] Given drop-out of target population with 50%, an average of 200 abortions will be required for each participating hospital.

Recruitment

We first developed the hospital sampling frame from 30 provinces that met the eligibility criteria based on the results of a cross-section survey conducted one year early. Each province provided a list of 12 eligible hospitals except three provinces (Ningxia, Qinghai and Inner Mongolia), where they were only able to provide 6 hospitals due to the limited available number of eligible hospitals in those low-income regions. Three hospitals in each province were randomly selected for inviting participation in study. Women who seek abortion at participating hospitals and meet the inclusion criteria will be invited for participating study. All the women visiting the participating hospitals will receive normal services regardless of their participation conditions.

Randomisation and Allocation

Random selection of participating hospital

Randomisation will be performed by the Aarhus University - Danish Epidemiology Science Centre (AU-DESC), Denmark.

A stratified design will be used to ensure that the three arms of the trial are as similar as possible at baseline. The stratification factor is province. Eligible hospitals will be listed in each province and provided to AU-DESC where 3 participating hospitals will be selected randomly.

Allocation sequence

The 90 hospitals will be divided into 30 blocks with 3 hospitals in each block using hospital size/type and locations matching criteria. Each block will be numbered 1 to 30 and each hospital within the block will be numbered 1, 2 or 3. The notation 15-2 means the second hospital in block 15 (range 1-1, …..30-3). Each arm will be labelled A, B and C. The order of hospitals within a block does not matter but it has to be done before the start of randomizing to the arms.

Randomisation to each arm A, B or C is then based on first appearance of the numbers 1,2 or 3 in a sequence of one digit random numbers, started at a random place on the list. If that first number is 2, the second hospital will be allocated to arm A in that block. If the second random number is 3 that hospital is randomized to arm B and hospital number 1 is then allocated to arm C. All hospitals within a block have to be randomized before the next block is was processed.

A detailed log file will be kept under lock for the randomization identifying the blocks and which arm each hospital was allocated to. The file should include the name of the one who did the randomization and who controlled the process – including dates and signatures.

Information on the allocation will not be provided before all hospitals are allocated. No change in allocation is allowed. A failure to accept the treatment allocation is considered as non-compliance to the protocol. The hospital is included in the intention to treat analysis.

Blinding

Due to the nature of the intervention neither participants (women) nor health providers can be blinded to allocation, the researchers who will analysis data will not be informedthe allocation status prior the analysis by using pre-coding system in the database.

Data Collection

Data collection will be conducted at 4-points during the study period:time of women seeking abortion before intervention im-

plementation (M0); 1 month after abortion (M 1); 3 months after abortion (M3) and 6 months after abortion (M6).

The M0 data will be presented as 'baseline' data, which will describe the characteristics of women in the participating hospitals immediately before trial entry, and the characteristic of abortion distribution in the hospitals.The 'outcome' data will describe the outcomes of the women undergone abortion during the follow-up period at month 3rd and month 6th after the abortion.

All abortion-seeking women who visited the selected hospitals will be collected about their socio-demographic information, contraceptive practices 3-6 months before abortion (history of contraception), contraceptive knowledge, reproductive history, and family planning services they received during their abortion at the hospital.

At the 1st, 3rd and the 6th month followed the abortion, all the participants will be asked about their contraceptive practices and if there is any unintended pregnancy and induced abortion happened after enrolment (follow-up interview: mostly telephone interview).

Structured questionnaires will be used to collect baseline and follow-up data.

Questionnaires for the follow-up period are slightly modified to capture the received intervention and its effect. Interviews will not blind to interviewers regarding intervention packages provided to the women. Interviews can be done by telephone or face-to face methods.

Analysis

The analysis of the trial will be by 'intention-to-treat', regardless of the management received by individual women in the trial. The sensitivity analyses will be conducted for evaluate bias related to missing data at the endpoint. Statistical analyses will be reported in accordance with the CONSORT guidelines for cluster RCTs.[25]

Analyses will be performed at individual level after adjusting the effect of clustering. Descriptive statistics (means and proportions) will be calculated to check for any major imbalances between the trial arms at baseline. The methods proposed by Donner and Klar,[22] will be used to compare the rate of the primary and secondary outcomes between the study groups controlling for the stratification variables. The level of statistical significance for the analysis will be $p<0.05$ (two sided). Odds ratios and 95% confidence intervals, adjusted for the effect of clustering, will be calculated to determine the magnitude of any differences in outcomes between the trial arms.

