





International Survey of

Childbirth-Related Trauma

Protocol



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**FUNDER:** City University Global Challenges Research Fund

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**COORDINATION CENTRE:** City, University of London, School of Health Sciences

**Ethical approval reference:**

**Ethical committee:** School of Health Sciences, City University

London

**Protocol authorised by:**

|  |  |  |
| --- | --- | --- |
| **Name & Role** | **Date** | **Signature** |
| Prof Susan AyersChief Investigator | 10/12/2020 |  |

# Key Contacts


## Project Management Group

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## Sponsor

City University London is the main research sponsor for this project. For further information regarding the sponsorship conditions, please contact insurance@city.ac.uk.

This protocol describes a project aimed at studying childbirth-related PTSD in an international context. This study involves researchers from various location around the world. The protocol provides information about procedures for recruiting women and carrying out the evaluation. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the project. Problems relating to this project should be referred, in the first instance, to the Chief Investigator.

This project will adhere to the principles outlined in the the Declaration of Helsinki for medical research involving human subjects. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

## Protocol Amendments

|  |  |  |  |
| --- | --- | --- | --- |
| Date | Version | Summary of amendments | Approved |
| 19.02.24 | 2.0 | Updated to reflect data collection for second release of the dataset (R2) in 2025/26. |  |
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# Project Summary

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| **TITLE** | International Survey of Childbirth-related Trauma (INTERSECT) |
| **ABSTRACT** | Being pregnant and having a baby is a time of huge physiological, psychological and social change for women. Although the birth of a baby is viewed positively in nearly all cultures, research suggests between 20 and 40% of women find childbirth psychologically traumatic. Some of these women go on to develop post-traumatic stress disorder (PTSD) as a result. Prevalence rates of PTSD after birth have yet to be established in Lower-Middle Income Countries (LMIC) and variation in experiences of birth trauma and the expression of PTSD between countries and cultures has yet to be explored. Therefore, INTERSECT aims to:1. Determine the prevalence of birth trauma and PTSD across countries.
2. Determine differences in symptom presentation across countries.
3. Determine risk factors for childbirth-related PTSD symptoms across countries.

This will be done through a cross-sectional survey of women 6-12 weeks postpartum. Principal investigators in each country will be responsible for:* **Translating the measures included in the INTERSECT survey -**  These include measures of adverse childhood experiences, obstetric details, birth satisfaction, birth trauma, PTSD and depression. Researchers in each location will be free to add other measures or follow-ups as needed.
* **Recruiting women** – PIs should aim to recruit a minimum of 250 women
* **Distributing the survey** – this can be done in person, over the phone or online depending on each locations sampling conditions
* **Uploading data to the project database**

International PIs will be authors on cross-country research outputs that include their data. Other international collaborators will be included as part of the ‘INTERSECT Consortium’. |
| **DESIGN** | Cross sectional survey |
| **AIMS** | This research aims to study birth trauma and PTSD in an international context. Specific aims are: 1. Determine the prevalence of birth trauma and PTSD across countries.
2. Determine differences in symptom presentation across countries.
3. Determine risk factors for childbirth-related PTSD symptoms across countries.
 |
| **POPULATION** | Women 6-12 weeks postpartum |
| **ELIGIBILITY** | Women are eligible if they are aged 16 or over, had a baby in the previous 6-12 weeks and provide informed consent.  |
| **duration** | Release 1 of the dataset was conducted from 2021 to 2024. For Release 2 of the dataset, we aim to complete recruitment by 31 June 2026 and data linkage and release by 31 December 2026. Researchers in different locations may recruit and follow up differently according to their IRB approval (given that they adhere to the basic research plan and do not change measures or inclusion criteria). |

# INTRODUCTION

Being pregnant and having a baby is a time of huge physiological, psychological and social change for women. It is therefore a period of rapid transition and adaptation. Although the birth of a baby is viewed positively in nearly all cultures, research suggests between 20 and 40% of women find childbirth psychologically traumatic (1–4).Some of these women go on to develop post-traumatic stress disorder (PTSD) as a result. Meta-analyses suggest 3-4% of women develop childbirth-related PTSD (5,6) with clinically significant PTSD symptoms observed in up to 16.8% of women (7).Birth trauma and PTSD have a substantial impact on women and their families. Posptartum PTSD is highly comorbid with depression and fear of subsequent births (8), as well as reduced breastfeeding (9,10), poorer child development (11) and strain on the couples relationship (12).

