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Title and Additional Identifiers

Submission number
38043

ISRCTN

DOI

Public title
Caesarean section or vaginal birth: Making an informed choice

Scientific title
Appropriate use of caesarean section through quality decision-making by women and providers

Acronym
QUALI-DEC

EudraCT number
Nil known

ClinicalTrials.gov number
Nil known

Protocol /serial number
847567

Condition category
Pregnancy and Childbirth

Date Applied
16/03/2020

Date Assigned

Last Edited
19/03/2020

Prospective/Retrospective

Overall Trial Status
Ongoing

Recruitment status

Not yet recruiting

Study Information

Study hypothesis
Our theorical framework highlights the concept that the four mutually reinforcing components of the multi-faceted intervention participate in promoting best practices and reducing unnecessary caesarean sections (C-sections).

Ethics approval
We have yet submitted the research protocol for Ethics approval to the Ethics Advisory Board for Research in Partnership of the French Research Institute for sustainable development (IRD), The Research Project Review Panel of the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP) and the Ethical Review Committee of the World Health Organization (WHO. In addition, for this multi-country studies, we have also submitted the research protocol to all Research Institutions of the country-partners: Argentine, Burkina Faso, Thailand and Vietnam.

Study design
Multi-site non-randomized hybrid effectiveness-implementation type III trial

Primary study design
Interventional

Secondary study design
Non randomised study

Trial setting
Hospitals

Trial type
Other

Overall trial start date
01/01/2020

Overall trial end date
31/12/2024

Overall trial status override

Reason abandoned (if study stopped)

Condition
Perinatal care

Interventions
Non-clinical interventions targeted simultaneously at clinicians, women and health organizations to reduce unnecessary C-sections in Argentina, Burkina Faso, Thailand and Vietnam. The QUALI-DEC strategy is designed to combine four key active ingredients:

1. Opinion leaders to implement evidence-based clinical guidelines
2. Caesarean audits and feedback to help providers identify potentially avoidable C-sections
3. A Decision-Analysis-Tool to help women make an informed decision on mode of delivery
4. Implementation of WHO recommendations on companionship during labour to support women during vaginal birth

The study will be conducted in 32 heathcare facilities (8 per country) with high C-section rates for the country, selected purposely with the Ministries of Health of Argentina, Burkina Faso, Thailand and Vietnam. We have selected hospitals to reflect the range of contexts in each country, such as district hospitals, regional or provincial hospitals, private clinics and tertiary/ academic hospitals. Centres have been included on the basis of formal, informed consent on the part of the hospital director and the person in charge of maternity services.
Health professionals involved in obstetric care in the various participating hospitals will be included in the study. We have defined health professionals as obstetricians and nurses/ midwives working on the maternity ward in the study facilities, and administrators as those working as managers on the maternity ward or health facility (e.g.: medical/clinical director, head of obstetrics, matron-in-charge).
All women who will be admitted to deliver in any participating facility during the study period will be included in the study. We have defined delivery as the birth of infant weighing ≥500 g or ≥ 22 weeks (≥1000 g in Burkina Faso and Thailand), alive or dead, with or without malformations, by any route.

Each country-level partner in Argentina, Burkina Faso, Thailand and Vietnam will implement the four components of the QUALI-DEC strategy in participating hospitals, with the support of European partners for capacity building.

Component 1 - Opinion leaders:
The intervention will start with the identification of one opinion leader (OL) in each participating hospital. OLs will be gynaecologists-obstetricians identified by their local authorities with reputable influence on their colleagues. The OLs will take part in a 5-day training session at the beginning of the implementation period. This training will include one day training for each of the following topics:
1. Use of evidence-based clinical guidelines for appropriate management of labour and birth
2. Implementation of the Ten Groups Classification System (TGCS)
3. Caesarean audit techniques
4. Use of the Decision-analysis-Tool (DAT)
5. Implementation of continuous companionship during labour
After the initial training, OLs will create local audit committes, launch the TGCS and caesarean audit, and encourage the use of the DAT and companionship during labour in their own hospitals. OLs will undergo a refresher 3-day training session during the 2-year intervention period. The aim of this session is to refresh OLs' knowledge, update them on the use of evidence-based clinical guidelines and process of the intervention, discuss their roles, share their experiences and confirm their capacity to provide leadership in their clinical settings.