This study is not expected to carry any risk neither to the women, nor at hospital level, thus will no formal interim analysis be performed.

ETHICAL APPROVAL AND CONSENT

This study has received ethical approval from the Ethical Committees at Ghent University, Belgium on 26 May 2014 (B670201421116) and National Research Institute for Family Planning, China (6 March 2014). The individual participant consent will be provided in Chinese and sought in all cases.

Trial Monitoring (Roles and Responsibilities)

Trial implementation and organization

Trial Steering Committee (TSC)

The trial Steering Committee comprises the INPAC project management team (PMT):
ICRH-UG, Belgium: Marleen Temmerman, Wei-Hong Zhang; CMA-CSFP, Beijing, China: Jian Li; FU, Shanghai, China: Xu Qian; NRIFP, Beijing, China: Shangchun Wu; SCU, China: Lina Hu; AU-DESC, Aarhus, Denmark: Jørn Olsen; LSTM, Liverpool, United Kingdom: Rachel Tolhurst.

The specific tasks of the Steering Committee will be the following:

- To approve the main study protocol
- To approve necessary changes in the protocol based on considerations of feasibility and practicability
- To resolve problems brought to it by the NCo team
- To approve study reports and papers for publication
- To ensuringthe implementation in compliance with the protocol

National Co-ordination (NCo)

The trial will be managed by CMA-CSFP team.

The responsibilities of NCo include the following:

- Identification of the eligible hospital listings
- Recruitment of participating hospitals
- Where relevant translation of the protocol and the other appropriate document into local language(s)
- Distribution and supply of data collection forms and other appropriate trial documentations to the provincial coordinators
- Field visits for monitoring the study progress and data collection process
- Data collection (via the provincial co-ordinations) and management
- Data entry except where provincial/hospital team prefer to transfer the electronic data and data cleaning

Provincial Co-ordination (PCo)

The responsibilities of PCo include the following:

- Recruitment of participating centres
- Distribution and supply of data collection forms to each hospital and other appropriate trial documentations
- Link between NCo and HCoData collection and cleaning and quality control

Hospital Co-ordination (HCo)

A local medical doctor and/or a local midwife/nurse or 1-2 medical doctors will be appointed as co-ordinator(s) in each participating hospital by NCo.

The responsibilities of the HCos will be the following:

- Data collection at the four time points and be the first line of data quality control
- Be familiar with the trial
- Liaise with the National/provincial Co-ordinating centre
- Ensure that all staff involved in the study are informed about the trial
- Ensure that supplies of data collection forms are always available, that they are correctly completed and returned to the National Co-ordinating centre timely, and to deal with any queries arising
- Facilitate other aspects of local collaboration as appropriate
- Make all data available for verification, audit and inspection purposes as necessary
- Ensure that the confidentiality of all information about trial participants is respected by all persons

AUTHORS' CONTRIBUTION

All the authors contributed. MT is the consortium coordinator and secured funding. WHZ is INPAC project leader and led on the study conception and design with the contributions from all co-authors. JO and JL are responsible for randomization procedure. SCW made contributions on ethical approval. The initial drafts of the manuscript was developed by WHZ, substantial revisions were made by JL. All authors read and approved the final manuscript.

TRIAL STATUS

This is ongoing trial and the data quality control is ongoing at the time of manuscript submission.

FUNDING

The study is supported by the European Commission FP7 -Health. 2011.3.4-1. Grant agreement No: 282490.

COMPETING INTERESTS

We declare that we have no conflicts of interest.

ACKNOWLEDGEMENTS

We thank the all members of INPAC's group, Scientific Advisor Board, Policy Advisor Board, Ethical Advisor Board and provincial and hospital coordinators who involved in this study.We thank the members of the Department of Reproductive Health and Research, World Health Organization (WHO) for their scientific advice.

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