**Global prevalence of postpartum PTSD**

Worldwide there are over 130 million births every year (13). A prevalence rate of 3% therefore means around 3.9 million women develop postpartum PTSD every year as a result of childbirth. However, most research on birth trauma and PTSD prevalence has been conducted in high-income countries (HIC) with good access to maternity care such as the UK, Australia, USA and European countries. Research on postpartum PTSD in low- or middle-income countries (LMIC) is sparse but the studies that are available generally find higher prevalence rates of postpartum PTSD of 6% in Nigeria (14),8-12% in Turkey (8,15),and 20-37% in Iran (16,17).Women in LMIC are also those most likely to have less access to maternity care, higher levels of socio-economic disadvantage and experience health inequalities. For example, research on postpartum anxiety and depression shows more women are affected in LMIC (18) and associated with poorer outcomes for the mother and infant (19).

It is therefore important to obtain information about the prevalence of postpartum PTSD and comorbid depression in LMIC. Valid data on the prevalence of birth-related PTSD across the globe are important for many reasons. Clinically, it is important to know the true extent of postpartum PTSD to raise awareness and provide appropriate interventions. Economically and politically, accurate estimates of prevalence enable researchers and policy makers to balance the cost of prevention and treatment against the public health consequences. Precise estimates of the prevalence of perinatal PTSD across different countries are therefore a scientific imperative (8).

It is also important to examine cultural variation in experiences of birth trauma and the expression of PTSD. Culture is a complex factor that refers to a “*group’s thoughts, experiences, and patterns of behaviour and its concepts, values and assumptions about life that guide behaviour*” (Jandt, p. 6) (20). Culture varies both across countries and within countries, as it can be affected by factors such as race, religion, gender etc. The concept of PTSD has been criticised as being a culturally constructed syndrome, present predominately in industrialized countries of the 20th century (21). Cross-cultural research in non-postpartum populations suggests that the prevalence and symptoms of PTSD depend in part on cultural factors. For example, what is deemed as a traumatic event is partly cultural, symptoms shown by those with PTSD vary across different cultures, as do strategies to cope with such symptoms (22). Variability in symptom presentations shows there is a need for further research in relation to factors such as the relative salience of avoidance/numbing symptoms; the role of the interpretation of trauma‐caused symptoms in shaping symptomatology; and the prevalence of somatic symptoms (23)

**Etiology of birth trauma and PTSD**

Meta-analyses of factors associated with postpartum PTSD have identified a number of vulnerability and risk factors in pregnancy, birth, and postpartum (24). In pregnancy key vulnerability factors were depression in pregnancy, fear of childbirth, poor health or complications in pregnancy, a history of PTSD and counselling for pregnancy or birth. Key risk factors in birth were negative subjective birth experiences, having an operative birth (assisted vaginal or caesarean section), lack of support and dissociation. After birth, PTSD was associated with poor coping and stress, and was highly co-morbid with depression (24).All of these variables may affect women’s experiences of childbirth differently in different cultures and settings but, as outlined above, little research is available from LMIC countries so these findings may only be generalizable to North American, European and Australian populations.

As birth settings and maternity care around the world are very different, they are likely to affect women’s childbirth experiences differently. A recent meta-analysis looking at negative childbirth experiences found that risk and protective factors were notably different depending on the country, study design, and methodology employed (25).The main risk factors in this meta-analysis were during birth, such as emergency caesarean and high labor pain, and poor support. The main protective factors were also during birth, such as high perceived control during labour or satisfaction with support from their partner (25). All these factors may vary as a function of culture, and thus may be manifested differently in the etiology of childbirth experiences, birth trauma and PTSD.

**Assessing postpartum PTSD**

Despite its relatively high prevalence and potential disease burden, postpartum PTSD remains largely unrecognized in maternity services and, unlike depression, PTSD is not routinely screened for so women are unlikely to be identified and treated (26). One of the barriers to this was that until recently there was no validated measure for postpartum PTSD that followed recent DSM-5 diagnostic criteria (27). Research in this area typically used questionnaires developed for use with other groups, such as war veterans, which may not have been appropriate to use with postpartum women (26).