Component 2 - Audit & feedback:
The process goes through the analysis of medical practices by the practitioners themselves (doctors) and advice either if the decision for C-section was appropriate or not, according to evidence-based clinical guidelines. The audit concerns several medical records, and as an output, provides a conclusive analysis presented to the rest of the medical staff (feedback). After the initial training of OLs, five 3-month audit cycles will be implemented by the local audit committees, with the support of a country-level coordinator and data manager who will make quarterly educational outreach visits. The audit committee is composed of the most involved

doctors into the experiment, led by a team leader (opinion leader).
Each cycle includes six standardized steps:
1. Data collection for the TGCS for all women delivering in the participating hospital in a given time period
2. Identification of selected medical records of lower-risk women (Categories 1 through 4 of the TGCS) who delivered by C-section for audit review
3. Extraction of data from routine medical records for women included in the audit, with the use of standardized forms (including the indication for C-section, and management of these women during labour and delivery)
4. Assessment of the relevance of indications for C-section by the local audit committee, with a focus on planned C-section and C-section during labour for fetal distress and labour dystocia to identify avoidable factors
5. Formulation of recommendations for best practices and the evaluation of previous recommendations, both performed by the committee
6. Web-based provision of formal written feedback to health professionals (maternity dashboard and recommendations)

Component 3 - Decision-analysis Tool (DAT):
The DAT booklet was developed for the QUALI-DEC strategy and has already been tested in Vietnam. It includes two sections: (i) an Information section, providing a description and an explanation of the risks and benefits of each option (planned vaginal birth vs planned C-section); and (ii) an Exercise section, allowing women to clarify and summarize their values and preferences with their physician and indicate what aspects of mode of delivery are important to them. The DAT will be tailored to each country following the assessment of the societal context in the baseline period and tested among a sample of 20-25 pregnant women. After initial training , OLs will encourage clinicians in their hospital to provide the DAT booklet to eligible patients during their initial booking visit at the antenatal clinic, between 34-36 weeks' gestation.
Women eligible for the DAT are those without contraindication to vaginal birth, and who receive antenatal care in participating facilities. They will be informed by their provider of the aim of the DAT booklet, how to use it, and they will be encouraged to discuss their values when they attend the clinic at 36-38 weeks to finalize their birth plan.

Component 4 - Companionship during labour:
In 2018 the WHO published recommendations on intrapartum care for a positive childbirth experience which include a recommendation for companionship during labour and childbirth. This recommendation is based on a Cochrane systematic review of 27 randomized controlled trials. Continuous support was defined slightly differently in different trials, but usually meant women were accompanied at least during the active stage of labour. The companions in different trials varied: sometimes labour companions (such as doulas) provided support while in other trials a female relative or husband was present throughout labour. These differences of acceptation of companionship will be considered through a gender dimension in each context.
The QUALI-DEC project will support the use of any type of culturally appropriate companion, including partners and non-clinician professionals. According to WHO recommendations, each country lead partner will follow different steps in a process to introduce companionship into existing organization of care: first, planning and advocacy activities will be conducted to engage stakeholders in the study hospitals. We will then carry out a situation analysis to describe the institutional, policy and societal context in the baseline period regarding current practices of companionship during labour in each study hospital, identifying differences between WHO recommendations and practices, as well as programmatic opportunities to introduce or strengthen opportunities for companionship during labour. Third, results from the situational analysis will inform the adaptation of WHO guidelines to each study country, taking into account health system factors (such as provider capacity and resources in the maternity unit), legal and

policy contect (such as who is permitted to be present on the labour ward), existing programmes, and women and men's preferences. Adapted guidelines will be translated into relevant local languages. Lastly, the audit committee in each study hospital will be responsible for implementing country-specific guidelines in their maternity unit: in some facilities, implementation of companionship during labour may require significant changes in service delivery, such as allowing the presence of companions in delivery rooms, or new supplies or amenities, (for example, providing screens to ensure privacy for women and their companions). The local audit committee will be responsible for making hospital-specific recommendations for changes to enable women to have a birth companion if they choose. In this process, the assessment of institutional context and the role of national professional associations (gynecologists-obstetricians and midwives) will be critical.

