

Integrating post-abortion family planning services into China's existing abortion services in hospital settings

Submission date 02/09/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/10/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/05/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Women who repeatedly have abortions are at high risk of long-term physical and psychological harm, and this can result in heavy economic and social costs. In China, there are a large number of abortions primarily due to the lack, or failure of, contraception. Here, we want to integrate post-abortion family planning (FP) services with existing abortion services offered by hospitals in China and to see whether it results in fewer unintended pregnancies and repeated abortions.

Who can participate?

Hospitals in mainland China offering abortion services and that carry out an average of 200-800 abortions a month.

What does the study involve?

The hospitals are randomly allocated into one of three groups. Two of these groups are intervention groups. Relevant personnel at these hospitals are trained to provide individual counselling (both before and after abortion), offer modern contraceptive methods, follow up counselling and educational materials. The hospitals in the control group offer their normal abortion services. A total of 18,000 women seeking abortion take part in the study and are treated according to whether they are in a intervention group or control group hospital. They are all asked to complete questionnaire surveys before their abortion, after their abortion, 1 month later and then 6 months later. At the end of the study, we will look at how well the intervention performs using both quantitative and qualitative methods.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part, but there should be benefits for the future. The project will contribute to standardizing the post-abortion family planning services and to reducing the long-term costs related to abortion in China. The results of this research will also be of interest to other countries with high abortion rates. The participants do benefit from free access to contraception and guidance services , free information materials on post-abortion care and contraception and free contraceptives.

Where is the study run from?
Hospitals in mainland China.

When is study starting and how long is it expected to run for?
September 2014 to May 2015.

Who is funding the study?
European Commission (EC) under the Seventh Framework Programme (FP7) (Belgium)

Who is the main contact?
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Study website
<http://www.inpacproject.eu>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effect of Post-Abortion Family Planning services on contraceptive practices in China: a cluster randomized controlled trial

Acronym

INPAC

Study objectives

The integrating of post abortion family planning intervention packages might increase the contraceptive use after abortion, and reduce the rates of unintended pregnancy and repeated abortions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee of University Hospital Ghent (ETHISCH COMITE Universitair Ziekenhuis, University Ghent); ref. B670201215002
2. Ethics Committee of National Research Institute for Family Planning, China; Ref. No.3 of 2014

Study design

Four-year open randomized controlled three-arm multi-site trial where the unit of randomization is the hospital

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Post-abortion contraception (or post-abortion family planning) services

Interventions

The trial is conducted in mainland China. There are two intervention groups and one control group (each 30 hospitals) allocated randomly.

Intervention package:

1. Training of service providers and managers
2. Providing relevant Information, Education and Communication (IEC) to women and their partners by abortion service providers
3. Providing individual counselling to women (and their partners) at pre- and post abortion by

abortion service providers

4. Offering modern contraceptive methods to the women immediately after the abortion
5. Continuous PAFP service/follow-up counselling
6. Incentive mechanism to service providers

The control group will keep the normal services without any project interventions.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Unintended pregnancies including clinical or self-reported at the time of follow-up interviews
2. Repeat induced abortions 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, sterilization (male/female) during follow-up period

Measured using both quantitative and qualitative methods.

Secondary outcome measures

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 periods
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

Overall study start date

01/08/2013

Completion date

31/12/2016

Eligibility

Key inclusion criteria

Hospital inclusion criteria was identified according to the situation analysis findings and Chinas current hospital settings:

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

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):

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

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

90 hospitals, 18,000 women

Total final enrolment

17235

Key exclusion criteria

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

Exclusion criteria for women:

1. Intention to become pregnant during the study

Date of first enrolment

01/07/2014

Date of final enrolment

28/02/2016

Locations**Countries of recruitment**

Belgium

China

Study participating centre

International Centre for Reproductive Health

Ghent

Belgium

9000

Sponsor information

Organisation

European Commission Seventh Framework (EC FP7) (Belgium)

Sponsor details

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Sponsor type

Government

Website

<http://ec.europa.eu/research/index.cfm>

ROR

<https://ror.org/00k4n6c32>

Funder(s)

Funder type

Government

Funder Name

European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκή Επιτροπή, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiripas Komisiju, Europos Komisijos, Európai Bizottságrol, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

Planned dissemination of findings at national and international levels by participating in the scientific conferences and workshops and submit manuscript for publication in a high-impact peer reviewed journal.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to ongoing data clean and analysis.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/12/2017	10/05/2021	No	No
Protocol article			10/05/2021	Yes	No