The City Birth Trauma Scale (26) was developed specifically to assess postpartum PTSD according to DSM-5 diagnostic criteria (27).This scale has/is being translated into multiple languages and shown consistently robust psychometric properties in samples from the UK, Israel, Croatia, Spain and USA (26,28–31). It therefore provides a promising method of assessing postpartum PTSD in cross-cultural research. A version is also available to assess birth trauma and PTSD in fathers/birth partners (32).

The current study therefore proposes to use the City BiTS to measure the prevalence, different manifestations and etiology of childbirth PTSD across the globe in culturally diverse samples from HIC and LMIC.

**The INTERSECT study**

This proposed INTERSECT study involves principal investigators (PIs) from different HIC and LMIC countries, with an emphasis on contacting researchers from under-represented countries in South-America, Asia and Africa. Each principal investigator will be responsible for translating the INTERSECT survey (where needed), having the study approved by their local research ethics board, and recruiting postpartum women in their country to complete the INTERSECT survey. This study will thus result in cross-cultural information on the prevalence of postpartum PTSD, as well as cross-cultural differences in the etiology and manifestation of childbirth-related PTSD worldwide.

# AIMS

This research aims to study childbirth PTSD in an international context. The aims of the first INTERSECT survey (i.e. INTERSECT 2024 V1) were to:

1. Determine the prevalence of birth trauma and PTSD across countries.
2. Determine differences in symptom presentation across countries.
3. Determine risk factors for childbirth-related PTSD symptoms across countries.

The second release of data in 2026 will enable us to broaden our understanding of the prevalence of birth trauma and PTSD in different countries, and further examine risk factors associated with birth-related PTSD.

# DESIGN

A cross-sectional survey of postpartum PTSD, depression, trauma exposure as well as demographic and obstetric details.

Women will be recruited through birthing centers, hospitals or clinics (depending on country and location). Inclusion criteria are that (i) participants gave birth to a baby in the last 6-12 weeks, (ii) aged 16 or over and (iiI) give informed consent to participate.

The survey includes measures of obstetric details, birth satisfaction, birth trauma, PTSD, depression and trauma history.

Principal Investigators in each country are able to add other measures or follow-ups as needed, as long they do not change the core measures, inclusion criteria or approach to sampling. Researchers will use validated translations of measures if possible. If no validated translations exist, researchers will be required to translate measures according to accepted cultural adaptation procedures (33). Researchers will be able to choose whether to administer measures online or use pencil and paper according to location’s conditions for recruitment and participation. The survey is designed to be self-report but can be adapted to be administered by telephone if ntrecessary.

All participants will be approached in person, by phone or video call. The study will be explained and participants will give informed consent. Survey completion can be at the time of recruitment or at a later date, as long as it is within the 6-12 weeks postpartum range.

# SAMPLE

Representative samples of postpartum women will be recruited from birthing centers, hospitals or clinics (by choice of researchers in each country). Women will be eligible if they are aged 16 or over, and had a baby in the previous 6-12 weeks. To minimise self-selection sampling bias participants are not to be recruited via social media or other online methods[[1]](#footnote-2).

# MEASURES

The measures that will be used are detailed below.

Birth trauma

Perceived birth trauma will be assessed using a single item question on 10 point scale for women to rate whether they perceived their birth to be traumatic from not at all (0) to extremely (10).

Birth-related PTSD

The City Birth Trauma Scale (26) (City BiTS) consists of 29 questions which map onto DSM-5 diagnostic criteria. Symptoms are rated for frequency over the last week and scored on a scale ranging from 0 (‘not at all’) to 3 (‘5 or more times’). A higher score indicates greater symptoms of PTSD. Diagnostic criterion A items are scored on a yes/no scale. Distress, disability and potential physical causes are rated as yes/no/maybe. The scale can be used as as a continuous measure of symptoms or as a diagnostic tool.

If administered by phone it is recommended that the instructions in relation to time are included in the items as follows:

*The next questions ask about symptoms that you might have experienced:*

* *In the last week how often have you had recurrent unwanted memories of the birth…*
* *In the last week how often have you had bad dreams or nightmares…*
* *etc.*

The response scale can either be given at the beginning and prompted as necessary, or repeated after each question.