Using document review and individual in-depth interviews (IDIs) with health professionals, women and potential companions, we will assess the feasibility, the fidelity, the acceptability and the scalability of the intervention. The feasibility of the intervention is the extent to which the four components of the intervention can be carried out in participating hospitals. The fidelity of the intervention is the degree to which the four components will implemented as it was designed in this original protocol. The acceptability is the perception among key stakeholders (women, companions, health care providers) that each component of the intervention is agreeable. Scalability will be measured using a checklist of critical factors facilitating scale up and which is structured in four sections, namely: attributes of the innovation; attributes of the implementers; attributes of the potential adopting organisations or communities; and socio-political context.

The starting point will be a document review of existing clinical protocols at the sites during baseline (pre-intervention) period. The document review will be conducted using a structured approach in order to ensure that important guidelines will not be omitted or overlooked. Information will be obtained from several different sources, such as reviewing policy documents in each country and meetings with opinion leaders and healthcare professionals in the hospitals as necessary.

We will conduct IDIs with health professionals during the baseline period and at the end of the intervention period.
1. IDIs with health professionals at baseline: The study instrument for IDIs with health professionals will be a semi-structured interview guide to investigate aspects of professional preferences, views on C-sections and vaginal births, and views on the role of women in the decision-making process.
2. IDIs with health professionals at the end of the intervention period: We will use a semi-structured interview guide covering the following topics: Communication; Inter-professional interaction; and Decision-making including aspects of position/seniority, gender weighing of alternatives and their implications, and information-sharing.

We will conduct IDIs with pregnant women and potential companions at baseline period and with post-partum women and their companions at the end of the intervention period. In the appropriate area of the health facility (e.g patient rooms), informational materials in appropriate local language(s) containing information about the study, eligible participants, and how to participate will be displayed. Female researchers will be on site to facilitate recruitment, and will not be involved in clinical care of the patient. The language used in informed consent forms will be easy to understand and free of technical jargon. Participants will be given sufficient time to reflect on the information and ask questions. Women will facilitate contact with companions, and researchers will follow up to schedule interviews. The study instruments will be different according to the time of interviews and the individuals.

1. IDIs with pregnant women and their potential companions. The study instrument will be a semi-structured interview guide covering the following topics: perceptions, preferences, and decision-making processes for mode of childbirth; perceived risks and benefits with different modes of childbirth; values and needs surrounding the childbirth period; fears related to pregnancy and childbirth; and preferences and perceptions about labour companionship. We will adapt the study instrument for pregnant women to be suitable for partners or potential companion.
2. IDIs with women and companions during post-partum period: The study instrument will be a semi-structured interview guide covering the following topics: decision-making process including aspects interactions with provider, companionship, gender and family influence on weighing of alternative modes of delivery and their implications; perception of self-esteem, knowledge and empowerment about decision-making during pregnancy and childbirth; perceptions and experience of support during childbirth including labour companionship; satisfaction with the birth experience including interactions with providers and facility environment.

Safety and effectiveness outcomes : Using questionnaires to post-partum women at two time points (month 6 and month 30 of trial period), we will assess maternal and perinatal morbidity and satisfication with birth.

The same procedure described above will be used to inform and recruit women in post-partum period. Pregnant adolescents will be provided with the patient information sheet and asked to provide their assent to participate; if assent is provided, we will obtain informed consent from their legal representative. It is ethical to involve pregnant teenagers in this study since they will be subject to only minimal risk and burden, and the results of the research will be of particular benefit to pregnant adolescents, who may suffer from especially limited agency in making choices for their care during pregnancy and childbirth, and may therefore particularly benefit from the Decision-Analysis Tool.

In the event of a stillborn child or a child with malformation, or when it is not possible to solicit the woman to participate (for example, in the event of major health problems), a minimum collection of indicators will be provided from the medical file, on a specific page of the questionnaire. These indicators correspond to the health status of children and medical practices at the time of birth. If a woman could not or refused to participate in the interview, the investigator will ask her if she would accept the collection of data from her medical file. In the event of refusal, only the minimum collection of the indicators will be carried out, in accordance with the authorization issued by the ethic committee of participating country and by local authority.