Birth Satisfaction

The Birth Satisfaction Scale-Revised (34) (BSS-R) is a 10-item, self-report scale that was reduced from the original 30-item BSS (35).The BSS-R assesses women's perceptions of birth in order to determine women's satisfaction with their birth experience. The BSS-R consists of one, higher-order factor (experience of childbearing) containing three lower-order factors (quality of care provision, women's personal attributes, and stress experienced during labour). Four items measure quality of care provision; four items measure stress during labour; and two items measure women's attributes. The BSS-R is a Likert-type scale that requests participants to rate their level of agreement with each item (0=Strongly Disagree to 4=Strongly Agree), with four of its items being reverse-coded (e.g. “I found giving birth a distressing experience”).

Previous trauma

Lifetime history of trauma will be measured using the trauma checklist taken from the Post-Traumatic Stress Diagnostic Scale (36). This scale has good reliability and validity (37), has been translated into multiple languages (38–42) and has been well used in the perinatal population (43,44). Previous traumatic birth and pregnancy loss/stillbirth will also be measured in 2 additional items.

Postpartum depression

The Edinburgh Postnatal Depression Scale (45) (EPDS) was developed as a screening tool for postpartum. The scale consists of 10 items rated on a 4-point scale, ranging from 0 to 3, with a maximum score of 30 with higher score meaning high depression. The EPDS demonstrated good internal consistency previously (α = .87) (45).

Demographic and Obstetric Information

Demographic and obstetric Information comprises basic demographic (age, ethnicity, relationship status) and obstetric details (number of children, gestation, time since birth, type of birth (i.e. vaginal, assisted vaginal, emergency or elective caesarean), maternal/infant complications). The purpose of this information is to gauge representativeness of the participating sample as well as study the etiology of childbirth-related PTSD. Obstetric information can be collected by self-report or from medical records.

History of psychological problems and treatment

Previous and current psychological disorders and treatment will be included to identify women who do or do not obtain treatment. For example, women will be asked whether they had had professional help or treatment (‘have you received professional help or treatment for your psychological or mental health problems?’) and what type of treatment they received (‘if you are currently receiving any help or treatment, what type of treatment is it?).

Maternity care

Release 2 will include questions on place of birth, main medical carer(s) during pregnancy and birth, and whether women had skin-to-skin contact after birth.

Non-INTERSECT measures

Researchers are able to add other measures to the survey to address other research questions of interest. This might include cultural factors (e.g. religion, nationality, sexuality, social class), etiological factors (e.g. fear of childbirth), or other outcome variables (e.g. mother-infant relationship). These data will not be shared with INTERSECT. Howeer, we keep a supplementary file of additional questions researchers have added to their study, to enable cross-country comparisons in sub-sets of data. This includes the Primary Care PTSD Screen (46) which we recommend is included if possible so that PTSD not related to childbirth is also identified in a sub-sample of INTERSECT. It also includes questions about infant feeding and other variables.

# ADVERSE EVENTS

This study is a survey of birth trauma and birth-related PTSD. For the majority of women who take part there is no risk of adverse events. However, for some women there is a risk that thinking about events during the birth of their child could be temporarily upsetting. These include women who have had complicated births where babies died, or babies with special needs. This will be avoided through careful wording of the participant information so that women are aware of the questions that will be asked before they consent to take part.

Safeguarding – The study is thought to be low risk, however, if a participant experiences distress the participant information sheet (“Frequently Asked questions”) will provide details of organisations that offer appropriate support. Participants will also be reminded of these again at the end of the survey. If possible, researchers can also contact women with high scores who provide their contact information to encourage them to seek help; and provide them with information on services they can contact for help.

Valid consent and right to withdraw - to ensure as best we can that participants have read and understood the participant information sheet, in particular, that they understand their participation is confidential and anonymous and they have a right to withdraw from the study.

The first page of the survey gives brief information about the study and has a link to the participant information sheet. Participants have to tick a box to confirm that they consent to the study and are the legal adult age in that country (usually 16 or 18 years of age or older). The participant information sheet gives information on how their answers will be used and their right to withdraw. If a participant decides to withdraw data can be withdrawn by identifying their survey responses either by email address (if they supplied it) or demographic information they supplied, such as date of birth of their baby and time and date of survey completion.