The data collection includes a face-to-face interview with women after childbirth and a collection of information from their medical records. All questionnaires will not allow any identification of the women in the computer file. The socio-demographic characteristics of the mothers, satisfaction with birth experience, the formal and informal direct payment for medical care, direct non-medical costs (i.e. transportation costs to seek care), and indirect costs (i.e. time and productivity losses, which can be translated into wages and income foregone), and the description of prenatal care (including use of the DAT) and intrapartum care (including companionship) will be obtained during the interview with the women before they leave the maternity ward. Data on pregnancy complications, childbirth and the health status of mother and child at birth will be collected from the medical records.

The study will also involve a cost-effectiveness analysis, including the incremental cost-effectiveness ratio (the net costs per one reduction in C-sections among lower-risk women), women’s out-of-pocket expenditures averted, and household medical impoverishment averted

by the QUALI-DEC strategy. This includes two metrics: cases of catastrophic health costs averted (estimating the number of individuals no longer crossing a 'catastrophic' threshold of income (e.g ., 10, 20, 40 % of income) as a result of the costs incurred), and number of cases of poverty averted (estimating the number of individuals no longer crossing a given 'poverty line' as a result of the costs faced.

Intervention Type
Behavioural

Phase

Drug name(s)

Primary outcome measure
Monthly C-section rate in participating hospitals among lower-risk women with no previous C-section with singleton pregnancy, with the foetus in cephalic presentation, and that has reached at least 37 weeks' gestation (Groups 1-4 of the Robson classification) in the 6 months before and the 48 months after the start of the intervention

Secondary outcome measures
1. Feasibility of the intervention assessed using document review and individual in-depth interviews with health professionals, women and potential companions during the baseline period and at the end of the intervention period
2. Fidelity of the intervention assessed using document review and individual in-depth interviews with health professionals, women and potential companions during the baseline period and at the end of the intervention period
3. Acceptability of the intervention assessed using document review and individual in-depth interviews with health professionals, women and potential companions during the baseline period and at the end of the intervention period
4. Scalability of the intervention assessed using document review and individual in-depth interviews with health professionals, women and potential companions during the baseline period and at the end of the intervention period
5. Maternal morbidity assessed using a questionnaire to post-partum mothers at months 6 and 30 of the study or from medical records
6. Perinatal morbidity assessed using a questionnaire to post-partum mothers at months 6 and 30 of the study or from medical records
7. Mother's satisfaction with the birth assessed using a questionnaire filled during the interview with post-partum women before they leave the maternity ward at months 6 and 30 of the study
8. Payment for medical care assessed using a questionnaire filled during the interview with post-partum women before they leave the maternity ward at months 6 and 30 of the study
9. Indirect costs of care for childbirth (e.g. cost of transportation to hospital) assessed using a questionnaire filled during the interview with post-partum women before they leave the maternity ward at months 6 and 30 of the study
10. Loss of earnings assessed using a questionnaire filled during the interview with post-partum women before they leave the maternity ward at months 6 and 30 of the study
11. Description of prenatal care (including use of the DAT) assessed using a questionnaire filled during the interview with post-partum women before they leave the maternity ward at months 6 and 30 of the study
12. Description of intrapartum care (including companionship) assessed using a questionnaire

filled during the interview with post-partum women before they leave the maternity ward at months 6 and 30 of the study
13. Pregnancy complications assessed using medical records at months 6 and 30 of the study
14. Childbirth complications assessed using medical records at months 6 and 30 of the study
15. Health status of mother at birth assessed using medical records at months 6 and 30 of the study
16. Health status of child at birth assessed using medical records at months 6 and 30 of the study

Trial website
https://www.qualidec.com

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Eligibility

Participant inclusion criteria
Healthcare professionals:
1. Involved in obstetric care in the various participating hospitals. Health professionals have been defined as as obstetricians and nurses/midwives working on the maternity ward in the study facilities, and administrators as those working as managers on the maternity ward or health facility (e.g. medical/clinical director, head of obstetrics, matron-in-charge).

Patients:
1. All women who are admitted to deliver in any participating facility during the study period. Delivery is defined as the birth of infant weighing ≥500 g or ≥22 weeks (≥1000 g in Burkina Faso and Thailand), alive or dead, with or without malformations, by any route.

Participant type
Mixed

Age group
Adult

Gender
Both

Target number of participants
852,905 women who will be admitted to deliver in any participating facility during the study period. Among these women, 3280 will be interviewed during postpartum period at the beginning and at the end of the intervention period. Furthermore, 96-192 individual in-depth interviews (3-6 IDIs per hospital) with will be conducted in each participating facility with women and companions during post-partum period.). Additionally, 96-192 individual interviews with health care professionals (3-6 per facility) will be performed.