Confidentiality – will be maintained by using software that is secure and data will be transferred to password protected files on researchers’ computers. Data will be kept for at least ten years after the research is published in accordance with current guidelines.

Data provided to INTERSECT will not include participants names so answers will be anonymous. Where personal information such as email addresses have been volunteered by the participant, they will be held by the Principal Investigator for that country in files that are password protected until data are anonymised. This allows for a period where participants can opt to withdraw their data.

Security and privacy threats

Data will be collected in each country by local researchers under the guidance of the Principal Investigator for that country. Data will be transferred to INTERSECT without any identifying information.

INTERSECT data will be held using a secure software programme at City University of London. The survey host has a privacy policy that treats data as private and confidential. Online data is only accessible through password protection by the principal researcher until the time the survey ends and data are deleted from the host site. Data are encrypted and secure connections are used when transferring data from the survey host to the principal researcher’s electronic storage. The survey host has rigorous procedures to ensure network, organisational and administrative security and procedures to deal with security breaches.

Email is not necessarily secure and care needs to be taken when emailing participants with details of the study. The researcher will email using a secure university email account, and all emailed documents will be password protected.

Debriefing

Participants who opt to be informed about the findings of the study will be emailed the details on publication. However, individual feedback on questionnaire scores cannot be provided.

Reliability of measurement

Participants will be recruited to the study in person via healthcare or community organisations. Recruitment will be done in person, via telephone or email/letter according to each local context. After recruitment, participants will either be given the measures by researchers in person, over the phone, or receive an online link.

Although this not an open survey, researchers have no way to verify the information participants provide. If data are collected using online survey software there is the potential for participants to enter multiple times and give false answers which has implications for the validity of the study. Survey results can be checked by demographic information such as date of birth of the child to guard against women entering more than once.

Complaints

If a complaint is made by a participant of the study it will be dealt with as defined by the local IRB. All such complaints will be followed up until there is resolution or the event is considered stable. Serious Adverse Events will be governed by the definitions and procedures set out in Good Clinical Practice guidelines. All SAEs will be reported to the Principal Investigator in that country and, if needed, to the INTERSECT Oversight Team.

# STATISTICS AND DATA ANALYSIS

## Sample size

A minimum sample of 250 women from each country is required. In the first release of the dataset we have 11,302 participants so we anticipate a combined total sample of over 18,000 participants in the second release of the dataset.

## Analysis plan

Prevalence of birth trauma and PTSD will be examined using descriptive statistics (frequencies, percentages, 95% confidence intervals). Multivariate models, such as multiple regression or logistic regression will examine the relative contribution and predictive power of etiological factors in different samples. The association between country, culture and symptom presentation and prevalence will be assessed using multivariate statistics as appropriate.

Applications for secondary analyses of the dataset will be considered and approved by the INTERSECT Scientific Committee. Teams applying to conduct secondary analyses are expected to have appropriate statistical expertise on their team.

# DIRECT ACCESS TO DATA/DOCUMENTS

Access to data and documents will be restricted to the INTERSECT Consortium and Oversight Team and authorised representatives from the sponsors in each country.

# QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES

The project will be conducted in compliance with the current revision of the Declaration of Helsinki (last amendment October 2008), with relevant regulations, and with MRC Guidelines for Good Clinical Practice in Clinical Projects (1998) which is based on ICH guidelines for Good Clinical Practice (CPMP/ICH/135/95) July 1996. The project will be conducted in compliance to local IRB guidelines according to the specific location.

Quality will be ensured by a number of procedures:

## Data collection and processing

Data will be collected in person, via telephone, or via self-report (online or by post). In person data will be inputted onto a programme used by all researchers. Data will be screened for quality and validity by the research team. Missing data will be examined to make sure there is no systematic bias in items not being completed and comprises less than 20% of the data. Missing data will be imputed using the expectation maximisation algorithm.

## Monitoring

The project progress and data collection will be monitored by the INTERSECT Oversight Team.

## Archiving

Data and appropriate study documents will be stored for a minimum of 10 years after completion of the project. The project master file and project documents will be held by the chief investigator on behalf of the sponsor in secure facilities at City, University of London. Reasonable requests for access to statistical information from the data (e.g. effect sizes for meta-analyses) will be considered.

# PROJECT MANAGEMENT

The project management structure is given in Figure 1. Day-to-day management of the project will be the responsibility of the chief investigator and the INTERSECT Oversight Team. Project co-ordination will be through the Centre for Maternal and Child Health Research, School of Health Sciences, at City University London.

**Figure 1. INTERSECT Consortium Structure**



# ETHICS

## Approvals

Prior to the study commencing Principal Investigators will obtain approval from their local Research Ethics Board. Any subsequent amendments to the protocol and associated documents will be submitted for approval prior to their implementation. The Principal Investigator will also provide a report to their local ethics committee at the end of the study if stipulated in the ethics committee guidelines.

## Participant confidentiality

Confidentiality of all participant information will be maintained throughout the project. The survey is anonymous with very little personally identifying information. Each participant will asked to provide their baby’s date of birth and will have the option to enter their email address if they want to hear about the results of the survey. This email address will be used for follow-up data collection and correspondence if needed.

In the INTERSECT database participants will be allocated a unique participant number and email addresses will be removed from data to ensure no personally identifiable information is retained in the project database. Access to all data will be restricted to personnel approved by the INTERSECT Oversight Team.

# DATA HANDLING

All project data will be entered on a project specific database with participants identified only by a unique ID number. The INTERSECT database will be developed and maintained by the INTERSECT Oversight Team. All databases will be stored on a secure server. Access to this information will be restricted to members of the research team, as authorised by the INTERSECT Oversight Team.

# FINANCING AND INDEMNITY

Multiple sources of funding have been used. Set up and launch of the project was funded by the City, University of London, Global Challenges Research Fund (PI: Webb). The data management has been funded by the Myriam de Senarclens Fondation (PI: Ayers). A doctoral scholarship to conduct specific analyses has been funded by the British Medical Association Foundation (PI: Ayers).

Other sources of funding will be applied for. City University of London will act as the main sponsor for this project. Standard indemnity applies.

# PUBLICATION POLICY

## Reporting, dissemination and notification of the results

Results will be disseminated to participants, the wider community, clinical and academic community as follows:

Research participants

Where possible results should be made available to participants through an e-newsletter if they have provided their email address. Results will also be publicised though social media, service user organisations, the local press, university and media.

Health services and clinical community

The INTERSECT Consortium consists of people with strong clinical backgrounds and significant roles in primary and secondary care health services. Results will be presented at relevant conferences, e.g. International Confederation of Midwives Conference, International Marce Society Conference, Society for Reproductive and Infant Psychology. This will ensure results are widely disseminated to those working with postpartum women.

Academic community

Project results will be presented at conferences and published in a peer reviewed journal. Reporting will be in compliance with methodological guidelines provided by the EQUATOR network (see <http://www.equator-network.org/> ).

Intellectual Property (IP)
IP for data collected in each country remains with the Principal Investigator for that country. The Principal Investigator in each country agrees to share anonymised data for the INTERSECT measures with the INTERSECT Oversight Team and agrees for this data to be publicly available to other researchers for secondary analysis at the end of the project. Requests from INTERSECT Consortium members to conduct secondary analyses will be invited before the end of the project, so that they are prioritised.

Additional measures collected in each country are not shared with the INTERSECT Oversight Team. As Principal Investigators hold the Intellectual Property for their data, they are free to analyse and disseminate results from the INTERSECT data in their country (i.e. within-country analysis) as they wish.

## Policy for publication and authorship

We will adhere to the recommendations for authors set out by the International Committee of Medical Journal Editors (ICMJE). These state that authorship should be based on the following 4 criteria:

1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

2) Drafting the work or revising it critically for important intellectual content; AND

3) Final approval of the version to be published; AND

4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

All named authors need to meet all four of these recommendations for authorship

# CONTRACTUAL NEEDS

A signed agreement between City University of London and each PI’s University will need to be in place before data can be transferred, to ensure appropriate research governance and data security.

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1. Once participants are recruited it is possible for them to complete the survey online. However, they cannot be recruited through online means to try to ensure sampling is robust and the sample is representative. [↑](#footnote-ref-2)