Total final Enrolment

Participant exclusion criteria

1. Women admitted to participating hospitals for abortions or miscarriages
2. Women who delivered at home or in another centre with postnatal transfer

Recruitment start date
01/07/2020

Recruitment end date
30/06/2024

Recruitment status override

Locations

Countries of recruitment
Argentina
Burkina Faso
Thailand
Viet Nam

Trial participating centres

Trial Centre

Trial Centre Name
Centro Rosarino de Estudios Perinatales

Address
Mariano Moreno 878

City
Rosario

Country
Argentina

Zip
S2000DKR

Trial Centre

Trial Centre Name
Institut de Recherche en Sciences de la Santé

Address
Rue 29.39 Porte 74

City
Ouagadougou

Country
Burkina Faso

Zip
03 BP 145

Trial Centre

Trial Centre Name
Khon Kaen University

Address
123 Mittrappa Road
Nai-Muang
Muang District

City
Khon Kaen

Country
Thailand

Zip
40002

Trial Centre

Trial Centre Name
Pham Ngoc Thach University

Address
2 Dương Quang Trung
Phưng 12
Qun 10

City
H Chí Minh

Country
Viet Nam

Zip
70000

Plain English Summary

Background and study aims
Unnecessary use of caesarean sections (C-sections) in low- and middle income-countries (LMIC) uses limited healthcare resources and reduces access to healthcare for other people in need. The aim of this research to design, adapt and test a strategy to reduce unnecessary C-sections and reach appropriate use in four countries: Argentina, Burkina Faso, Thailand and Vietnam. The objective of this strategy is to improve quality decision-making for type of birth, so that only those women who need to have a C-section have one. The strategy will involve women, healthcare professionals and organizations involved and will focus on how to best and most effectively implement it taking into account the local needs and resources in each country.

Who can participate?
Women attending prenatal care and admitted to deliver in any participating health centre during the study period and health professionals involved in obstetric care in the various participating hospitals.

What does the study involve?
Selected healthcare professionals in participating hospitals will receive training in best practice. These professionals will then create, in their own centres, obstetric teams who will implement the intervention with the support of external facilitators. There are four aspects to this. Local opinion leaders will be identified and will then create evidence-based guidelines for when a C-section is required. There will be caesarean audits and feedback to help providers identify target groups and strategies for safely reducing unnecessary C-sections. The teams will create user-friendly booklet to act as a an information source and decision tool to help women make an informed decision on whether to have a vaginal birth or C-section. They will also encourage companions (such as a doula, relative or partner) to support women during labour and vaginal birth.

What are the possible benefits and risks of participating?
Pregnant women will benefit from the decision tool, which can help them to become more informed and active in their care and may also reduce the likelihood of healthcare workers' preferences dictating their care pathway. Women in labour will benefit from the support of a companion who can enhance their feelings of control and competence, which might reduce their reliance on medical resources.
Healthcare professionals will receive feedback from the audit on caesarean section and will be able to change their practice and clinical management in response to the feedback, with the support of local opinion leaders. Healthcare professionals will also benefit from the labour companion intervention, as the labour companion will help them to better support women. They will also benefit from the decision tool as it will help them to discuss and clarify women’s perspectives and preferences on the mode of birth.
The researchers do not anticipate that the decision tool or companionship during labour will have any associated risks for women.
Potential risks to hospital participation in the clinical audits (including psychological risks through potential blame) will be minimised by emphasising that audits are instruments for learning and their objective is not to identify individuals responsible (for example, for an unnecessary caesarean) but to identify parts of the system which may be improved to minimise the chance of unnecessary C-section in future. This will be further reinforced during in-country supervision visits of participating facilities.

Where is the study run from?
Institut de Recherche pour le Développement [Development Research Institute] (France)

When is the study starting and how long is it expected to run for?

January 2020 to December 2024

Who is funding the study?
European Commission (EU) and UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction

Who is the main contact?
Alexandre Dumont, alexandre.dumont@ird.fr

Results and Publications

Publication and dissemination plan

The following publications are expected:
1. The research protocol is intended to be published in June 2020.
2. The formative research presenting the findings from the baseline document review, readiness assessment and interviews with women, healthcare providers and administrators is intended to be published in December 2020.
3. The feasibility outcomes are expected to be published in December 2022.
4. The safety and efficacy outcomes are expected to be published in December 2024.
5. The cost-effectiveness analysis is expected to be published in December 2024.

IPD sharing statement:
Datasets generated during the current study will be stored in a publically available repository: qualidec.com.

Several types of data will be generated, including aggregate-level quantitative data, individual-level quantitative data, qualitative data, and documents. Quantitative data will be entered into databases, while documents and qualitative data will be stored in PDF/word or audio recording format. Novel deliverables will also be generated during the project, including newly developed clinical guidelines, training materials, films and animations, as well as dissemination outputs such as policy briefs and peer-reviewed articles.

A key proposal of our plan is to create an online platform accessible to study liaisons in each hospital to contribute their data. Ease of data entry will be optimised by providing each hospital liaison with a unique identifier linked to hospital information, and by creating an online form for entering a limited number of fields (number of vaginal and caesarean deliveries across the 10 Robson groups). Once entered, the data will be used to automatically generate a maternity dashboard showing the distribution of women across Robson groups, the caesarean rate in each group and the contribution of each group to the overall caesarean rate. These indicators will be added to month-by-month graphs of process and outcome indicators for the hospital, and will enable convenient tracking of trends over time and comparison with anonymised facilities in the four study countries. Other quantitative data collected on paper forms will be entered into a database.

We will make the online platform of monthly hospital summary statistics accessible to people outside of the study team after the end of the project, with interactive graphs allowing for filtering according to geographic area, time or facility type. Health facility managers will further be able to voluntarily contribute data from their facilities using the same standardised online forms used during the project, thereby contributing to creating an online repository of key facility statistics on caesareans across the world (including overall caesarean rate, distribution of women and caesarean rate across Robson groups, and maternal and perinatal outcomes where

available). Health facility managers and policy-makers will be able to easily visualise how their facilities compare to others in the same geographical area or facility level. Automated email reminders will prompt participants to upload data each month.

We also aim to create an online repository of clinical guidelines relating to caesarean section decision-making (including protocols and algorithms) at country and facility level, for both participating and non-participating countries and facilities. There are no standardised, agreed upon clinical guidelines for decision-making on caesarean sections before or during labour, and existing protocols have not been collated. Policy-makers and facility managers will be able to compare protocols across different settings and view the Decision-Analysis Tool for women adapted for each study country, stimulating innovation and cross-fertilisation for improving care at birth.

More information on the types and sources of data, potential users and uses of each type of data have been summarised in a table. Please contact the study team for more information.

Intention to publish date
31/12/2024

Participant level data
Stored in repository

Basic results (scientific)

Results (plain English)

Publication list

Publication citation(s)

Contact(s)

Contact

Type
Public

Title
Dr

Name
Alexandre Dumont

ORCID ID
https://orcid.org/0000-0003-3826-0193

Address
45 rue des Saints Pères

City
Paris

Country
France

Zip
75006

Tel
+33 (0)176533464

Email
alexandre.dumont@ird.fr

Privacy
Public

Sponsor(s)

Sponsor

Organisation
Institut de Recherche pour le Développement

Address
44 Boulevard de Dunkerque

City
Marseilles

Country
France

Zip
CS 900009

Tel
+33 491999232

Email
laurence.lombard@ird.fr

Type
Research organisation

Website
https://www.ird.fr

Privacy
Public

Funder(s)

Funding Type
Not defined

Funder

Funder Name
European Commission

Alternative Name(s)
European Union EU EC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder

Funder Name
UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

Alternative Name(s)

Funding Body Type

Funding Body Subtype

Location

Applicant Details

Name
Alexandre Dumont

ORCID ID

Address

City

Country

Zip

Tel

Email
alexandre.dumont@ird.fr

Payment Method

Payment method
Offline payment

Trusted funder

Invoice Details

Name
Suzanne Koublanou

Institution
IRD Bondy

Address
32 Avenue Henri Varagnat

City
Bondy Cedex

State

Country
France

Zip
93143

Email
Suzanne.koublanou@ird.fr

Purchase order/ reference number
18000602500027

VAT number
FR75180006025

Why did you choose ISRCTN to register your trial?
Funding agency policy